MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

CONFERENCE AGREEMENT

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Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Short Title; Amendments to Social Security Act; References to BIPA and Secretary; Table of Contents. (Section 1 of Conference Agreement; Section 1 of House bill; Section 1 of Senate bill).

Present Law

No provision.

House Provision

The provision specifies the title of the Act as the "Medicare Prescription Drug and Modernization Act of 2003". The provision also includes a table of contents.

Senate Provision

The provision specifies the title of the Act as the "Prescription Drug and Medicare Improvement Act of 2003". The provision also includes a table of contents.

Conference Agreement

The provision specifies the title of the Act as the "Medicare Prescription Drug, Improvement and Modernization Act of 2003". The provision also includes a table of contents.

Title I - Medicare Prescription Drug Benefit

Voluntary Prescription Drug Benefit Program (Section 101 of Conference agreement, Section 101 of House bill; Section 101 of Senate bill).

Present Law

Medicare does not cover most outpatient prescription drugs. Beneficiaries who are inpatients of hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs. Medicare also makes payments to physicians for drugs or biologicals, which cannot be self-administered. This means that coverage is generally limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, the law specifically authorizes coverage for the following: 1) drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare covered organ transplant; 2) erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis; 3) drugs taken orally during cancer chemotherapy providing they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service; and 4) hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those, which must be put directly into the equipment (e.g., tumor chemotherapy agents used with an infusion pump). Medicare also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

The Committee on Ways and Means, the Committee on Energy and Commerce and the Senate Finance Committee have held numerous hearings on providing prescription drug benefits to seniors, modernizing the program by making benefits, cost sharing and the delivery of care more rational, and strengthening Medicare financially for current and future generations.

The typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases. While seniors are taking more drugs than any other demographic group, they are often paying the highest prices because about twenty five percent of seniors have no prescription drug coverage. Similarly, low-income beneficiaries must often make unacceptable choices between life-saving medicines and other essentials.

The addition of a prescription drug benefit to Medicare, while providing seniors additional choices in how they receive their health services, is a critical modernization of the program.

Legislation to achieve these goals passed the House in 2000 (H.R. 4680, the Medicare Rx 2000 Act), in 2002 (H.R. 4954, the Medicare Modernization and Prescription Drug Act), and in 2003 (H.R. 1, the Medicare Prescription Drug and Modernization Act). The Senate passed

legislation (S.1, the Prescription Drug and Medicare Improvement Act) to modernize the program and provide prescription drugs in 2003.

The conference report is the culmination of this legislative process.

House Bill

The provision would establish a new Voluntary Prescription Drug Benefit Program under a new Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage. In 2006, "standard coverage" would have a $250 deductible, 20% cost-sharing for costs between $251 and $2,000, then no coverage until the beneficiary had out-of-pocket costs of $3,500 when full coverage would be provided. The out-of-pocket limit would be higher for higher income beneficiaries. Low-income subsidies would be provided for persons with incomes below 150% of poverty. Coverage would be provided through prescription drug plans (PDPs) or Medicare Advantage (MA) Rx plans or Enhanced Fee-For-Service (EFFS) Rx plans. The program would rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies would be provided to encourage participation. Plans would determine payments and would be expected to negotiate prices. The new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS) would administer the benefit.

Senate Bill

Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage. In 2006, "standard coverage" would have a $275 deductible, 50% cost-sharing for costs between $276 and $4,500, then no coverage until the beneficiary had out-of-pocket costs of $3,700; and 10% cost-sharing thereafter. Individuals with incomes below 160% of poverty would receive additional assistance. The bill would rely on private plans to provide coverage and to bear a portion of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. (A fallback mechanism would be provided in areas where private risk bearing plans were not available. Under the fallback mechanism, Medicare would contract with a private plan to provide the benefit in the area; the plan would not be at financial risk, except for a small portion of management fees tied to performance). Coverage would be provided through Medicare Prescription Drug Plans (PDPs) or MedicareAdvantage plans (MAs). A new Center for Medicare Choices (CMC) would be established within the Department of Health and Human Services (HHS) to administer the Part D benefit and the new MA program.

Conference Agreement

The provision establishes a new voluntary prescription drug benefit under a new Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new optional benefit will be established under a new Part D. Beneficiaries could purchase either "standard coverage" or alternative coverage with actuarially equivalent benefits. In 2006, "standard coverage" will have a $250 deductible, 25% coinsurance for costs between $251 and $2,250, and catastrophic coverage after out of pocket expenses of $3,600. Once the beneficiary reached the catastrophic limit, the program would pay all costs except for nominal cost-sharing. Low income subsidies would be provided for persons with incomes below 150% of poverty. Coverage would be provided through prescription drug plans or Medicare Advantage prescription drug (MA-PD)

plans. The program will rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies will be provided to encourage participation. Plans will determine premiums through a bid process and will compete based on premiums and negotiated prices.

Part D- Voluntary Prescription Drug Benefit Program

Subpart 1 - Eligible Beneficiaries and Prescription Drug Benefits.

Eligibility, Enrollment and Information (New Section 1860D-1 of conference agreement; New Section 1860D-1 and New Section 1860D-5 of House bill; new sections 1860D-1, 1860D-2, 1860D-3, and 1860D-4 of Senate bill).

Present Law

People generally enroll in Part B when they turn 65. Persons who have applied for Social Security or railroad retirement benefits automatically receive a Medicare card when they turn 65. Persons who have not applied for Social Security or railroad retirement benefits must file an application for Medicare benefits. An individual who becomes entitled to Medicare Part A is automatically enrolled in Part B unless he or she specifically opts out of this coverage. An aged person not entitled to Part A may still enroll in Part B.

House Bill

The new Section 1860D-1 would specify that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage. The benefit is completely voluntary. MA organizations and EFFS plans would be required to offer plans that included qualified prescription drug coverage. An individual enrolled in an MA Rx plan or EFFS Rx plan would obtain their drug coverage through the plan. An individual not enrolled in either an MA or EFFS plan could enroll in a new prescription drug plan (PDP). The provision would specify that an individual eligible to make an election to enroll in a PDP, or with an MA Rx or EFFS Rx plan, would do so in accordance with regulations issued by the Administrator of the new Medicare Benefits Administration (MBA). Enrollments and changes in enrollment could occur only during a specified election period. The election periods would generally be the same as those established for MA and EFFS programs including annual coordinated election periods and special election periods. An individual discontinuing a MA election during the first year of eligibility would be permitted to enroll in a PDP at the same time as the election of coverage under the original fee-for-service plan.

The provision would establish initial election periods. A six month election period, beginning on October 1, 2005, would be established for persons entitled to Part A or enrolled under Part B on that date. For persons first entitled to Part A or enrolled in Part B after that date, an initial election period, which was the same as that for initial part B enrollment, would be established. The Administrator would be required to establish special election periods for persons in special circumstances to ensure no or little disruption in coverage. Specifically these would apply to: persons having and involuntarily losing prescription drug coverage; in cases of enrollment delays or non-enrollment attributable to government action; in the case of an individual meeting exceptional circumstances specified by the Administrator (including circumstances identified by the Administrator for MA enrollment); and in cases of individuals who become eligible for Medicaid drug coverage.

General information on PDP, MA Rx and EFFS Rx plans would be made available during election periods. The Administrator could provide information on individuals eligible to enroll in plans to plan sponsors and organizations.

The provision would provide that elections would take effect at the same time that elections take effect for MA plans. However, no election could take effect before January 1, 2006. The Administrator would provide for the termination of an election in the case of termination of Part A and Part B coverage or termination of an election for cause (including failure to pay the required premium).

The new Section 1860D-5 would require the Administrator to establish a process for the selection of a PDP plan or a MA Rx or EFFS Rx plan that provided qualified prescription drug coverage. The process would include the conduct of annual coordinated election periods under which individuals could change the qualifying plans through which they obtained coverage. The process would also include the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Further, the process would provide for the coordination of elections through filing with an entity offering a MA Rx or EFFS Rx plan or a PDP sponsor in a manner consistent with that provided under MA. The plan would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold.

In order to ensure no duplication of coverage, the section would specify that an MA Rx or EFFS Rx enrollee could only elect to receive drug coverage through the plan.

Senate Bill

Under the New Section 1860D-1, the Administrator would provide for and administer a voluntary prescription drug delivery program under which each Part D eligible individual enrolled in Part D would be provided access to drug coverage. In general, MedicareAdvantage enrollees would obtain drug benefits through their MedicareAdvantage plan. Other Part D enrollees would receive their drug coverage through enrollment in a Medicare Prescription Drug Plan offered in the geographic area in which the beneficiary resides. MedicareAdvantage enrollees in MSA plans would also receive drug coverage through enrollment in a Medicare Prescription Drug plan. MedicareAdvantage enrollees in private fee-for-service plans would receive drug benefits through such plan if the plan provided qualified prescription drug coverage; otherwise they would enroll in a Medicare Prescription Drug plan. The program would begin January 1, 2006

Under the New Section 1860D-2, the Administrator would establish an enrollment process, which would be similar to that for Part B. An initial open enrollment period would be established. For beneficiaries eligible as of November 1, 2005, this would be the 6-month period beginning November 1, 2005. Persons becoming eligible after this date would have an initial 7-month enrollment period similar to that established for Part B.

The New Section 1860D-3 would require the Administrator to establish a process through which a Part D eligible individual who was not enrolled in a MedicareAdvantage Plan (except for an MSA plan or private-fee-for-service plan not offering qualified drug coverage) could enroll in a Medicare Prescription Drug plan serving the geographic area where the beneficiary

resides. The beneficiary could make an annual election to change enrollment to another plan. A beneficiary in Part D who failed to enroll in a plan would be enrolled in a plan designated by the Administrator.

The Administrator would use rules similar to the rules established for enrollment, disenrollment and termination of enrollment with MedicareAdvantage plans. Included would be requirements relating to establishment of special election periods and application of the guaranteed issue and renewal provisions. The Administrator would also coordinate enrollments, disenrollments, and terminations of enrollments under Part C with those under Part D.

The enrollment process established by the Administrator would ensure that beneficiaries who enrolled in the first open enrollment period (beginning November 2005) would be permitted to elect an eligible entity prior to January 1, 2006, in order to assure coverage was effective on that date.

In general, persons enrolled in MedicareAdvantage Plans would receive drug coverage through their MedicareAdvantage Plans and be subject to their enrollment rules. Persons enrolled in MSA plans or private-fee-for-service plans not offering qualified drug coverage would be subject to Part D enrollment rules.

The Administrator would be authorized to provide information about eligible beneficiaries to eligible entities with contracts under Part D. Such information would be provided as the Administrator determined necessary to facilitate enrollment with such entities and for only so long and to the extent necessary to carry out this objective.

The new Section 1860D-4 would require the Administrator to broadly disseminate information to beneficiaries regarding Part D coverage. Current beneficiaries would be provided such information at least 30 days prior to beginning of the first enrollment period.

Information activities would be similar to those performed for MedicareAdvantage and be coordinated with such activities. Comparative plan information would include a comparison of benefits, monthly beneficiary obligation, quality and performance, beneficiary cost-sharing, consumer satisfaction surveys, and other information specified by the Secretary.

Conference Agreement

The New Section 1860D-1 of the conference agreement specifies that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage through enrollment in a prescription drug plan. A beneficiary enrolled in a Medicare Advantage (MA) plan providing qualified prescription drug coverage (MA-PD plan) will obtain coverage through that plan. MA enrollees may not enroll in a prescription drug plan (PDP) under Part D except for: 1) Enrollees in private-fee-for service MA plans not offering qualified prescription drug coverage; and 2) Enrollees in Medicare medical savings accounts (MSAs). Coverage first begins January 1, 2006.

The Secretary is required to establish a process for enrollment, disenrollment, termination, and change of enrollment of eligible beneficiaries in prescription drug plans. The Secretary is required to use rules similar to, and coordinated with rules established for MA-PD plans relating to: residency requirements, exercise of choice, coverage election periods (including initial periods, annual coordinated election periods, special election periods, and

election periods for exceptional circumstances); coverage periods (relating to effectiveness of elections and changes of elections); guaranteed issue and renewal; and marketing material and application forms.

The agreement establishes a default election process for full-benefit dual eligible beneficiaries, that is, persons eligible for both Medicare and full benefits (including prescription drugs) under the state's Medicaid program. The Secretary will enroll any full-benefit dual eligible who has not enrolled in a prescription drug plan or MA-PD plan, in a plan that has a premium equal to or below the premium subsidy amount available to persons with incomes below 135% of poverty. If more than one plan is available, the Secretary will enroll the beneficiary on a random basis among all such plans in the PDP region. Nothing prevents the beneficiary from declining enrollment or changing such enrollment.

The provision would establish a six-month initial enrollment period, beginning November 15, 2005, for all persons who are eligible beneficiaries on that date; it is the same period established for enrollment period established for MA plans for that year. An initial enrollment period will apply for individuals becoming eligible after that date; in no case can such period be less than six months, which follows the current enrollment process for Part B. Conferees intend the enrollment process to be administratively simple to encourage enrollment in the new plans.

The Secretary will establish enrollment periods for special circumstances. These include the involuntary loss of creditable prescription drug coverage such as under a group health plan, or a reduction in coverage such that it no longer meets the actuarial equivalence test. Failure to pay the required premium does not meet the definition of involuntary loss of coverage. A special enrollment period is also established for persons who discontinue their enrollment in a MA-PD plan during their first year of eligibility.

The Secretary is authorized to provide each PDP sponsor and MA organization such identifying information about eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of plans and enrollment of beneficiaries in plans. The Secretary may provide such information only to the extent necessary to carry out these activities and such PDP sponsor or MA organization may only use it to facilitate marketing and enrollment of beneficiaries in PDP and MA-PD plans. Conferees intend this provision to facilitate outreach to beneficiaries to ensure participation in the program. A consistent barrier to encouraging enrollment in the existing Medicare+Choice program is the high cost of marketing to individuals. With Secretarial assistance, Conferees expect these costs to be reduced so that plans can readily identify eligible beneficiaries and target information effectively.

The Secretary is required to conduct activities that are designed to broadly disseminate information to eligible beneficiaries and prospective eligible beneficiaries. It must be available at least 30 days prior to the initial enrollment period. The information dissemination requirements are similar to and are to be coordinated with the activities the Secretary is required to perform for MA plans.

The Conferees expect that in carrying out the annual dissemination of information requirement that the Secretary will conduct a significant public information campaign to educate beneficiaries about the new Medicare drug benefit to ensure the broad dissemination of accurate and timely information. In particular, the Conferees expect that in carrying out this public information campaign that HHS will place a priority on, and make a best and concerted effort to,

ensuring that the lower income seniors are aware of the additional benefits available to them and how to enroll. Therefore, the public information campaign should include a program of outreach, information, appropriate mailings, and enrollment assistance with and through appropriate state and federal agencies, including State health insurance counseling an assistance programs, in coordination with other federal programs of assistance to low-income individuals, to maximize enrollment of eligible individuals. In addition, special outreach efforts shall be made for disadvantaged and hard-to-reach populations, including targeted efforts in historically underserved populations, and working with low-income assistance sites and a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information shall be made available in languages other than English, where appropriate.

It is also critical that eligibility determination forms and paperwork should be as simple as possible, with mail-in or electronic filings possible. In addition, face-to-face interviews should not be required except where necessary. The Secretary shall encourage multi-year enrollment (provided eligible individuals will be required to report disqualifying income and asset changes on a timely basis). It is the desire of the Conferees that, within three years after program enactment, the Secretary shall report on best practices in the successful enrollment of low-income beneficiaries.

The Secretary is also required to disseminate comparative information to beneficiaries for the annual open enrollment period. Comparative information is to include information on benefits and formularies under a plan; monthly beneficiary premium; quality and performance; beneficiary cost-sharing; and consumer satisfaction surveys. The Secretary is not required to provide information on quality and performance or consumer satisfaction during the first plan year or the next plan year if the information is not available. The Secretary is also required to provide information concerning the methodology for determining late enrollment penalties.

To promote informed decisions, comparative information is to include information on benefits and formularies under a plan; monthly beneficiary premium; quality and performance; beneficiary cost-sharing; and consumer satisfaction surveys. The Secretary is not required to provide information on quality and performance or consumer satisfaction during the first plan year or the next plan year if the information is not available. The Secretary is also required to provide information concerning the methodology for determining late enrollment penalties.

Prescription Drug Benefits (New Section 1860D-2 of conference agreement; New Section 1860D-2 of House bill; New Sections 1860D-6, 1860D, and 1860D-1 of Senate bill**)**.

Present Law

No provision.

House Bill

a. Benefits. The new Section 1860D-2 would specify the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either “standard coverage” or actuarially equivalent coverage. In both cases, access would have to be provided to negotiated prices.

For 2006, "standard coverage" would be defined as having a $250 deductible; 20% coinsurance up to the initial coverage limit ($2,000); catastrophic coverage would begin after an individual incurred $3,500 in out of pocket costs. Beginning in 2007, the annual dollar amounts would be increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12-month period ending in July of the previous year.

Plans would be permitted to substitute cost-sharing requirements, for costs up to the initial coverage limit that were actuarially consistent with an average expected 20% coinsurance for costs up to the initial coverage limit. They could also apply tiered copayments, provided such copayments were actuarially consistent with the average 20% cost-sharing requirements.

The provision would specify incurred costs that would count toward meeting the catastrophic limit. Costs would be treated as incurred costs only if they were paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, under the Medicaid program, or under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs. The Administrator would be authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by an individual (as defined in standards set by the Administrator through a process established by the Administrator) would constitute grounds for termination of Part D enrollment.

The provision would permit a PDP or MA Rx or EFFS Rx plan to offer, subject to approval by the Administrator, alternative coverage providing certain requirements were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, stop loss protection would be the same as that under standard coverage.

Both standard coverage and actuarially equivalent coverage would have to offer access to negotiated prices. Coverage offered by a PDP plan sponsor or a MA or EFFS entity would be required to provide beneficiaries with access to negotiated prices (including applicable discounts). Access would be provided even when no benefits were payable because of the application of cost-sharing or an initial coverage limits. Insofar as a state elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. (Further, the negotiated prices would not be taken into account in making "best price" determinations under Medicaid.) The PDP sponsor or MA or EFFS entity would be required to disclose to the Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions were made available to the sponsor or organization and passed through to enrollees through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Administrator under the same conditions currently required for Medicaid.

Qualified prescription drug coverage could include coverage exceeding that specified for standard coverage or actuarially equivalent coverage. However, any additional coverage would be limited to covered outpatient drugs. The Administrator could terminate a contract with a PDP sponsor or MA or EFFS entity if a determination was made that the sponsor or organizations engaged in activities intended to discourage enrollment of classes of eligible Medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage.

b. Income-Related Out-of-Pocket threshold. The provision would increase the annual out-of-pocket threshold for each enrollee whose adjusted gross income exceeded a specified income threshold. The portion of income exceeding this income threshold ($60,000 in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows. First, the ratio of the annual out-of-pocket limit to the income limit would be calculated and expressed as a percent. For 2006, this would be $3,500 divided by $60,000 equaling 5.8%. This percentage would be multiplied by any excess income over $60,000, or, if less, by the difference between income threshold limit and the income threshold ($140,000 in 2006). Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. Beginning in 2007, the income threshold and income threshold limits would be increased by the percentage increase in the consumer price index (CPI) for all urban consumers, rounding to the nearest $100.

The income used for making the income determination would be adjusted gross income. (Individuals filing joint returns would each be treated separately with each person considered to have an adjusted gross income equal to one-half of the total.) The determination would be the most recent return information disclosed by the Secretary of the Treasury to the Secretary of HHS, (as provided for under Section 106 of this Act) before the beginning of the year. The Secretary, in coordination with the Secretary of the Treasury, would provide a procedure under which an enrollee could elect to use more recent information, including information for a taxable year ending in the current calendar year. The process would require: 1) the enrollee to provide the Secretary with the relevant portion of the more recent return; 2) the Medicare Beneficiary Ombudsman offering assistance to the enrollees in presenting such information and the toll-free number being a point of contact for beneficiaries to inquire how to present the information; 3) verification by the Secretary of the Treasury; and 4) payment by the Secretary to the enrollee equal to the benefit payments that would have been payable under the plan if more recent information had been used. If such payments were made, the PDP sponsor would pay the Secretary the requisite amount, less the applicable reinsurance that would have applied. The payment would be credited to the Prescription Drug Account.

The Secretary would be required to provide, through the annual Medicare handbook, general information on the calculation of out-of-pocket thresholds. The Secretary would periodically transmit to the Secretary of the Treasury the names and TINs of enrollees in PDPs or MA Rx or EFFS Rx plans and request that the Secretary of the Treasury disclose information as provided for under Section 106 of this Act. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. Individuals could opt out of the Secretarial disclosure requirements, if they elected to have the maximum out-of-pocket threshold applied in a year. Criminal and civil penalties would apply to any unauthorized disclosure of information obtained pursuant to Section 106. In disclosing such information, stringent new confidentiality protections would apply.

c. Covered Drugs. Covered outpatient drugs would be defined to include: 1) a drug which could only be dispensed subject to a prescription and which was described in subparagraph (A)(i) or (A)(ii) of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid); 2) a biological product described in paragraph B of such subsection; 3) insulin described in subparagraph C of such section and medical supplies associated with the injection of insulin; and 4) vaccines licensed under section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition would include any use of a covered outpatient drug for a medically accepted indication. Drugs, which could be paid for under Medicare Part B, would not be covered under Part D. A plan could elect to exclude a drug, which would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed under the new Section 1860D-3. In addition, a PDP or MA Rx or EFFS Rx plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug, which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D.

Senate Bill

a. Benefits. Under the new Section 1860D-6 of the Senate bill, plans would be required to offer "qualified coverage." "Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage." Both would require access to negotiated prices. In 2006, standard coverage would be defined as having a $275 deductible, 50% cost-sharing for drug costs between $276 and the initial coverage limit of $4,500, then no coverage, except that beneficiaries would have access to negotiated drug prices, until the beneficiary had out-of-pocket costs of $3,700 ($5813 in total spending); and 10% cost-sharing thereafter. These amounts would be increased in future years by the percentage increase in average per capita expenditures for covered drugs for the year ending the previous July.

Out-of-pocket costs counting toward the limit would include costs paid by the individual (or by another individual such as a family member), paid on behalf of a low-income individual under the low-income provisions, paid under Medicaid, or paid under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise could not be counted. The Administrator would be authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by an individual (as defined in standards set by the Administrator through a process established by the Administrator) would constitute grounds for termination of Part D enrollment.

Entities could offer more generous drug coverage, if approved by the Administrator, but only if they also offered a plan providing standard coverage. Entities could offer a plan design different from standard coverage provided certain conditions were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of coverage would have to be at least equal to the unsubsidized value of standard coverage. Further, the coverage would be designed, based on a representative pattern of utilization, to cover the same percentage of costs up to the initial benefit limit as provided under the standard plan. The limitation on the deductible and out-of-pocket expenditures would be the

same as under standard coverage. The entity would have to apply for and receive approval from the Administrator for an alternative benefit design.

The Administrator would establish processes for determining the actuarial value of prescription drug coverage. The processes would take into account any effect that providing actuarially equivalent rather than standard coverage would have on utilization.

Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable. The entity would be required to issue a card or other technology for this purpose. The Administrator would be required to provide for development of national standards relating to a standardized format for the card or other technology. The standards would be compatible with those provided for under the administrative simplification and electronic prescribing requirements of Title XI. The standards would be implemented no later than January 1, 2008.

The bill would exempt any prices negotiated by a Medicare Prescription Drug plan, MedicareAdvantage plan, or qualified retiree program from Medicaid's determination of "best price" for purposes of the Medicaid drug rebate program.

b. Income-Related Out-of-Pocket Threshold. No provision.

c. Covered Drugs. The New Section 1860 D would define covered drugs as drugs, biological products, and insulin (including syringes, and necessary medical supplies associated with the administration of insulin, as defined by the Administrator) which are covered under Medicaid and vaccines licensed under Section 351 of the Public Health Service Act. Coverage would be extended to any use of a covered drug for a medically accepted indication. The term would not include drugs or classes of drugs, or their medical uses, which could be excluded from coverage under Medicaid, except for smoking cessation agents. The term would not include drugs currently covered under Medicare Part A or Medicare Part B to the extent payment is available under those Parts. A drug prescribed for an individual, which would ordinarily be a covered drug, would not be covered if a plan's formulary excluded the drug and the exclusion was not successfully resolved. Further, a Medicare Prescription Drug plan or a MedicareAdvantage plan could exclude drugs which did not meet Medicare's definition of "reasonable and necessary" under Section 1862(a) of the Act or which were not prescribed in accordance with the requirements of the plan or Part D.

New Section 1860D-1 would specify that the program would provide coverage for all therapeutic categories and classes of covered drugs (though not necessarily for all drugs within such categories and classes).

Conference Agreement

a. Benefits. The New Section 1860D-2 specifies the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits. In both cases, access would have to be provided to negotiated prices.

Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable. The

entity would be required to issue a card or other technology for this purpose. The Administrator would be required to provide for development of national standards relating to a standardized format for the card or other technology. The standards would be compatible with those provided for under the administrative simplification and electronic prescribing requirements of Title XI.

Plans are permitted to provide supplemental prescription coverage consisting of either certain reductions in cost-sharing (i.e. reduction in deductible, reduction in coinsurance percentage, and increase in initial coverage limit) or coverage of drugs which are excluded because of application of the Medicaid definition of covered drugs. A PDP sponsor may not offer a plan that provides supplemental benefits unless it also offers a basic plan in the area.

For 2006, "standard prescription drug coverage" is defined as having a $250 deductible; 25% coinsurance up to the initial coverage limit ($2,250); and catastrophic coverage after an individual incurred $3,600 in out of pocket expenses. Once the beneficiary reached the catastrophic limit, the program would pay all costs except for nominal cost-sharing.

Once the beneficiary reached the catastrophic ("stop loss") limit, the program would pay all costs, except for nominal cost-sharing. Low-income beneficiaries would have no cost-sharing. The cost-sharing is equal to the greater of: 1) a copayment of $2 for a generic drug or preferred multiple source and $5 for any other drug; or 2) five percent coinsurance. Nothing is to be construed as preventing a PDP sponsor or MA organization from reducing the cost-sharing for preferred or generic drugs. Beginning in 2007, the annual dollar amounts would be increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12-month period ending in July of the previous year.

Plans would be permitted to substitute cost-sharing requirements, for costs up to the initial coverage limit that were actuarially consistent with an average expected 25% coinsurance for costs up to the initial coverage limit. They could also apply tiered copayments, provided such copayments were actuarially consistent with the average 25% cost-sharing requirements.

The agreement specifies incurred costs that count toward meeting the catastrophic limit. Costs are only considered incurred if they are incurred for the deductible, cost-sharing, benefits not paid because of application of the initial coverage limit. Incurred costs do not include amounts for which no benefits are provided because of the application of a formulary. Costs would be treated as incurred costs only if they were paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, or under a state pharmaceutical assistance program (SPAP). Conferees intend SPAP spending to fill in beneficiary cost sharing and deductibles and have that spending count against the catastrophic. State liability will be limited to spending below the catastrophic limit, and for which there is no coverage. The state pharmacy assistance programs could use money saved from the Medicare drug benefit to extend their assistance to persons with incomes above 150% of poverty. For example, 200% of poverty or even 300% of poverty.

Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs. The Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by

an individual (as defined in standards set by the Secretary through a process established by the Secretary) would constitute grounds for termination of Part D enrollment.

The provision permits a prescription drug plan or MA-PD plan to offer, subject to approval by the Secretary alternative prescription drug coverage providing certain requirements are met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, stop loss protection would be the same as that under standard coverage. The deductible could not exceed that under standard coverage.

Under the conference agreement, prescription drug plans and MA-PD plans are permitted to offer alternative coverage that is at least actuarially equivalent to the standard Part D benefit, provided that the alternative coverage includes an initial deductible that is no more than the deductible in the standard plan and provides the same threshold for catastrophic coverage under the standard Part D benefit. Within these requirements plans may change the cost sharing for the drug benefit, implement different formularies, and the benefit limit can be modified while still maintaining actuarial equivalence.

For beneficiaries who desire additional drug coverage beyond that offered in the basic Medicare benefit, MA-PD and PDP plans may also provide supplemental prescription drug coverage. Supplemental policies may be offered by a plan to its own enrollees and may provide for a reduction in the annual deductible, reductions in coinsurance or cost-sharing required, or increases in drug coverage above the benefit limit. However, the conferees recognize that the conditions under which the government provides reinsurance subsidies may create significant disincentives for private sector plans to provide supplemental prescription drug coverage.

To address this concern, the conference agreement clarifies the Secretary's current Medicare demonstration authority to include Part C and Part D with the intent that this authority be used to conduct demonstration projects to allow private sector plans maximum flexibility to design alternative prescription drug coverage. CMS's authority to conduct Medicare demonstrations is provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. § 1395b-1). Under section 402(b), the Secretary is authorized to waive requirements in Title XVIII that relate to reimbursement and payment. Consistent with the Secretary's current-law demonstration authority, the Conference committee intends that any demonstration of benefit flexibility be limited to evaluate innovations in drug benefit design and to not increase total prescription drug outlays as a result of the demonstrations.

Under this authority, CMS could alter the payments to prescription drug plans, Medicare Advantage plans and regional PPOs, or some subset thereof. A number of subsections of 402 could be used as authority to demonstrate the impact of providing additional drug coverage to filling in the gap in coverage or for providing benefit flexibility, as long as the provisions being waived could reasonably be characterized as related to payment provisions.

Specifically, CMS should demonstrate the effect of filling in the gap in coverage by reimbursing participating plans a capitated payment that is actuarially equivalent to the amount that plans would otherwise receive from the government in the form of specific reinsurance when

an individual plan enrollee reaches the catastrophic attachment point ($3,600). In order to demonstrate the impact of plans offering flexible benefits, CMS could alter reinsurance payments for MA plans, regional PPOs, or prescription drug plans participating in a waiver program. For example, it is expected that CMS would change the reinsurance payment methodology for a group of plans and compare spending under this alternative methodology to those plans that continue to receive payments as outlined in Title I. However, all plans would be required to at least offer the required benefits, including those required under Part D. CMS is not permitted to waive the minimum benefits provided by the plans. The conferees anticipate that CMS would use this authority to demonstrate that paying MA plans, regional PPOs or PDPs a capitated payment in lieu of specific reinsurance for prescription drug coverage increases plan efficiency and improves the quality of the services.

Consistent with current law, CMS also is also permitted to develop and engage in demonstrations to determine whether payments for non-Medicare services would result in more economical provision and more effective utilization of Medicare services provided by MA plans, regional PPOs, or prescription drug plans as long as the additional services are incident to Medicare covered services, and provided by entities that meet certain requirements (MA plans and regional PPOs would meet these conditions). Under this subsection, CMS could demonstrate that paying MA plans or regional PPOs a payment to provide non-Medicare benefits (including prescription drug coverage or preventative services not provided under Part C or Part D) results in more economical provision and more effective utilization of comprehensive health care services. Any additional benefits must be determined to be budget neutral, and it is the intention of the Conference committee that any demonstration authority be used in a manner as to not increase Medicare outlays.

The conferees fully expect that the Secretary will use this demonstration authority to conduct projects to evaluate new methods of providing reinsurance payments that remove disincentives for private sector plans to offer additional prescription drug benefits to their enrollees. In order to meet the budget neutrality requirement, it may be necessary to implement such a demonstration after implementation of the new Part D benefit for one to two years. Using the results of this type of demonstration, the Conferees would expect the Secretary to submit to Congress any recommend changes in the drug payment methodology under this Part.
Both standard coverage and alternative coverage would have to offer access to negotiated prices. Coverage offered by a PDP plan sponsor or a MA-PD entity would be required to provide beneficiaries with access to negotiated prices. Access would be provided even when no benefits were payable because of the application of cost-sharing or an initial coverage limits. Negotiated prices are to take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include dispensing fees. The negotiated prices would not be taken into account in making “best price” determinations under Medicaid. Under the current Medicaid best price policy, the largest discount a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program as well. As GAO and CBO have noted, because manufacturers can only influence market share and volume in the private sector, not Medicaid, the “best price” policy has led to less discounting by manufacturers.

The PDP sponsor or MA-PD entity is required to disclose to the Secretary the aggregate negotiated price concessions made available to the sponsor or organization and passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Secretary, but that information would remain confidential.

b. Income-Related Out-of-Pocket Threshold. No provision.

c. Covered Drugs. Covered outpatient drugs are defined to include: 1) a drug which could only be dispensed subject to a prescription and which was described in subparagraph A of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid); 2) a biological product described in paragraph B of such subsection; 3) insulin described in subparagraph C of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary); and 4) vaccines licensed under section 351 of the Public Health Service Act. It is the intent of conferees that the definition of insulin, and medical supplies associated with the administration of insulin, as a covered prescription drug shall include medical supplies that the Secretary determines to be reasonable and necessary, such as insulin, insulin syringes, and insulin delivery devices that are not otherwise covered under the durable medical equipment benefit. Drugs excluded from Medicaid coverage are excluded from the definition except for smoking cessation drugs. The definition would include any use of a covered outpatient drug for a medically accepted indication. Drugs, which can be paid for under Medicare Part B, are not covered under Part D. A PDP plan or MA-PD plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D.

Access to a Choice of Qualified Prescription Drug Coverage (New Section 1860D-3 of Conference agreement; New Section 1860D-5 of House bill; New Section 1860d-13 of Senate bill).

Present Law

No provision.

House Bill

New section 1860D-5 would require the Administrator to assure that all eligible individuals residing in the U.S. would have a choice of enrollment in at least two qualifying plan options, at least one of which was a PDP, in their area of residence. The requirement would not be satisfied if only one PDP sponsor or one MA or EFFS organization offered all the qualifying plans in the area. If necessary to ensure such access, the Administrator would be authorized to provide partial underwriting of risk for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan, including offering such plan on a regional or nationwide basis. The assistance would be available only so long as, and to the extent, necessary to assure the guaranteed access. However, the Administrator could never provide for the full underwriting of financial risk for any PDP sponsor. Additionally, the Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and entities offering MA Rx or EFFS Rx plans. The Administrator would be required to report to Congress annually on the exercise of this authority and recommendations to minimize the exercise of such authority.

Senate Bill

New Section 1860D-13 of the Senate bill would require the Administrator to approve at least 2 contracts to offer a Medicare Prescription drug Plan in an area. If the Administrator

determined that at least 2 plans were not going to be available in the subsequent year, the Administrator would reduce the amount of risk required by plans in a region. This would be achieved by adjusting the percentages applicable to risk corridors established under the bill. Alternatively, the reinsurance percentage could be increased. The Administrator could not provide for the full underwriting of financial risk for any entity and could not provide for the underwriting of any financial risk for a public entity. The Administrator would seek to maximize the assumption of financial risk to ensure fair competition among plans. The authority would be used only so long as, and to the extent necessary, to assure access. The authority could not be used if 2 or more qualified bids were submitted in an area by qualified entities.

Not later than September 1 of each year, beginning in 2005, the Administrator would make a determination as to whether there were 2 approved bids. If not, the Administrator would enter into an annual fallback contract with an entity to provide Part D enrollees in the area with standard coverage (including access to negotiated prices) for the following year.

In the case of an area with only one competitively bid contract, the plan (at the plan's option) could be offered under the rules established for risk-bearing plans. Beneficiaries could enroll with such plan or with the fallback plan.

Conference Agreement

New Section 1860D-3 of the conference agreement requires the Secretary to assure that each beneficiary has available a choice of enrollment in at least 2 qualifying plans in the area in which the beneficiary resides. At least one plan has to be a prescription drug plan. The requirement is not satisfied for an area if only one PDP sponsor or one MA organization offering a MA-PD plan offers all the qualifying plans for the area. A qualifying plan is defined as a prescription drug plan or an MA-PD plan that provides either: 1) basic prescription drug coverage; or 2) qualified prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied (due to the application of a credit against the premium of a rebate). In any case where plans are not available, the beneficiary is given the opportunity to enroll in a fallback plan.

The conference agreement permits the Secretary, in order to assure access, to approve limited risk contracts as specified under the new Section 1860D-11. Only if access is still not provided, will the Secretary provide for the offering of a fallback plan.

Beneficiary Protections for Qualified Prescription Drug Coverage (New Section 1860D-4 of conference agreement; New Section 1860D-3 of House bill; New Section 1860D-5 and Section 121 of Senate bill**)**.

Present Law

a. Beneficiary Protections. Medicare+Choice plans are required to meet a number of beneficiary protection requirements. They are required to disclose plan information to enrollees. They are required to have procedures relating to coverage decisions, reconsiderations, and appeals. Further, they are required to assure the confidentiality and accuracy of enrollee records.

Marketing material used by Medicare+Choice plans must be approved by the Secretary.

b. Electronic Prescription Program. Part C (Administrative Simplification) in Title XI of the Social Security Act requires the Secretary to develop transaction and security standards to support the growth of electronic record keeping and claims processing in the nation's health care system.

Section 1171 defines health care clearinghouse, health care provider, health plan, personally identifiable health information, and standard setting organization. Section 1172 specifies that the administrative simplification standards apply to individual and group health plans, health care clearinghouses, and health care providers who transmit health information electronically in a standard format in connection with one of the transactions specified in Section 1173, or who rely on third-party billing services to conduct such transactions. The Secretary is required either to adopt standards that have already been developed by standard setting organizations or to develop different standards, provided they substantially reduce administrative costs to health plans and providers. If no standard has been adopted by a standard setting organization, the Secretary must develop a new standard based on the recommendations of various specified organizations and agencies.

Section 1173 instructs the Secretary to adopt the following standards: (1) uniform electronic formats for various common transactions between health care providers and health plans (e.g., health claims, eligibility and enrollment); (2) code sets for data elements in standard electronic transactions; (3) unique health identifiers for individuals, employers, plans, and providers; (4) security standards to safeguard confidential patient information against unauthorized access, use, or disclosure; and (5) electronic signatures to verify the authenticity of transactions. Section 1174 provides a timetable for the adoption of the administrative simplification standards and permits the Secretary to modify the standards as frequently as once every 12 months.

Section 1175 requires health plans and providers that process electronic transactions to use standard formats and data elements. Plans and providers may transmit and receive such data either directly or by contracting with a clearinghouse to convert nonstandard data elements into standard transactions. Most entities covered by the administrative simplification standards have 24 months to comply. Small health plans have 36 months to comply.

Section 1176 establishes civil monetary penalties of up to $25,000 per person for violations of the standards. Section 1177 establishes criminal penalties for wrongfully obtaining or disclosing personally identifiable health information. Penalties range from a $50,000 fine and/or 1 year in prison, up to a $250,000 fine and/or up to 10 years in prison if the offense is committed with the intent to sell, transfer, or use the information for commercial advantage, personal gain, or to inflict malicious harm. Section 1178 specifies that the standards preempt contrary provisions in state law pertaining to health information. However, the standards may not preempt or limit state laws that are necessary to prevent fraud and abuse, regulate health insurance companies, or report on health care delivery and costs. Also, the standards may not limit the authority of the state to collect and report for public health purposes.

House Bill

a. Beneficiary Protections. The New Section 1860D-1 would establish guaranteed issue and community-rating requirements. The provision would specify that individuals electing qualified prescription drug coverage under a PDP plan or MA Rx or EFFS Rx plan could not be denied enrollment based on health status or other factors. MA provisions relating to priority

enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors. The provision would require PDP sponsors to make drug coverage available to all eligible individuals residing in the area without regard to their health or economic status or their place of residence in the area.

The New Section 1860D-3 would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the new Section 1860D-1, access to negotiated prices as specified in the new Section 1860D-2, and the non-discrimination provisions specified in the new Section 1860D-6.

PDP plan sponsors would be required to disclose, to each enrolling beneficiary, information about the plan's benefit structure. The plan would have to disclose information on: 1) access to specific covered drugs, including access through pharmacy networks; 2) how any formulary used by the sponsor functioned; 3) copayment and deductible requirements (including any applicable tiered copayment requirements); and 4) grievance and appeals procedures. In addition, beneficiaries would have the right to obtain more detailed plan information. Plans would be required to have a mechanism for providing specific information to enrollees on request. The sponsor would be required to make available, through an Internet web site and, on request, in writing, information on specific changes in the formulary. Plans would be required to furnish to enrollees, at least monthly, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to permit the participation of any pharmacy that met the plan's terms and conditions. A PDP and an MA Rx or EFFS Rx plan could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Administrator to the plan. PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. The Administrator would establish convenient access rules that were no less favorable to enrollees than rules for convenient access established by the Secretary of Defense on June 1, 2003, for purposes of the TRICARE Retail Pharmacy program. The rules would include adequate emergency assess for enrolled beneficiaries. Sponsors would permit enrollees to receive benefits through a community pharmacy, rather than through mail-order, with any differential in cost paid by enrollees. Pharmacies could not be required to accept insurance risk as a condition of participation.

PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs when coverage was not otherwise provided under the plan. The Administrator would provide for the development of uniform standards relating to a standardized format for the card or other technology. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act.

The provision would specify that if a PDP sponsor or an MA or EFFS entity used a formulary, it would have to meet certain requirements. It would be required to establish a pharmaceutical and therapeutic committee to develop and review the formulary. The committee would include at least one physician and one pharmacist, independent and free of

conflict with respect to the committee, both with expertise in the care of elderly or disabled persons. The majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice. This would include assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. The committee would also take into account whether including a particular covered drug had therapeutic advantages in terms of safety and efficacy. The formulary would have to include drugs within each therapeutic category and class of covered outpatient drugs, although not necessarily all drugs within such categories or classes. When establishing such classes, the committee would take into account the standards published in the United States Pharmacopeia Drug Information. It would be required to make available to plan enrollees, through the Internet or otherwise, the bases for the exclusion of coverage of any drug on the formulary. The committee would be required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary. Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to beneficiaries and physicians. The plan would provide for periodic evaluation and analysis of treatment protocols and procedures. Further, the PDP sponsor or entity offering a MA Rx or EFFS Rx plan would be required to have, as part of its appeals process, a process for appeals of coverage denials based on application of the formulary.

The PDP sponsor would be required to have (directly, or indirectly through arrangements) an effective cost and drug utilization management program; quality assurance measures including a medication therapy management program; and a program to control waste, fraud, and abuse. Utilization management programs would be required to include medically appropriate incentives to use generic drugs and therapeutic interchange where appropriate. Medication therapy management programs would be designed to assure, for beneficiaries at risk for potential medication problems such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that drugs under the plan were appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. The program would be developed in cooperation with licensed pharmacists and physicians. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. The sponsor or entity would disclose the amount of such fees to the Administrator upon request; the fees would be confidential.

Each PDP sponsor and entity offering a MA Rx or EFFS Rx plan would ensure that each pharmacy or other dispenser informed enrolled beneficiaries at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent.

Each PDP sponsor would be required to have meaningful procedures for the hearing and resolving of any grievances between the organization (including any entity or individual through which the organization provided covered benefits) and enrollees. Enrollees would be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provided for tiered cost-sharing could request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician

determined that the preferred drug for the treatment of the same condition was not as effective for the enrollee or had adverse effects for the enrollee.

In general, PDP plan sponsors would be required to meet the requirements for independent review and appeals of coverage denials and tiered cost-sharing in the same manner that such requirements applied to MA organizations. An individual enrolled in a PDP plan could appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug for treatment of the same condition was not as effective for the individual or had adverse effects for the individual. The PDP sponsor would be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements applied to MA organizations.

b. Electronic Prescription Program. PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required, effective January 1, 2007, to have in place an electronic prescription program. The program would have to be consistent with national standards developed by the Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases). It would also have to provide for the electronic transmittal of information to the prescribing health professional of information that included: 1) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for the patient; 2) cost-effective alternatives (if any) for the prescribed drug; and 3) information on drugs included in the applicable formulary. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive real time basis.

The Administrator would provide for the development of uniform standards relating to the electronic prescription drug program. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act. The Administrator would be required to establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the administrator on such standards, including recommendations relating to: 1) the range of available computerized prescribing software and hardware and their costs to develop and implement; 2) the extent to which such standards and systems could be readily implemented by physicians, pharmacies, and hospitals; 3) efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information; 4) efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such information; 5) the cost of implementing such systems; 6) implementation issues as they relate to the administrative simplification provisions of Title XI and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing. The Administrator would constitute the task force by April 1, 2004; it would submit recommendations to the Administrator by January 1, 2005. The Administrator would provide for the development and promulgation of national standards by January 1, 2006. The standards would be issued by a standards organization accredited by the American National Standards Institute and be compatible with administrative simplification standards.

Senate Bill

a. Beneficiary Protections. Eligible entities offering Medicare Prescription Drug Plans would be required to disclose plan information comparable to that required for MedicareAdvantage plans. Entities would have to disclose information on access, operation of any formulary, beneficiary cost-sharing, and grievance and appeals procedures. Further, upon request of an individual, they would be required to disclose general information on coverage, utilization, and grievance procedures. An eligible entity would be required to have a mechanism for providing specific information to enrollees, upon request, including information on coverage of specific drugs and changes in its formulary. Entities would be required to provide easily understandable explanation of benefits and a notice of benefits in relation to the initial coverage limit and the annual out-of-pocket limit. The MedicareAdvantage requirements relating to approval of marketing materials would apply to information provided by entities on drug plans.

The bill would include several provisions designed to assure beneficiary access to drugs. Eligible entities would be required to have in place procedures to ensure that beneficiaries were not charged more than the negotiated price of a covered drug. The procedures would include the issuance of a card or other technology that could be used by a beneficiary to assure access to negotiated prices for which coverage was not otherwise provided under the plan. Entities would be required to secure the participation in the network of a sufficient number of pharmacies that dispensed drugs directly to patients (other than by mail order) to ensure convenient access for beneficiaries. The Administrator would be required to establish standards to ensure convenient access, including emergency access. The standards would take into account reasonable distances to pharmacy services in both urban and rural areas and to pharmacy services and access to pharmacy services of the Indian health service and Indian tribes and tribal organizations.

An entity would be required to establish a point-of-service method of operation under which the plan would provide access to any or all pharmacies not participating in the network and could charge beneficiaries, through adjustments in cost sharing, the additional costs associated with this option. This additional cost sharing would not count toward the program's cost-sharing requirements or benefit limits. Entities would be required to permit enrollees receiving benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order and may permit a differential amount to be paid by enrollees.

New Section 1860D-6 would permit entities to use a variety of cost control mechanisms including formularies, tiered copayments, selective contracting with drug providers, and mail order pharmacies. Under New Section 1860D-5, plans electing to use a formulary would be required to establish a pharmacy and therapeutic committee to develop and review the formulary. The pharmacy and therapeutics committee would include at least one academic expert, at least one practicing physician, and at least one practicing pharmacist, all of whom must have expertise in the care of elderly or disabled persons. The committee would base clinical decisions on the strength of scientific evidence and standards of practice. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been provided to beneficiaries, physicians, and pharmacists. An enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug was not as effective for treatment of the same condition for the individual or had adverse effects for the individual. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable for a preferred drug if the prescribing physician determined that the preferred drug was not as

effective for treatment of the same condition for the individual or had adverse effects for the individual.

The formulary would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes). For purposes of defining therapeutic categories and classes, the Administrator would be required to use the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, the DRUGEX Information System, and American Medical Association Drug Evaluations.

Eligible entities would be required to have a cost-effective drug utilization management program (including incentives to reduce costs when appropriate). They would be required to have a program to control fraud, abuse, and waste. Further, they would be required to have quality assurance measures, including a medication therapy management program, to reduce medical errors and adverse drug interactions. The medication therapy management program would be designed to assure that drugs for beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or multiple prescriptions were appropriately used to optimize therapeutic outcomes and reduce the risk of adverse events including adverse drug interactions. The program could include enhanced beneficiary understanding of appropriate use through education, counseling and other appropriate means; increased adherence with prescription regimens through refill reminders, special packaging and other appropriate means; and detection of patterns of overuse and underuse of drugs. The program would be developed in cooperation with pharmacists and physicians. Associated costs would be taken into account by the entity when establishing fees for pharmacists and others providing services under the medication therapy management program.

Pharmacies or other dispensers would be required to assure that beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that is therapeutically equivalent and bioequivalent and that is available at the pharmacy or other dispenser. Entities would also be required to have meaningful procedures for hearing and resolving grievances, comparable to those established for MedicareAdvantage plans. In addition, eligible entities would be required to meet MedicareAdvantage requirements relating to coverage determinations. Entities would be required to safeguard the privacy of individually identifiable beneficiary information, maintain such records in an accurate and timely manner, ensure timely access by beneficiaries, and otherwise comply with laws relating to patient privacy.

Eligible entities would be required to conduct consumer satisfaction surveys with respect to the plan and entity. The Administrator would establish uniform requirements for such survey.

b. Electronic Prescription Program. The provision would establish a new Part D in Title XI of the Social Security Act. The new Section 1180 would mandate the development or adoption of standards for transactions and data elements for such transactions, to enable the electronic transmission of medication history, eligibility, benefit and other prescription information. In developing the standards, the Secretary would be required to consult with representatives of physicians, hospitals, pharmacists, standard setting organizations, pharmacy benefit managers, beneficiaries, information exchange networks, technology experts, and representatives of the Departments of Veterans Affairs and Defense and other interested parties. The standards developed or adopted by the Secretary would be consistent with the objective of improving patient safety and improving the quality of care.

Standards would be required to comply with certain requirements. Patients could request a written prescription and not be charged for such request. The standards would accommodate the electronic transmittal of a patient's medication history, eligibility, benefit and other prescription information among prescribing and dispensing professionals at the point of care. The information that could be transmitted using the standards would include: information on the drugs prescribed for the patient; cost-effective alternatives (if any) to the drug prescribed; information on eligibility and benefits (including the drugs included in the applicable formulary and any requirements for prior authorization); information on potential drug interactions; and other information to improve the quality of care and to reduce medical errors. The standards would be designed so that, to the extent practicable, they did not impose an undue administrative burden on the practice of medicine, pharmacy, or other health professions.

The standards developed or adopted by the Secretary would be consistent with Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the 1996 Health Insurance Portability and Accountability Act (HIPAA), and would be compatible with HIPAA's Administrative Simplification standards.

The Secretary would be required to adopt standards for the appropriate data elements needed for the electronic exchange of prescription drug information among prescribers, insurers, and other entities.

The Secretary would have to adopt the standards by Jan. 1, 2006, and would be permitted to modify them, but in a manner that minimized the disruption and cost of compliance. Individuals that transmit or receive prescriptions electronically would be required to comply with the standards. However, individuals would not be required to transmit or receive electronic prescriptions. The standards would preempt state electronic prescription laws. Entities covered by the standards would have 24 months to comply. Small health plans, as defined by the Secretary, would have an additional 12 months to comply.

The Secretary would be required to consult with the Attorney General to ensure that the standards resulted in the secure electronic transmission of prescriptions for controlled substances.

Conference Agreement

a. Beneficiary Protections. New Section 1860D-4 establishes beneficiary protection requirements for qualified prescription drug plans. PDP plan sponsors are required to disclose, to each enrolling beneficiary, information about the plan's benefit structure. The plan will disclose information on: 1) access to specific covered drugs (including access through pharmacy networks); 2) how any formulary (including a tiered formulary) used by the sponsor functions, including how a beneficiary might obtain information on the formulary; 3) copayment and deductible requirements (including any applicable tiered copayment requirements; and 4) grievance and appeals procedures. In addition, beneficiaries will have the right to obtain more detailed plan information. Plans will be required to have a mechanism for providing specific information to enrollees on request. The sponsor will be required to make available, through an Internet website, information on specific changes in the formulary (including tiered or preferred status). Sponsors will be required to furnish to enrollees, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors are required to permit the participation of any pharmacy that meets the plan's terms and conditions. The conference report would require plans to accept any and all pharmacies willing to agree to the terms and conditions of the plan. A PDP could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Secretary to the plan. The PDP sponsor is required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. The Secretary will establish convenient access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906-03-R-0002) by the Department of Defense on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. The conference report adopts the House language, with the clarification that the minimum in-network pharmacy for each plan offered by a PDP or MA plan in a geographic area must provide access to pharmacies that is not less restrictive than the TRICARE access standards. These standards require that 90 percent of plan enrollees in urban areas will have access to a retail pharmacy within 2 miles; that 90 percent of suburban plan enrollees will have access to a retail pharmacy within 5 miles; and that 70 percent of rural plan enrollees will have access to a pharmacy within 15 miles. PDP sponsors or MA sponsors can offer broader networks than those meeting the TRICARE access standards.

Plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards. PDP plan sponsors or MA sponsors cannot include mail order only pharmacies. The rules would include adequate emergency assess for enrolled beneficiaries. The rules may include standards with respect to access for enrollees in long-term care facilities. Sponsors will permit enrollees to receive benefits (which may include a 90-day supply) through a community pharmacy, rather than through mail-order, with any differential in charge paid by enrollees. In addition, the conference report clarifies that pharmacies could not accept insurance risk.

PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs. The Secretary will provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology. These standards are to be compatible with the administrative simplification requirements of Title XI of the Social Security Act. The standards will be implemented by such date the Secretary determines to be sufficient to ensure PDP sponsors utilize such standards beginning January 1, 2006, and developed in consultation with the National Counsel for Prescription Drug Programs (NCPDP) and other standard setting organizations.

The provision would specify that if a PDP sponsor used a formulary, it would have to meet certain requirements. A pharmaceutical and therapeutic committee would develop and review the formulary. The committee would include at least one practicing physician and one practicing pharmacist, independent and free of conflict with respect to the committee, both with expertise in the care of elderly or disabled persons. The majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. The committee would also take into account whether including a particular covered drug in the formulary (or in a particular tier in a formulary) had therapeutic

advantages in terms of safety and efficacy. The formulary would have to include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes.

The Secretary is required to request the United States Pharmacopeia to develop a list of categories and classes that may be used by plans. The Secretary's request would also include the revision of such classification from time to time to reflect changes in therapeutic uses of covered drugs and the addition of new covered drugs. The plan sponsor cannot change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as the Secretary may permit to take into account new therapeutic uses and newly approved covered drugs. Each sponsor is required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary. Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to the Secretary, beneficiaries, and physicians, pharmacies, and pharmacists. The plan must provide for periodic evaluation and analysis of treatment protocols and procedures.

The PDP sponsor would be required to have (directly, or indirectly through arrangements) a cost-effective drug utilization management program; quality assurance measures, a medication therapy management program; and a program to control fraud, waste, and abuse. A medication therapy management program is a program of drug therapy management and medication administration, that may be furnished by a pharmacist and that is designed to assure with respect to targeted beneficiaries that drugs under the plan are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Targeted individuals are those with multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or are taking multiple drugs or are likely to incur annual costs that exceed a specified level. The program would be developed in cooperation with licensed practicing pharmacists and physicians. Such plans would be coordinated with disease management programs to the extent beneficiaries are enrolled in such programs. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. The sponsor or entity would disclose the amount of such fees to the Administrator upon request; the fees would be confidential.

The Secretary will be required to conduct consumer satisfaction surveys in order to provide comparative information during the enrollment period.

Each PDP sponsor is required to have meaningful procedures for the hearing and resolving of any grievances between the sponsor (including any entity or individual through which the sponsor provided covered benefits) and enrollees. Enrollees will be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provides for tiered cost-sharing can request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determines that that the preferred drug for the treatment of the same condition is not as effective for the enrollee or has adverse effects for the enrollee. A PDP is required to have an exceptions process consistent with guidelines established by the Secretary.

In general, PDP plan sponsors will be required to meet the requirements for independent review and appeals of coverage denials and tiered cost-sharing in a similar manner that such

requirements applied to MA organizations for fee-for-service benefits. An individual enrolled in a PDP plan may appeal to obtain coverage for a drug not on the formulary only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not as effective for the individual or would have adverse effects for the individual or both. The PDP sponsor will be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements applied to MA organizations.

Each PDP sponsor will provide that each pharmacy that dispenses a covered drug shall inform enrolled beneficiaries at the time of purchase (or at the time of delivery in the case of mail order drugs) of any price differential between the price to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent and available at the pharmacy. The Secretary is permitted to waive this requirement.

b. Electronic Prescription Program. The conference agreement requires the Secretary to develop electronic prescription standards. The standards apply to prescriptions for covered part D drugs and required information that are transmitted electronically under an electronic prescription drug program conducted by a PDP or MA plan. The program must provide for the electronic transmittal of information on eligibility and benefits (including formulary drugs, any tiered formulary structure, and prior authorization requirements), information on the drug being prescribed and other drugs listed in the patient's medication history (including drug-drug interactions), and information on the availability of lower-cost, therapeutically appropriate alternative drugs. The conferees intend for prescribing health care professionals to have ready access to neutral and unbiased information on the full range of covered outpatient drugs available. Disclosure of information must meet the requirements of the HIPAA privacy rule and, to the extent feasible, be on an interactive, real-time basis. The conferees do not intend for the provision relating to "interactive, real-time" transmission of information to preclude an individual or entity from complying with the standards under this part by virtue of such individual's or entity's inability to transmit information on an interactive, real-time basis.

The standards must be consistent with the objectives of improving patient safety and the quality and efficiency of patient care. To the extent practicable, the standards must be designed so that they do not impose an undue administrative burden on prescribing physicians and pharmacists. The standards must also be compatible with the HIPAA Administrative Simplification standards and other health information technology standards, and must permit the electronic exchange of drug labeling and drug listing information maintained by the FDA and the National Library of Medicine. Finally, the standards must accommodate the messaging of information about appropriate prescribing of drugs and allow a beneficiary (consistent with their prescription drug plan) to designate a particular pharmacy to dispense a prescribed drug.

The conference agreement requires the Secretary to promulgate initial standards by September 1, 2005, taking into account recommendations from the National Committee on Vital and Health Statistics (NCVHS). The NCVHS is required to develop such recommendations in consultation with standard setting organizations, practicing physicians, hospitals, pharmacies, practicing pharmacists, pharmacy benefit managers, state boards of pharmacy and medicine, and appropriate federal agencies. Prior to the promulgation of final standards, the Secretary must enter into voluntary agreements with physicians, pharmacies, hospitals, and PDP sponsors and MA plans to conduct a pilot project to test the initial standards. The pilot project must be conducted during the 1-year period that begins on January 1, 2006, except that pilot testing is not

required where there is adequate industry experience. The Secretary must then evaluate the pilot project and report to Congress not later than April 1, 2007. Based on the evaluation and not later then April 1, 2008, the Secretary must promulgate final standards to take effect within one year. The electronic prescriptions standards shall supercede any contrary state laws.

The agreement requires the Secretary, in consultation with the Attorney General, to provide a safe harbor from both criminal sanctions under Section 1128(b)(1 and 2) of the Act and the self-referral prohibition under Section 1877 of the Act with respect to the provision of nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information in accordance with Part D standards. Nonmonetary remuneration includes hardware, software, or information technology and training services. This safe harbor is to apply: 1) in the case of a hospital by the hospital to members of its medical staff; 2) in the case of a medical group practice by the practice to prescribing health care professionals who are members of the practice; and 3) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in its network and to prescribing health processionals.

The conferees intend for electronic prescribing to serve as a vehicle to reduce medical errors and improve efficiencies in the health care system, but not for it to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians.

Subpart 2 - Prescription Drug Plans; PDP Sponsors; Financing.

PDP Regions; Submission of Bids; Plan Approval (New Section 1860D-11 of Conference Agreement; New Section 1860D-6 and New section 1860D-4 of House bill; New Section 1860D-7, 1860D-12, and 1860D-13 of Senate bill).

Present Law

a. PDP Regions. No provision.

b. Submission of Bids. No provision.

c. Plan Approval. No provision.

d. Fallback. No provision

House Bill

a. PDP Regions. The Administrator would designate at least 10 service areas in the U.S., consistent with EFFS regions, to the extent practicable.

b. Submission of Bids. The new Section 1860D-6 would require each PDP sponsor to submit to the Administrator specified information in the same manner as such information was submitted by MA organizations. The information to be submitted would be information on the qualified drug coverage to be provided, the actuarial value of the coverage, and information on the bid and premium for the coverage. The PDP sponsor would have to include an actuarial certification of: 1) the actuarial basis for the bid and premium; 2) the portion of the bid and premium attributable to benefits in excess of the standard coverage; 3) the reduction in the

premium resulting from reinsurance subsidies; 4) the reduction in the bid resulting from direct and reinsurance subsidy payments; and
5) such other information required by the Administrator.

c. Plan Approval. The Administrator would review the submitted information for purposes of conducting negotiations with the plan. The Administrator would approve the premium only if it accurately reflected the actuarial value of the benefits and the 73% average subsidy provided for under the new Section 1860D-8. The Administrator would apply actuarial principles to approval of a premium in a manner similar to that used for establishing the monthly Part B premium. These requirements would not apply to private fee-for-service plans.

d. Fallback. No provision

Senate Bill

a. PDP Regions. New Section 1860D-10 would require the Administrator to establish by April 15, 2005, and periodically review, service areas in which plans could offer benefits. The Administrator would establish service areas so that they maximized the availability of Medicare Prescription Drug Plans to eligible beneficiaries and minimized the ability of entities offering plans to favorably select beneficiaries. In establishing the service areas, the Administrator would establish at least 10 service areas, which would have to include at least one state. The Administrator could not divide states so that portions of a state were in different service areas. To the extent possible, the Administrator would include multi-state metropolitan statistical areas (MSAs) in a single service area. The Secretary could divide MSAs where it is necessary to establish service areas of such size and geography as to maximize plan participation. The Administrator could conform service areas to those established for preferred provider organizations under MedicareAdvantage.

Under the New Section 1860D-12, plan service areas could either be, the entire area of one of the service areas established by the Administrator or the entire area covered by Medicare. Entities could submit separate bids for multiple service areas, provided each bid was for a single service area.

b. Submission of bids. The new Section 1860D-12 of the Senate bill would require entities to submit bids to the Administrator on an annual basis. The bid would be submitted at such time in the previous year as specified by the Administrator. The bid would contain information on proposed plans including benefits, actuarial value of the qualified prescription drug coverage, the service area for the plan, and the monthly premium. Premium information would have to include an actuarial certification of the basis for the premium, the portion of the premium attributable to benefits in excess of standard coverage, and the reduction in bids attributable to reinsurance payments. Entities would also be required to provide information on whether the entity planned to use any funds in the plan stabilization reserve fund that were available to the entity for the purpose of stabilizing or reducing the monthly premium.

c. Plan Approval. The new Section 1860D-13 would prohibit the Administrator from approving a plan unless the premium, for both standard coverage and for any additional benefits, accurately reflected the actuarial value of the benefits less the actuarial value of reinsurance payments and any stabilization funds used. The bid submitted by an entity for a qualified plan must reasonably and equitably reflect the cost of benefits provided under that plan. The Administrator would have the authority to negotiate the terms and conditions of the proposed

monthly premiums and other terms and conditions of proposed plans. The Administrator could disapprove, or limit enrollment in, a proposed plan based on costs to beneficiaries, the quality of coverage and benefits, the adequacy of the plan network, average aggregate projected costs of covered drugs and other factors determined appropriate by the Administrator. The Administrator could approve a plan only if it provided the required benefits and was not designed to result in a favorable selection of beneficiaries. The Administrator would approve at least 2 contracts to offer a Medicare Prescription Drug plan in an area. Contracts would be awarded for 2 years.

d. Fallback. Under New Section 1860D-13, the Administrator, not later than September 1 of each year, beginning in 2005, would make a determination as to whether there were 2 approved bids. If not, the Administrator would enter into an annual contract with an entity to provide Part D enrollees in the area with standard coverage (including access to negotiated prices) for the following year. The Administrator could enter into only 1 contract for each such area. A single entity could be awarded contracts for more than one such area. The Administrator could not enter into such a contract if the Administrator received two or more qualified bids after exercise of the authority to reduce risk for entities. Entities would be required to meet beneficiary protection requirements.

Beneficiary premiums for a fallback plan would be set at the premium amount that would apply if the plan premium equaled the national weighted average premium for the area, as adjusted for geographic differences in drug prices. The Administrator would establish a methodology for making this calculation, which could take into account geographic differences in utilization and the results of the ongoing study on spending and utilization required under the Act. The contract with the plan would provide for payments to the plans for the negotiated costs of covered drugs and payment of prescription management fees tied to performance management fees established by the Administrator. Performance requirements established by the Administrator would include the following; 1) the entity contained costs to taxpayers and to beneficiaries; 2) the entity provided quality clinical care; and 3) the entity provided quality services. The fallback plan would not be permitted to engage in any marketing or branding of the contract. Entities that submitted bids to be a qualified risk-bearing entity could not submit a bid to be a fallback plan.

Conference Agreement

a. PDP Regions. New Section 1860D-11 of the conference agreement provides for the establishment of PDP regions. The service area for a plan includes an entire PDP region. The Secretary shall establish, and may revise PDP regions in a manner that is consistent with the requirements for establishment and revision of MA regions. To the extent practicable, PDP regions shall be the same as MA regions. The Secretary may establish different regions if the Secretary determines that it would improve access to drug benefits. The Secretary will establish PDP regions for the territories. A plan can be offered in more than one PDP region, including all PDP regions.

b. Submission of Bids. Each PDP sponsor is required to submit to the Secretary specified information at the same time and in a similar manner as such information is submitted by MA organizations. The information to be submitted is: 1) information on the prescription drug coverage to be provided; 2) the actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile; 3) information on the bid including the basis for the actuarial value, the portion of the bid attributable to basic coverage and if applicable, the portion attributable to supplemental benefits, and assumptions regarding

reinsurance subsidy payments and administrative expenses; 4) service area; 5) level of risk assumed including whether the sponsor requires a modification of risk level and if so the extent of the modification; and 6) such other information required by the Secretary. A modification of risk levels applies to all PDP plans offered by a PDP sponsor in a region; it may include an increase in the federal percentage assumed in the risk corridor or decrease in the size of risk corridors. The Secretary is to establish requirements for information submission in a manner that promotes the offering of plans in more than one PDP region.

The Secretary is to establish processes and methods for determining the actuarial valuation of prescription drug coverage including: 1) an actuarial valuation of standard coverage; 2) actuarial valuations relating to alternative coverage; 3) use of generally accepted actuarial principles and methodologies; and 4) applying the same methodology for determinations of alternative coverage as is used for determinations of standard coverage; and 5) actuarial valuation of reinsurance subsidies. The processes and methods are to take into account the effect that providing alternative coverage (rather than standard coverage) has on drug utilization.

PDP sponsors and MA organizations are responsible for the submission of required actuarial valuations for plans they offer. They may use actuarial opinions certified by independent, qualified actuaries.

c. Plan Approval. The Secretary will review the submitted information for purposes of conducting negotiations with the plan. The Secretary has the authority to negotiate the terms and conditions of the plans. The authority is similar to the authority the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans.

After review and negotiation, the Secretary will approve or disapprove the plan. The Secretary may only approve a plan if certain requirements are met. The plan must comply with Part D requirements, including for actuarial determinations. The Secretary must determine that the portion of the bid that is related to basic coverage is supported by the actuarial bases provided and reasonably and equitably reflects the revenue requirements (as the term is used under Section 1302(8)(c) of the Public Health Service Act) for benefits provided under the plan, less the sum of the actuarial value of the reinsurance payments provided. Similarly, the Secretary must determine that the portion of the bid that is related to supplemental coverage is supported by the actuarial bases provided and reasonably and equitably reflects the revenue requirements for coverage provided under the plan.

The Secretary can only approve a plan, if the plan and the benefits (including any formulary and tiered formulary structure) are not likely to discourage enrollment by certain beneficiaries.

The agreement provides that the Secretary may only approve a limited risk plan for a PDP region if the access requirements for the region would otherwise not be met except for the approval of a limited risk or fallback plan. Only the minimum number of limited risk plans necessary for a region to meet access requirements may be approved. The Secretary shall provide priority to those with the highest level of risk. In no case can the reduction of risk provide for no (or a de minimus) level of financial risk. There is no limit on the number of full risk plans that may be approved.

d. Fallback. The New Section 1860D-3, discussed above, establishes access requirements. If access is not provided, including through a limited risk plan, the conference

agreement establishes a fallback process. The Secretary is required to establish a separate process for the solicitation of bids from eligible fallback entities for the offering in all fallback service areas in or more PDP regions of a fallback prescription drug plan during the contract period. A single fallback entity may not offer all fallback plans throughout the United States. Except as otherwise provided, the general provision relating to approval or disapproval of bids under New Section 1860D-11(e) applies with respect to fallback plans. The Secretary can only approve one fallback plan for all fallback service areas in any PDP region for a contract period. Competitive contracting provisions apply. The Secretary shall approve fallback plans so that if there are any fallback service areas in the region for the year, they are offered at the same time as prescription dug plans would otherwise be offered.

The fallback entity could not submit a bid for a prescription drug plan for any region for the first year of a contract period. A fallback service area is an area within a PDP region in which, after applying the provisions relating to limited risk plans, the access requirements will not be met. Fallback prescription drug plans are permitted to offer only standard prescription drug coverage, pass on negotiated discounts and meet such other requirements specified by the Secretary. The fallback plan would not be permitted to engage in any marketing or branding of the contract.

Under a fallback contract, the Secretary would pay actual costs of Part D covered drugs taking into account negotiated price concessions. Payment would also be made for prescription management fees tied to performance management requirements, established by the Secretary. Performance requirements established by the Secretary would include the following; 1) the entity contained costs to the Medicare Prescription Drug Account and to beneficiaries; 2) the entity provided quality clinical care, including reduction in adverse drug interactions; and 3) the entity provided timely and accurate delivery of services, including pharmacy and beneficiary support services; and 4) efficient and effective benefit administration and claims adjudication services. Beneficiary premiums under fallback plans would be uniform and equal to 26 percent of the Secretary's estimate of the average monthly per capita actuarial cost (including administrative costs) to the entity offering the fallback plan.

In general, contract requirements for fallback plans would be the same as those established for prescription drug plans. A contract for a fallback plan would be for 3 years (and be renewable after a subsequent bidding process). However, a contract could not apply in an area in any year unless the area was a fallback service area.

The Secretary will submit an annual report to Congress that describes the instances in which limited risk plans and fallback plans are offered. The secretary will include such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk.

In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and PDP sponsors. Further, the Secretary may not require a particular formulary or require a particular price structure for the reimbursement of covered drugs. Conferees expect PDPs to negotiate price concessions directly with manufacturers.

PDP sponsors shall permit State pharmaceutical assistance programs and prescription plans under Section 1860D-24 to coordinate benefits with the plan. Fees may not be imposed that are unrelated to coordination. Conferees want to ensure the new Medicare plans are required to

coordinate with State plans to ensure those plans can efficiently enroll seniors without unnecessary constraints. Conferees want to ensure a seamless transition for both States and beneficiaries.

Requirements for and Contracts With Prescription Drug Plan (PDP) Sponsors (New Section 1860D-12 of Conference agreement; (New Section 1860D-4 of House Bill; New Sections 1860D-7, 1860D-10, 1860D-12, and 1860D-13 of Senate Bill).

Present Law

Medicare+Choice plans are required to meet a number of financial and organizational requirements. In general they are required to be organized and licensed under state law, except that a special exception may be established for provider-sponsored organizations. In addition, entities must assume full financial risk for required services.

House Bill

New Section 1860D-4 would specify organizational plan requirements for entities seeking to become PDP plan sponsors. In general, the section would require a PDP sponsor to be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the Administrator for entities not licensed by the state. Plans would be required to assume full financial risk on a prospective basis for covered benefits except: 1) as covered by federal subsidy payments and reinsurance payments for high cost enrollees; or 2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish new plans. The entity could obtain reinsurance or make other arrangements for the cost of coverage provided to enrollees.

PDP plan sponsors would be required to enter into a contract with the Administrator under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. Contracts would be for at least one year. The Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans. The Administrator would be required to take into account subsidy payments for covered benefits in negotiating the terms and conditions regarding premiums. The Administrator would designate at least 10 service areas, consistent with EFFS regions.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rata user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20% of the maximum fee permitted for an MA or EFFS plan.

The new Section would permit the Administrator to waive the state licensure requirements under circumstances similar to those permitted under Part C for provider sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the Administrator. The Administrator would establish such standards by regulation by October 1, 2004.

The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the Administrator.

Senate Bill

Under the New Section 1860D-7, an entity eligible to offer a Medicare Prescription Drug Plan would be organized and licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state it offers a plan. Alternatively, the Administrator could waive the requirement that the entity be licensed in the state, if the Administrator determined that grounds for approval of the application had been met. By January 1, 2005, the Administrator would, in consultation with the National Association of Insurance Commissioners, establish and publish solvency standards for non-licensed entities.

Entities would be required to assume financial risk on a prospective basis for costs of benefits in excess of amounts received from premium payments and reinsurance payments. Entities would be permitted to obtain private reinsurance for the portion of the costs for which they were at risk.

Beneficiaries could not elect a Medicare Prescription Drug Plan unless the Administrator had entered into a contract with the eligible entity for the plan. A contract with an entity could cover more than one plan.

The New Section 1860D-12 would require the Administrator, by January 1, 2005, to establish by regulation standards to implement Part D. Such standards would be periodically reviewed and revised as appropriate. Significant new regulatory requirements could only be implemented at the beginning of a calendar year. The standards would supersede any state law and regulation to the extent such law or regulation was inconsistent with such standards and in the same manner those standards were superseded for Medicare Advantage plans. Standards specifically superseded include those relating to benefits (including requirements relating to cost-sharing and the structure of formularies), premiums, requirements relating to inclusion or treatment of providers, coverage determinations (including related grievance and appeals processes), and requirements relating to marketing materials and summaries and schedules of benefits for a plan.

States would be prohibited from imposing a premium or similar tax with respect to premiums paid to the Administrator for Medicare Prescription Drug Plans and any payments made by the Administrator to eligible entities offering such a plan.

Conference Agreement

The conference agreement establishes organizational requirements for PDP sponsors under the New Section 1860D-12. In general, the section would require a PDP sponsor to be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the Secretary for entities not licensed by the state. To the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that is not covered by direct subsidy payments. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

PDP plan sponsors would be required to enter into a contract with the Secretary under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. The Secretary may not enter into a contract with a PDP sponsor if the entity submitted a bid for the year (as the first year of the contract period) to offer a fallback plan in any region or offered a fallback plan in the region during the previous year. An entity is to be treated as submitting a bid if it is acting as a subcontractor of a PDP sponsor that is offering a plan; however this does not apply to a MA organization insofar as it is acting as a PDP sponsor.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans including minimum enrollment, contract periods, protections against fraud and abuse, intermediate sanctions, and contract terminations. Pro rata user fees may be established to help finance enrollment activities.

The new Section 1860D-12 permits the Secretary, in order to expand choice, to waive the state licensure requirement under circumstances similar to those permitted under Part C for provider sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the Secretary. The Secretary, in consultation with the National Association of Insurance Commissioners, would establish and publish such standards by January 1, 2005. The Secretary may periodically review and revise the standards; however, the Secretary may not implement significant new regulatory requirements except at the beginning of a calendar year.

The standards established under Part D supersede state laws or regulations in the same manner that such laws or regulations are superseded for purposes of MA organizations and plans. In addition, states are prohibited from imposing premium taxes with respect to premiums for PDP plans.

Premiums; Late Enrollment Penalty (New Section 1860D-13 of the Conference agreement; New Section 1860D-1 and New Section 1860D-6 of House Bill; New Sections 1860D-2, 1860D-6, 1860D-14, 1860D-15, 1860D-17, and 1860D-18 of Senate bill).

Present Law

Persons who delay enrollment in Part B after their initial enrollment period are subject to a premium penalty. Certain persons, including a working individual and/or spouse of a working individual, may be able to delay enrollment in Medicare Part B without being subject to the delayed enrollment penalty.

House Bill

New Section 1860D-1 would specify that PDP sponsors and MA or EFFS organizations providing qualified prescription drug coverage could not deny, limit, or condition the coverage or provision of benefits or increase the premium based on any health-related status factor in the case of persons who maintained continuous prescription drug coverage since the date they first qualified to elect drug coverage under Part D. Individuals who did not maintain continuous coverage could be subject to an adjusted premium or a pre-existing condition exclusion in a manner reflecting the additional actuarial risk involved. Such risk would be established through an appropriate actuarial opinion. The Administrator would provide a mechanism for assisting

sponsors and entities in identifying eligible individuals who had, or had not, maintained continuous coverage.

The provision would specify that an individual would be considered to have had continuous prescription drug coverage if the individual established that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another plan): 1) qualified prescription drug coverage under a PDP or MA Rx or EFFS Rx plan; 2) Medicaid prescription drug coverage; 3) prescription drug coverage under a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP; 4) prescription drug coverage under a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP; 5) state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP; and 6) veterans coverage for prescription drugs, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified prescription drug plan. They could make such application if they could establish that they were not adequately informed that the coverage did not provide such level of coverage.

New Section 1860D-6 would specify that the bid and premium for a PDP could not vary among individuals enrolled in the plan in the same service area, provided they were not subject to late enrollment penalties. A PDP sponsor would permit each enrollee to have their premiums withheld from their Social Security checks in the same manner as is currently done for Part B premiums. Beneficiaries could also make payment of the premium through an electronic funds transfer mechanism. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in MA or EFFS plans could be used to reduce the premium otherwise applicable.

Under certain conditions, the PDP sponsor or entity offering an MA Rx or EFFS Rx plan in an area would be required to accept, for an individual eligible for a low-income premium subsidy, the reference premium amount (premium for standard coverage) as payment in full for the premium for qualified prescription coverage. This requirement would apply if there was no standard coverage available in the area.

Senate Bill

New section 1860D-2 would specify that persons enrolling in Part D after their initial enrollment period would be subject to delayed enrollment penalties. The actuarially sound increase for each 12-month period of delayed enrollment would be determined by the Administrator.

Eligible beneficiaries with creditable drug coverage could elect to continue to receive such coverage, not enroll in Part D, and subsequently enroll in Part D without penalty if the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under the plan to below the actuarial value of standard prescription drug coverage. Subject to certain conditions, creditable drug coverage would include drug coverage through Medicaid or through a Section 1115 waiver for persons who are not dual eligibles, a group health plan, state pharmaceutical assistance program, Veterans' programs, and Medigap. Entities offering creditable coverage would be required to disclose whether coverage equals or exceeds the actuarial value of standard coverage. A special enrollment period would apply for persons losing

creditable coverage. In general, it would be the 63-day period beginning on the date the individual lost such coverage. Entitlement would begin the first day of the first month following enrollment.

The New Section 1860D-14 would require the Administrator to compute a monthly standard coverage premium for each Medicare Prescription Drug plan and for each Medicare Advantage plan. This would equal the value of standard coverage or actuarially equivalent coverage if the plan provided no additional benefits. If the plan offered additional benefits, the calculation would reflect only the value of standard coverage or, alternatively the approved plan premium for the required qualified coverage plan offered by the entity.

The New Section 1860D-15 would require the Administrator, each year, beginning in 2006, to compute a monthly national average premium equal to the average of the monthly standard coverage premium for each Medicare Prescription Drug plan and each Medicare Advantage plan. The calculation would be a weighted average based on the number of enrollees in the plan in the previous year. The Administrator would establish a methodology for making an adjustment to take into account differences in prices among different areas. In making this calculation, the Administrator could take into account geographic differences in utilization. Any adjustment would be budget neutral.

The Administrator would establish procedures for making the calculation for 2005.

New Section 1860D-17 would specify that if the plan's monthly approved premium for standard coverage was equal to the national monthly weighted average premium for such coverage, the beneficiary would pay: 1) the applicable percentage, established for the area, of the monthly national average. If the plan's monthly approved premium was less than the national average the beneficiary would pay: 1) the applicable percentage for the area, *minus*, 2) the difference between the national average and the plan's premium. If the plan's monthly premium was greater than the national average, the beneficiary would pay: 1) the applicable percentage for the area, *plus* 2) the difference between the national average and the plan's premium. The applicable percentage for an area would be 30% divided by 100% minus a percentage equal to: total reinsurance payments that will be made in a year (including such payments to qualified retiree plans) divided by such amount plus total payments that would be made to plans, including Medicare Advantage plans, in the year for standard coverage (or actuarially equivalent coverage).

New Section 1860D-18 would specify that premiums would be collected in the same manner as Part B premiums. The collections would be credited to the Prescription Drug Account. The Administrator would establish procedures whereby the sponsor of employment-based retiree coverage could pay the premium. The Administrator would transmit the information necessary for collection to the Commissioner of Social Security.

New section 1860D-6 would specify that premiums for a plan would not vary within a region. However, this requirement would not apply to enrollees who were enrolled in a plan pursuant to a contract between the plan and the employer or other group plan that provided employment-based retiree health coverage, if the premium amount was the same for all such enrollees under such agreement.

Conference Agreement

The conference agreement establishes a new section 1860D-13 which sets requirements for beneficiary premiums. The monthly beneficiary premium for a prescription drug plan is defined as the base beneficiary premium, as adjusted. The base beneficiary premium equals the product of the beneficiary premium percentage and the national average monthly bid amount. The beneficiary premium percentage is equal to: 1) 26%, divided by 2) 100 % minus a percentage equal to total reinsurance payments divided by the sum of such reinsurance payments and total payments the Secretary estimates will be paid to prescription drug plans in a year that are attributable to the standardized bid amount (taking into account amounts paid by the Secretary and enrollees and the application of risk adjustment). The national average monthly bid amount is a weighted average of standardized bid amounts for each prescription drug plan and each MA-PD plan. It does not take into account bids submitted for MSA plans, MA private fee-for-service plans, specialized MA plans for special needs beneficiaries, PACE programs, and reasonable cost reimbursement contracts. Once the base beneficiary premium is calculated, it is adjusted up or down, as appropriate, to reflect differences between it and the geographically-adjusted national average monthly bid amount. It is further increased for any supplemental benefits and decreased if the individual is entitled to a low-income subsidy. The premium is uniform for all persons enrolled in the plan, except for those receiving low-income subsidies or those subject to a late enrollment penalty.

Late enrollment penalties would be applied to beneficiaries who failed to maintain creditable coverage for a period of 63 days (within a continuous period of eligibility), beginning on the day after the individual's initial enrollment period and ending on the date of enrollment in a prescription drug plan or MA-PD plan. The amount of the penalty is equal to the amount that is the greater of what the Secretary determines is actuarially sound or 1 percent of the national average monthly beneficiary basic premium (not geographically adjusted) for each uncovered month.

The provision specifies that an individual is considered to have had creditable prescription drug coverage if the individual establishes that he or she had coverage under one of the following: 1) prescription drug plan or MA-PD; 2) Medicaid; 3) group health plan, including a Federal Employees Health Benefits (FEHB) plan and a qualified retiree prescription drug plan; 4) state pharmaceutical assistance program; 5) veterans coverage of prescription drugs; 6) prescription drug coverage under a Medigap plan; 7) military coverage including TRICARE; and 8) other coverage the Secretary determines is appropriate. Coverage meets the definition of creditable coverage only if the actuarial value of prescription drug coverage equals or exceeds the actuarial value of such coverage under standard prescription drug coverage. Individuals could apply to the Secretary to waive the requirement that such coverage be at least equivalent to benefits under a qualified prescription drug plan if they could establish that they were not adequately informed that the coverage did not provide such level of coverage. The Secretary will establish procedures for the documentation of creditable prescription drug coverage. Entities offering creditable coverage would be required to provide disclosure that the coverage does not meet the requirement and the fact that the eligible individual could face late enrollment penalties.

Beneficiary premium payments may be paid directly to the PDP sponsor or MA organization. Alternatively the beneficiary has the option of having the amount withheld from his or her Social Security payment or having payment made through an electronic funds transfer mechanism. Payments withheld are to be paid to the PDP sponsor; however, in the case of late enrollment penalties only that portion attributable to increased actuarial costs is to be paid to the plan.

Premium and Cost-Sharing Subsidies for Low-Income Subsidy Individuals (New Section 1860D-14 of the Conference agreement; New section 1860D-7 of House bill; New Section 1860D-19 of Senate bill).

Present Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Medicaid is a federal-state program, which provides health insurance coverage to certain low-income individuals. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual eligibles," Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare. Perhaps the most important service for the majority of dual eligibles is prescription drugs. These dual eligibles typically have comprehensive drug coverage with only nominal cost-sharing.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLMBs), and certain qualified individuals. QMBs and SLMBs are not entitled to Medicaid's prescription drug benefit unless they are also entitled to full Medicaid coverage under their state's Medicaid program. Qualifying individuals are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits).

Qualified Medicare Beneficiaries (QMBs) are aged or disabled persons with incomes at or below the federal poverty level. In 2003, the monthly level is $769 for an individual and $1,030 for a couple. ($9,228 per year for an individual and $12,360 per year for a couple). The qualifying levels are higher than the HHS federal poverty guidelines because, by law, $20 per month of unearned income, rounded to the next dollar, is disregarded in the calculation. QMBs must also have assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid).

Specified Low-Income Medicare Beneficiaries (SLMBs) are persons who meet the QMB criteria, except that their income is over the QMB limit. The SLMB limit is 120% of the federal poverty level. In 2003, the monthly income limits are $918 for an individual and $1,232 for a couple ($11,016 per year for an individual and $14,784 for a couple). Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid.)

Qualifying Individuals (QI-1s) are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. The monthly income limit for QI-1 for an individual is $1,031 and for a couple $1,384 ($12,372 per year for an individual and $16,608 for a couple). Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium. In general, Medicaid payments are shared between the federal government and the states according to a matching formula. However, expenditures under the QI-1 program are

paid 100% by the federal government (from the Part B trust fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. This temporary program, originally slated to end September 30, 2002, was extended through March 31, 2004 by P.L.108-89.

Eligibility determinations for Medicaid, QMB, SLMB, and QI-1 programs are made by the states.

House Bill

The New Section 1860D-7 would provide income-related subsidies for low-income individuals. Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135% of poverty would have a subsidy equal to 100% of the value of standard drug coverage provided under the plan. For individuals between 135% and 150% of poverty, there would be a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. For those with incomes under 135% of poverty, beneficiary cost-sharing for spending up to the initial coverage limit would be reduced to an amount not to exceed $2 for a multiple source or generic drug and $5 for a non-preferred drug. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than $5 per prescription. (Beginning in 2007, these amounts would be increased by the percentage increase in per capita beneficiary drug costs.) Sponsors and entities could reduce to zero the cost-sharing otherwise applicable for generic drugs.

In 2006, persons eligible for low-income subsidies would have to have resources at or below three times the level applicable for the Supplemental Security Income program (i.e. $6,000 for an individual and $9,000 for a couple). Beginning in 2007, these amounts would be increased by the annual percentage increase in the consumer price index.

The determination of whether an individual was a subsidy eligible individual, and the amount of the subsidy, would be made by the State Medicaid program or the Social Security Administration. Such funds as necessary would be appropriated to the Social Security Administration. Individuals not in the 50 states or the District of Columbia could not be subsidy eligible individuals but could be eligible for financial assistance with drug costs under new Section 1935(e) added by Section 103.

The premium subsidy amount would be defined as the benchmark premium amount for the qualified prescription drug coverage that the beneficiary selects whether offered by a PDP plan or an MA Rx or EFFS Rx plan in the area. The benchmark premium amount for a plan means the premium amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for standard coverage (or alternative coverage if the actuarial value was equivalent). If a plan provided alternative coverage with a higher actuarial value than that for standard coverage, the benchmark amount would bear the same ratio to the total premium as the actuarial value of standard coverage was to the actuarial value of alternative coverage.

The Administrator would provide a process whereby the Administrator would notify the PDP sponsor or MA Rx or EFFS Rx entity that an individual was eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy. The Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of the reductions.

Part D benefits would be primary to any coverage available under Medicaid. The Administrator would be required to develop and implement a plan for the coordination of Part D benefits and Medicaid benefits. Particular attention would be given to coordination of payments and preventing fraud and abuse. The Administrator would be required to involve the Secretary, the States, the data processing industry, pharmacists, pharmaceutical manufacturers, and other experts in the development and administration of the plan.

Senate Bill

Medicaid beneficiaries eligible for medical and drug benefits under their state Medicaid program (including the medically needy) would continue to receive drug benefits through Medicaid. Persons meeting the definition of QMB, SLMB, or QI-1, and not eligible for Medicaid medical and drug benefits, as well as other persons below 160% of the federal poverty level, would receive their drug benefits through Part D. They would receive assistance for the Part D premium and cost-sharing charges.

QMBs, SLMBs and QI-1s would have a 100% premium subsidy for premiums provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average).

The benefit package for the QMB population would be defined as having a zero deductible, cost-sharing of 2.5% for costs below the initial coverage limit; 5.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 2.5% cost-sharing for costs above the catastrophic limit. The benefit package for the SLMB and QI-1 population would be defined as having a zero deductible, 5.0% cost-sharing for costs below the initial coverage limit; 10.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 2.5% cost-sharing for costs above the catastrophic limit. Plans could waive or reduce cost-sharing otherwise applicable.

Persons with incomes below 160% of poverty, not otherwise eligible for low-income benefits would have a sliding scale premium subsidy ranging from 100% of the premium at 135% of poverty to 0% at 160% of poverty with no additional premium costs provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average). The benefit package for this population would be defined as having a $50 deductible in 2006 (indexed in subsequent years by the annual percentage increase in average per capita Medicare drug expenditures), 10.0% cost-sharing for costs below the initial coverage limit; 20.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 10.0% cost-sharing for costs above the catastrophic limit. Plans could waive or reduce cost-sharing otherwise applicable.

QMBs, SLMBs and QI-1s and other Part D enrollees with incomes below 160% of poverty could enroll in MedicareAdvantage and receive their low-income assistance through such plans.

Beginning November 1, 2005, eligibility for low-income individuals would be determined by states. The Administrator would implement a process to notify the eligible entity or MedicareAdvantage plan that the individual was eligible for a cost-sharing subsidy and the amount of the subsidy. The entity would reduce the applicable cost-sharing and submit information to the Administrator on the amount of the reduction. The Administrator would

periodically and on a timely basis reimburse the entity or organization for the amount of the reductions.

Beginning January 1, 2009, to the extent a state had not already eliminated application of an asset test, it would be required to permit individuals to make a self-declaration that assets did not exceed $10,000 for an individual or $20,000 for a couple. In subsequent years, these amounts would be increased by the increase in the consumer price index. The Secretary would develop a model declaration form.

Conference Agreement

New Section 1860D-14 of the conference agreement provides premium and cost-sharing subsidies for low-income subsidy-eligible individuals. There are groups of subsidy eligible individuals. The first group is composed of persons who: 1) are enrolled in a prescription drug plan or MA-PD plan; 2) have incomes below 135% of poverty; and 3) have resources in 2006 below $6,000 for an individual and $9,000 for a couple (increased in future years by the percentage increase in the CPI), or 4) who is a full benefit dual eligible, regardless whether that person meets other eligibility standards. The second group of subsidy eligible individuals are persons meeting the same requirements, except that the income level is 150% of poverty and an alternative resources standard may be used; this alternative standard in 2006 is $10,000 for an individual and $20,000 for a couple (increased in future years by the percentage increase in the CPI.)

Individuals with incomes below 135% of poverty, and resources meeting the requirement for the first group, would have a premium subsidy equal to 100% of the low-income benchmark premium amount, but in no case higher than the actual premium amount for basic coverage under the plan. The low-income benchmark premium amount for a region equals either: 1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or 2) the weighted average of premiums for prescription drug plans and MA-PD plans, if plans in the region are offered by more than one PDP sponsor. Other low-income subsidy eligible persons will have a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. Persons below 135% of poverty would have a premium subsidy for any late enrollment penalty equal to 80 percent for the first 60 months and 100 percent thereafter.

Beneficiaries in both groups are entitled to cost-sharing subsidies. Individuals with incomes below 135% of poverty, and resources meeting the requirement for the first group will have no deductible, cost-sharing for all costs up to the out-of-pocket threshold of $2 for a generic drug or preferred multiple source and $5 for brand name or non-preferred drug. Institutionalized dual eligibles will have no cost sharing. Full benefit dual eligibles with incomes under 100 percent of poverty will have cost sharing up to the out-of-pocket threshold of up to $1 for a generic drug or preferred multiple source and $3 for a brand name or nonpreferred drug. Other low-income subsidy eligible persons will have a $50 deductible, 15 percent cost-sharing for all costs up to the out-of-pocket limit, and cost-sharing for costs above the out-of-pocket threshold of $2 for a generic drug or preferred multiple source and $5 for brand name or non-preferred drug. The deductible and cost-sharing amounts are increased each year beginning in 2007 by the annual percentage increase in per capita beneficiary expenditures for Part D covered drugs except for $1 and $3 cost-sharing, which will increase by the percentage increase in CPI.

Eligibility determinations are to be made under the state Medicaid plan for the state or by the Commissioner of Social Security. Conferees believe that more beneficiaries will enroll in the new Part D benefit if given the option to apply at the Social Security office as well as the welfare office. Low-income subsidy applications, information, and application assistance shall be available to beneficiaries in all Social Security offices and State Medicaid offices. It is the intent of the conferees that while enrollment at the SSA offices is important, both Medicaid programs and the Social Security Administration should engage in outreach activities to encourage eligible individuals to apply for subsidies under this section. The determinations shall remain effective for a period determined by the Secretary, not to exceed one year. Redeterminations or appeals are to be made in the same manner as such redeterminations and appeals are made by state Medicaid plans or the Commissioner for the supplemental security income program, whichever is appropriate.

Full dual eligible persons are to be treated as subsidy eligible persons; the Secretary may provide that other Medicaid beneficiaries be treated as subsidy eligible. Otherwise, income is to be determined in the same manner as determinations are made for the QMB program; however, Section 1902(r)(2) which permits the use of less restive methodologies does not apply for determining whether an individual is a low-income subsidy eligible individual. However, Section 1902(r)(2) continues to apply to all state Medicaid eligibility determinations. The Secretary is to develop a model simplified application form and process for determining and verifying eligibility. The Commissioner may only require submission of statements from financial institutions for an application for low-income subsidies to be considered complete. No other documentary evidence may be required with the submission of the application. The Secretary is permitted to verify information submitted on the application.

The Secretary will provide a process whereby the Secretary will notify the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy. The Administrator will periodically, and on a timely basis, reimburse the sponsor or entity for the amount of the reductions. Reimbursement for cost-sharing subsidies may be computed on a capitated basis.

The residents of the territories are not eligible for low-income subsidies. However, they may be eligible for financial assistance under the new section 1935(e), as added by Section 103.

Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage (New Section 1860D-15 of Conference agreement; New Section 1860D-8 of House bill; New Sections 1860D-20, 1860D-11, and 1860D-16 of Senate bill).

House Bill

a. Subsidies. New Section 1860D-8 would provide for subsidy payments to qualifying entities. The stated purpose of such payments would be to reduce premiums for all beneficiaries consistent with an overall subsidy level of 73%, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies and through reinsurance. The section would constitute budget authority in advance of appropriations and represent the obligation of the Administrator to provide for subsidy payments specified under the section.

Direct subsidies would be made for individuals enrolled in a PDP, MA Rx or EFFS Rx plan, and equal to 43% of the national weighted average monthly bid amount. Each year, the Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each drug plan (not including those offered by private-fee-for service entities) adjusted to add back in the value of reinsurance subsidies. The benchmark bid amount would be defined as the portion of the bid attributable to standard coverage or actuarial equivalent coverage. The bid amount would be a weighted average with the weight for each plan equal to the average number of beneficiaries enrolled in the plan for the previous year. (The Administrator would establish a procedure for determining the weighted average for 2005).

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP plan, or a MA Rx or EFFS Rx plan. The Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA Rx or EFFS Rx plans. Reinsurance payments would be provided for 30% of an individual's allowable drug costs over the initial reinsurance threshold ($1,000 in 2006) but not over the initial coverage limit ($2,000 in 2006). Reinsurance, not to exceed 80% would also be provided for costs over the out-of-pocket threshold ($3,500 in 2006). In the aggregate, reinsurance payments would equal 30% of total payments made by qualifying entities for standard coverage.

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that were actually paid by the plan (net of discounts, chargebacks, and average percentage rebates), but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were standard coverage. Gross covered drug costs would be defined as costs (including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded standard coverage and regardless of when the payment for the drugs was made.

The Administrator would be required to estimate the total reinsurance subsidy payments that would be made during the year (including those made to qualified retiree plans) and total benefit payments to be made by qualifying entities for standard coverage during the year. The Administrator would proportionately adjust payments such that total subsidy payments during the year were equal to 30% of total payments made by qualifying plans for standard coverage during the year. The Administrator could, in a budget neutral manner, adjust direct subsidy payments in order to avoid risk selection. The payment method would be determined by the Administrator who could use an interim payment system based on estimates. Payments would be made from the Medicare Prescription Drug Trust Fund.

b. Risk corridors. No provision.

Senate Bill

a. Subsidies. New Section 1860D-20 of the Senate bill would provide for reinsurance payments on behalf of: 1) persons enrolled in a PDP; 2) MA plan (except for MSA plan or private fee-for-service plan not providing qualified coverage); 3) persons eligible for but not enrolled in Part D and covered under a qualified retiree plan; 4) persons eligible for but not enrolled in Part D and covered under a qualified state pharmaceutical assistance program. Qualified retiree plans and state pharmaceutical assistance programs would have to provide

coverage at least equal to the actuarial value of standard coverage. Reinsurance payments would be made to plans in the case of individuals whose spending exceeded the out-of-pocket limit. Payments to plans would equal 80% (65% in the case of persons in a state pharmaceutical assistance program) of allowable drug costs exceeding the limit. Allowable costs would be equal to actual costs above the limit. Entities would be required to notify the Administrator of the total actual costs (if any) incurred for providing benefits for an individual after the individual exceeded the out-of-pocket threshold. Administrative costs, costs for coverage in excess of the standard benefit, and discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations would not be included. Payment methods would be determined by the Administrator. Such methods could include the use of interim payments.

Any plan sponsor that was not an employer would be required to redistribute reinsurance payments to employers contributing to the plan maintained by the sponsor; the payments would be allocated proportionately among all employers contributing to the plan.

The New Section 1860D-11 would require the Administrator to establish an appropriate method for adjusting payments to plans to take into account variations in costs based on the differences in actuarial risk of different enrollees being served. Any risk adjustment would be designed in a budget neutral manner. The Administrator could take into account similar methodologies used to adjust payments for Medicare Advantage organizations. The Administrator would be required to publish such risk adjusters not later than April 15 each year (beginning in 2005) to be used for computing payments to plans for standard coverage.

New Section 1860D-16 would require the Administrator to pay each entity offering a Medicare Prescription Drug Plan an amount equal to the full monthly approved premium, with appropriate risk adjusters. Payment terms would be determined by the Administrator and be based on terms used for Medicare Advantage plans. Payments to plans would be adjusted to account for differences in actuarial risk of different enrollees being served.

b. Risk corridors. New section 1860D-16 would require entities to notify the Administrator for each year (beginning in 2007) of the total actual costs the entity incurred in providing standard coverage in the preceding year. Total actual costs would reflect total payments made to pharmacies and other entities for coverage and the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity. The notification would not include spending for administrative costs, amounts spent for coverage in excess of standard coverage, or amounts for which the entity subsequently received reinsurance payments.

The provision would establish risk corridors, which would be defined as specified percentages above and below a target amount. The target amount would be defined as the total of plan premiums minus a percentage (negotiated between the Administrator and the entity) for administrative costs. No payment adjustment would be made if allowable costs were not more than the first threshold upper limit or less than the first threshold lower limit for the year, i.e. if the plans were within the first risk corridor. A portion of any plan spending above or below these levels would be subject to risk adjustments. If allowable costs exceeded the first threshold upper limit, then payments would be increased. If allowable costs were below the first threshold lower limit, payments would be reduced.

During 2006 and 2007, plans would be at full risk for drug spending within 2.5% above or below the target. Plans would be at risk for 25% of spending exceeding 2.5% (first

threshold upper limit) and below 5% of the target (second threshold upper limit). That is their payments would equal 75% of the allowable costs for spending in this range. They would be at risk for 10% of the spending exceeding 5% of the target. That is their payments would equal 90% of the allowable costs for spending in this range. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 90% of any amounts below 5% of the target.

A special transition corridor would be established in the first two years. The Administrator would make a payment adjustment if the Administrator determined that 60% or more of all participating plans (including Medicare Advantage plans) representing at least 60% of covered beneficiaries had allowable costs that were more than 2.5% above the target. Risk corridor payments would equal 90% of any spending greater than 2.5% of the target but below 5% of the target.

For 2008-2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5.0% above or below the target level. Plans would be at risk for 50% of spending exceeding 5.0% and below 10.0% of the target level. They would be at risk for 10% of the spending exceeding 10% of the target level. Payments would be increased by 50% of allowable costs exceeding the first threshold upper limit and 90% for costs exceeding the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 50% of the savings if costs fell between 5% and 10% below the target level, and 90% of any amounts below 90% of the target. For years after 2011, the Administrator would establish risk corridors. The first threshold risk percentage could not be less than 5% and the second threshold risk percentage could not be less than 10%.

Administrative costs would be not be included in the calculation of whether or nor plan spending fell within a particular risk corridor. Administrative costs would be negotiated separately, on a plan by plan basis, with the Administrator. Administrative costs would be subject to performance risk.

For purposes of making risk corridor calculations, allowable costs would be based on actual costs reported by the plan.

The Administrator could require disclosure of any data as needed to administer the benefit. The Administrator would have the right to inspect and audit any books and records of the entity pertaining to amounts reported for drug spending. Information could be used by officers and employees of the Department of Health and Human Services, but only to the extent necessary to carry out this section.

The Administrator would be required to establish a stabilization reserve fund, within the Prescription Drug Account. Amounts in this fund would be made available to eligible entities beginning with their 2008 contract year. Payments to the fund would be determined as follows. If the target amount for a plan for any year 2006 - 2010 exceeded applicable costs by more than 3% for the year, the entity would pay the Administrator the amount of such excess; the Administrator would deposit such amount in the fund on behalf of the entity. Applicable costs would be defined as the sum of allowable costs and the amount by which monthly payments were reduced through application of the risk corridor provisions. At appropriate intervals, the Administrator would notify a participating entity of the balances in any of its stabilization accounts. Beginning in 2008, entities would be permitted to use account funds to stabilize or reduce plan premiums. The

accounts would expire after 5 years. Any amounts not used by an eligible entity or that was deposited for use by an entity that no longer had a Part D contract would revert to the use of the Prescription Drug Account.

Conference agreement

a. Subsidies. New Section 1860D-15 of the conference agreement provides for subsidy payments to qualifying entities. Such payments would reduce premiums for all beneficiaries consistent with an overall subsidy level of 74% for basic coverage, to reduce adverse selection among plans, and to promote the participation of PDP sponsors and MA organizations. Such payments would be made as direct subsidies and through insurance.

The direct monthly per capita subsidy amount is equal to the plan's standardized bid amount adjusted for health status and risk and reduced by the base beneficiary premium as adjusted to reflect the difference between the bid and the national average bid.

Reinsurance payments, equal to 80% of allowable costs, would also be provided for an enrollee whose costs exceeded the annual out-of-pocket threshold ($3,600 in 2006). For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that were actually paid by the plan (net of discounts, chargebacks, and average percentage rebates), but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were basic coverage or, in the case of supplemental coverage, standard coverage. Gross covered drug costs would be defined as costs (not including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded basic coverage and regardless of when the payment for the drugs was made.

The Secretary is required to establish an appropriate method for adjusting the standardized bid amount to take into account variations in costs for basic coverage based on the differences in actuarial risk of different enrollees being served. Any risk adjustment would be designed in a budget neutral manner. The Secretary may take into account similar methodologies used to adjust payments for MA organizations. The Secretary would require PDP sponsors and MA organizations offering MA-PD plans to submit data. The Secretary is required to publish such risk adjusters at the same time as risk adjusters are published for MA organizations.

The Secretary is required to establish an appropriate method for adjusting the national average monthly bid amount per capita subsidy amount to take into account differences. If the Secretary determines that price variations are de minimus, no adjustment is to be made. Any adjustments must be applied in a budget neutral manner.

The Secretary is to establish payment methods, which may include interim payments. Payments are conditional upon the PDP sponsor and MA organization furnishing necessary information to the Secretary. Information may be used by officers and employees of HHS only for the purposes of and to the extent necessary to carry out the section.

c. Risk corridors. New Section 1860D-15 of the conference agreement provides for the establishment of risk corridors, which are defined as specified percentages above and below a target amount. The target amount is defined as total payments paid to the plan, taking into

account the amount paid by the Secretary and enrollees, based on the standardized bid amount, risk adjusted, and reduced by total administrative expenses assumed in the bid. No payment adjustments will be made if adjusted allowable costs for the plan are at least equal to the first threshold lower limit of the first risk corridor but not greater than the first threshold upper limit of the risk corridor for the year, i.e. if the plans are within the first risk corridor. A portion of any plan spending above or below these levels is subject to risk adjustment. If adjusted allowable costs exceed the first threshold upper limit, then payments are increased. If adjusted allowable costs are below the first threshold lower limit, then payments are reduced. Adjusted allowable costs are reduced by reinsurance and subsidy payments. Payment adjustments would not affect beneficiary premiums.

During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5% above or below the target. Plans with adjusted allowable costs above this level would receive increased payments. If their costs were between 2.5% of the target (first threshold upper limit) and 5% of the target (second threshold upper limit), they would be at risk for 25% of the increased amount; that is their payments would equal 75% of adjusted allowable costs for spending in this range. If their costs were above 5% of the target they would be at risk for 25% of the costs between the first and second threshold upper limits and 20% of the costs above that amount. That is their payments would equal 80% of the adjusted allowable costs over the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 80% of any amounts below 5% of the target.

A higher risk sharing percentage would apply in 2006 and 2007 if the Secretary determines that 60 percent of prescription drug plans and MA-PD plans, representing at least 60 percent of beneficiaries enrolled in such plans have adjusted allowable costs that are more than the first threshold upper limit. In this case, payment to plans would equal 90 percent of adjusted allowable costs between the first and second upper threshold limits.

For 2008-2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5% above or below the target level. Plans would be at risk for 50% of spending exceeding 5% and below 10% of the target level. Additionally, they would be at risk for 20% of any spending exceeding 10% of the target level. Payments would be increased by 50% of adjusted allowable costs exceeding the first threshold upper limit and 80% for any costs exceeding the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 50% of the savings if costs fell between 5% and 10% below the target level, and 80% of any amounts below 10% of the target. For years after 2011, the Administrator would establish risk corridors. The first threshold risk percentage could not be less than 5% and the second threshold risk percentage could not be less than 10% of the target amount. Conferees intend the risk corridors to create incentives for plans to enter the market.

If allowable risk corridor costs are less than the first threshold lower limit, but not greater than the first threshold upper limit for the plan year, then no payment adjustment is made.

Plans are at full financial risk for all spending for supplemental prescription drug coverage.

The subsidy and risk corridor provisions would not apply to fallback plans.

Medicare Prescription Drug Account in the Federal Supplementary Insurance Trust Fund (New Section 1860D-16 of conference Agreement; New Section 1860D-9 of House Bill; New Section 1860D-25 of Senate Bill).

Present Law

Medicare Part B is financed by a combination of enrollee premiums and federal general revenues. Income from these sources is credited to the Federal Supplementary Insurance Trust fund. Payments are made from the Trust Fund for Part B benefits.

House Bill

New Section 1860D-9 would create a Medicare Prescription Drug Trust Fund. Requirements applicable to the Part B trust fund would apply in the same manner to the Drug Trust Fund as they apply to the Part B Trust Fund. The Managing Trustee would pay from the Fund, from time to time, low-income subsidy payments, subsidy payments, and payments for administrative expenses. The Managing Trustee would transfer, from time to time, to the Medicaid account amounts attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the fact that Medicaid becomes the secondary payer of drug benefits for the dual eligibles. The provision would authorize appropriations to the Trust Fund an amount equal to the amount of payments from the Trust Fund reduced by the amount transferred to the Trust Fund.

The provision would specify that any provision of law relating to the solvency of the trust fund would take into account the Fund and the amounts received by, or payable from, the Fund.

Senate Bill

A separate account, known as the Prescription Drug Account, would be established within the Part B Trust Fund. Funds in this Account would be kept separate from other funds within the Trust Fund. Payments would be made from the Account to eligible entities and Medicare Advantage plans and for low-income subsidies, reinsurance payments, and administrative expenses. Appropriations would be made to the Account equal to the amount of payments and transfers made from the Account.

Conference agreement

The conference agreement establishes a Medicare Prescription Drug Account in the Part B Trust Fund. Funds in this Account will be kept separate from other funds within the Trust Fund. Payments will be made from the Account for low-income subsidies, subsidy payments, payments to qualified retiree prescription drug plans, and administrative expenses. Transfers would be made to the Medicaid account for increased administrative costs. States would make payments to the Account for dual eligibles as provided for under Section 1935(c). Appropriations would be made to the Account equal to the amount of payments and transfers from the Account. In order to ensure prompt payments in the early months of the program, there are appropriated such amounts the Secretary certified as necessary, not to exceed 10% of estimated expenditures for 2006.

Subpart 3 - Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans.

Application to Medicare Advantage Program and Related Managed Care Programs (New Section 1860D-21 of Conference agreement; Section 101 of House bill; Sections 201 and 205 of Senate bill).

Present Law

No provision.

House Bill

Beginning January 1, 2006, at least one MA plan offered by an MA organization in an area would be required to: 1) offer qualified drug coverage under Part D; 2) meet the beneficiary protections outlined in the new Section 1860D-3, including requirements relating to information dissemination as well as grievance and appeals; and 3) provide the same information required from prescription drug plan sponsors when submitting a bid, unless waived by the Administrator. MA organizations providing qualified drug coverage would receive low-income subsidy payments and direct and reinsurance subsidies. A single premium would be established for drug and non-drug coverage.

There would be exceptions for the prescription drug coverage offered by private fee-for-service (PFFS) plans. PFFS plans would not be required to negotiate prices or discounts; however, to the extent a plan did so, it would be required to meet related Part D requirements.

Senate Bill

In addition to current law requirements, Medicare beneficiaries would also be required to be enrolled in the new Part D (prescription drug program) in order to enroll in MA (except for PFFS).

Beginning on January 1, 2006, MA plans, other than PFFS and MSA plans, would be required to offer each enrollee qualified prescription drug coverage that met the requirements for such coverage under the MA program and under Part D of Medicare. An MA plan could offer qualified prescription drug coverage that exceeded the coverage required under Part D, as long as it also offered an MA plan in the area that provided only the required coverage. This provision would also establish payments to each MA organization offering an MA plan that provided qualified prescription drug coverage, including a low-income drug subsidy.

Conference Agreement

Beginning January 1, 2006, an MA organization can not offer an MA plan in an area unless either that plan (or another MA plan offered by the organization in the same service area) includes required prescription drug coverage, and could not offer prescription drug coverage (other than that required under parts A and B) to an enrollee under an MSA plan or under another MA plan unless such drug coverage was qualified prescription drug coverage and unless the requirements of this section, with respect to such coverage are met. Qualified coverage is basic coverage or qualified coverage that provides supplemental drug benefits so long as there is no MA monthly supplemental beneficiary premium under the plan.

An individual enrolled in a health benefits plan would not be considered to have been deemed to make an election into an MA-PD plan, unless the plan provides prescription drug coverage. An individual enrolled in an MA plan would not be considered to have been deemed to make an election into an MA-PD plan, unless: (1) for purposes of the January 1, 2006 election, the MA plan provided as of December 31, 2005 any prescription drug coverage; or (2) for periods after January 1, 2006, such MA plan was an MA-PD plan. An individual who discontinues enrollment in an MA-PD plan during his/her first year of eligibility could enroll in a prescription drug plan under part D at the time of their election of coverage under original Medicare fee-for-service program.

If an individual is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, and the organization discontinues offering all MA plans without prescription drug coverage, then the individual would be deemed to have elected the original Medicare fee-for-service program, unless the individual affirmatively enrolls in an MA-PD plan. This disenrollment would be treated as an involuntary termination of the MA plan.

The provisions of this part would apply under Part C of Medicare with respect to prescription drug coverage provided under MA-PD plans in lieu of other Part C provisions that would apply to such coverage. The Secretary could waive these provisions to the extent that they duplicate provision under Part C or as may be necessary in order to improve coordination. The Secretary may also waive the pharmacy network requirements of section 1860D-4(b)(1)(C) in the case of an MA-PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organizations. The Secretary must determine the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

Private fee-for-service plans (PFFS) plans would not be required to negotiate prices or discounts; however, to the extent a plan did so, it would be required to meet related Part D requirements. If the PFFS plan provided coverage for drugs purchased from all pharmacies, without additional cost-sharing, requirements for pharmacy access and public disclosure of pharmaceutical prices for equivalent drugs would not apply. For PFFS plans, the drug utilization management program and the medication therapy management program would not be required. For PFFS plans, the Secretary would determine the amount of reinsurance payment using a methodology that bases such amount on the Secretary's estimate of the amount of such payment that would be payable if the plan were an MA-PD plan and that takes into account the average reinsurance payment made for a population of similar risk under MA-PD plans. The risk corridor provisions would not apply, and plans would be exempt from negotiations on bid terms.

If an organization provides benefits under a reasonable cost reimbursement contract and also elects to provide qualified prescription drug coverage, then the provisions of this section and related provisions in part C would apply in the same manner as applied to local MA-PD plans. Individuals, who were not enrolled in the reasonable cost plan, could not enroll in the prescription drug plan. The bid of the reasonable cost plan would not be taken into account in computing any standardized bid amount under this section.

In general, the provisions of Part D and related provisions of Part C apply to PACE programs in the same manner as they apply to MA-PD plans. The organization may not enroll persons not enrolled in PACE. Bids are not taken into account in computing the standardized bid amount.

Special Rules for Employer-Sponsored Programs (New Section 1860D-22 of Conference agreement; New section 1860D-8 of House bill; New Section 1860D-21 and 1860D-22 of Senate bill).

Present Law

No provision.

House Bill

Under New section 1860D-8, special subsidy payments would be made to a "qualified retiree prescription drug plan." A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The Administrator would have to determine that coverage had at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless: the individual was covered under the retiree plan, entitled to enroll under a PDP or MA Rx or EFFS Rx plan but elected not to. Subsidy payments would equal 28% of allowable costs between $250, but not greater than $5,000, indexed annually by the percentage increase in Medicare per capita prescription drug costs. The provision would clarify that nothing in the section would be construed as precluding an individual covered under an employment- based retiree plan from enrolling in a PDP plan or MA or EFFs plan or having the employment based plan from paying the premium. Employment-based supplemental coverage would be considered the primary payer for purposes of the Medicare secondary payment provisions.

Senate Bill

New Section 1860D-21 of the Senate bill would authorize the Administrator to make direct payments to sponsors of qualified retiree prescription drug plans (as defined under New Section 1860D-20) for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would equal the direct subsidy percent of the monthly national average premium for the year, as adjusted by risk adjusters. The direct subsidy percent would be 100% minus the applicable percent as defined under the new Section 1860D-17. The applicable percentage for an area would be 30% divided by: 1) 100%, minus two) a percentage equal to total reinsurance payments that would be made in a year divided by such amount plus total payments that would be made to plans in the year for standard coverage.

The Administrator would establish payment methods, which could include interim payments. Payments would be made from the Prescription Drug Account.

New Section 1860D-22 would require the Administrator to make direct payments to sponsors of qualified state pharmaceutical assistance programs for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would be calculated in the same way that such payments were calculated for retiree plans. Further, the Administrator would provide for additional payments in behalf of each person who would otherwise qualify for a low-income subsidy, if the individual were enrolled in Part D. The payment would equal the amount the Administrator estimates would have been paid under the subsidy provisions, but in no case

more than the average payment made under the subsidy provisions for an individual in the same income group.

Conference agreement

New Section 1860D-22 of the conference agreement establishes special rules for employer-sponsored programs. Under certain conditions, the Secretary is required to make special subsidy payments to sponsors of qualified retiree prescription drug plans. These payments are to be made on behalf of an individual covered under the retiree plan, entitled to enroll under a PDP or MA-PD plan but elected not to. Subsidy payments will equal 28% of gross covered retiree plan-related prescription drug costs greater than $250 but not greater than $5,000, adjusted annually by the percentage increase in Medicare per capita prescription drug costs.

Qualified retiree prescription drug plans must be employment- based group health plans. Group health plans include welfare plans defined under the Employee Retirement Income Security Act, federal and state governmental plans, including such plans as the Federal Employee Health Benefits program and CalPERS, collectively bargained plans, and church plans. Conferees expect that in the case of interpretive matters with regard to plan sponsors of group health plans, CMS will coordinate with the Department of Labor and Treasury Department for guidance. The sponsor must provide the Secretary with an attestation that the actuarial value of prescription drug coverage under the plan is at least equivalent to the actuarial value of standard prescription drug coverage. The sponsor, or administrator designated by the sponsor, shall maintain and afford the Secretary access to necessary records for the purpose of audits and other oversight activities. The sponsor is required to provide disclosure of information in accordance with disclosure of information on creditable coverage.

Nothing in the section is to be construed as precluding an individual covered under an employment-based retiree plan from enrolling in a PDP plan or MA-PD plan or having the employment-based plan from paying the premium. The PDP or MAPD plan would constitute primary coverage, not the employer. Employment-based retiree coverage may provide coverage that is better than standard coverage to retirees under a qualified retiree prescription drug plan. Employment-based retiree health coverage may provide coverage that is supplemental to benefits provided under a prescription drug plan or MA-PD plan to enrollees in such plans. Nothing is to prevent employers from providing flexibility in benefit design and pharmacy access provisions for basic drug coverage so long as actuarial equivalence requirements are met.

About one-third of Medicare beneficiaries receive coverage for prescription drugs from their former employers. Retirees are generally happy with their coverage and want to keep it. But employer plans are under increasing pressure to drop or scale back coverage. In 1988, 66% of large employers provided health benefits. In 2002, that number slipped to just 34%. Costs for retiree health coverage rose 16.0% in 2002, while prescription drug expenditures increased by 11.8% last year, and most employers predict double-digit health inflation well into the future. Conferees believe the employer retiree subsidies included in the conference report will help employers retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve. Absent this assistance, many more retirees will lose their employer sponsored coverage.

State Pharmaceutical Assistance Programs (New Section 1860D-23 of Conference agreement**)**.

Present Law

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

House Bill

No provision.

Senate Bill

No provision.

Conference agreement

New Section 1860D-23 of the conference agreement requires the Secretary, by July 1, 2005, to establish requirements to ensure effective coordination between a Part D plan (both a prescription drug plan and MA-PD plan) and a state pharmaceutical assistance program (SPAP). The coordination requirements relate to payment of premiums and coverage and payment for supplemental drug benefits, and assistance with cost-sharing. Requirements must be included for enrollment file-sharing, claims processing, claims reconciliation reports, application of the catastrophic out-of-pocket protection, and other administrative procedures specified by the Secretary. Requirements are to be consistent with applicable law, to safeguard the privacy of any identifiable beneficiary information. The agreement provides that the requirements must include a method for the application by a Part D plan of specified funding amounts for enrolled beneficiaries for supplemental benefits. The Secretary is required, when developing the requirements, to consult with state programs, the PDP sponsors, MA organizations, States, pharmaceutical benefit managers, employers, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

This legislation allows state pharmacy assistance programs to act as administrative intermediaries for the purpose of facilitating enrollment of SPAP members in prescription drug plans and in the discount card program.

A state pharmaceutical program that this provision applies to is one: 1) that provides financial assistance for the purchase or provision of supplemental prescription drug coverage on behalf of eligible individuals; and 2) which, in determining program eligibility and amount of payment, provides assistance to beneficiaries in all Part D plans and does not discriminate based on the Part D plan in which the individual is enrolled. A card used under Part D may also be used for benefits under the state program.

The agreement authorizes the Secretary, based on an approved application, to provide payments to state pharmaceutical assistance programs for the purpose of educating program beneficiaries about Part D coverage, providing technical assistance to facilitate selection and enrollment in plans, and other activities to promote effective coordination. The report provides $62.5 million in mandatory spending in each fiscal year 2005 and 2006 to help promote coordination between Medicare plans and SPAPs.

Coordination Requirements for Plans Providing Prescription Drug Coverage (New Section 1860D-24 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill.

No provision.

Conference Agreement

The New Section 1860D-24 of the conference agreement requires the Secretary to apply the coordination requirements established under the New Section 1860D-23 for state pharmaceutical assistance programs, to other prescription plans including Medicaid (including a plan operating under an 1115 waiver), group health plans, federal employees health benefits plan, military coverage (including TRICARE), and other coverage specified by the Secretary.

The coordination requirements include coordination of procedures to establish third-party reimbursement of out-of-pocket costs. The provision does not change the application of these procedures. The Secretary may impose user fees for the transmittal of information necessary for benefit coordination.

Medicare Prescription Drug Discount Card and Transitional Assistance Program (New Section 1860D-31 of Conference agreement; Section 105 of House bill; Section 111 of Senate Bill**)**.

Present Law .

On July 12, 2001, the President announced a new national drug discount card program for Medicare beneficiaries. Under this program, CMS would endorse drug card programs meeting certain requirements. This program was viewed as an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, was enacted. Implementation of the drug discount card program was suspended by court action.

House Bill

The provision would require the Secretary to establish a program to: 1) endorse prescription drug discount card programs meeting certain requirements; 2) provide for prescription drug accounts; and 3) make available information on such programs to beneficiaries. The Secretary would begin operation of the endorsement program within 90 days of enactment. The account part of the program would begin no later than September 2004. The Secretary would provide for an appropriate transition and termination of the program on January 1, 2006. The program would be voluntary.

Eligible beneficiaries would be defined as persons eligible under Part A or enrolled in Part B, but not enrolled in an MA plan offering qualified prescription drug coverage. The Secretary would establish a process through which an Part D eligible individual could make an election to enroll under the new Section 1807 with an endorsed program. The beneficiary would have to enroll for a year in order to receive the benefits for the year. An individual would, in general have only one opportunity for enrollment. This would occur during an initial, general enrollment period as soon as possible after enactment, and annually thereafter. The annual open enrollment periods would be coordinated with those for MA. An individual who enrolled in the new Section 1807, subsequently enrolled in an MA plan with drug coverage, and then discontinued such MA enrollment would be permitted to reenroll under Section 1807.

In general, eligible beneficiaries would not be permitted to enroll after their initial enrollment period (as defined under Part B). The Secretary would establish an open enrollment period for current beneficiaries.

The Secretary would establish a process through which an Part D eligible individual, enrolled under the new Section 1807, would select an eligible entity to provide access to negotiated prices. The entity would be one, which had been awarded a contract and served the state in which the beneficiary resided. Eligible entities would be pharmaceutical benefit management companies, wholesale and retail pharmacy delivery systems, insurers, MA organizations, other entities, or any combination of these.

The enrollment process, established by the Secretary, would use rules similar to those established for MA. Individuals could not select more than one entity at a time and, except for unusual circumstances (including changing residential setting, such as nursing home placement.) change the selection once a year. The process would provide for selecting eligible entities for individuals who enrolled in the New Section 1807, but failed to select an entity. Entities would compete for beneficiaries on the basis of discounts, formularies, pharmacy networks, and other services.

The Secretary would broadly disseminate information to eligible beneficiaries regarding enrollment, selection of eligible entities, and the coverage made available by entities. The enrollment fee would be $30 with the 2004 fee including any portion of 2003 covered by the program. The fee would be collected in the same manner as Part B premiums are collected from social security payments, except the collection would be made only once a year. States could pay the fee for some or all low-income enrollees in the state. No federal matching payments would be available. The Secretary would make 2/3 of the fee collected available to the eligible entity.

Each eligible entity would be required to issue a card and an enrollment number to each enrolled beneficiary and to provide for electronic methods to coordinate with prescription drug accounts established under the New Section 1807A.

Beneficiary protections would be established including guaranteed issue and nondiscrimination provisions. If an eligible entity served a state, it would be required to serve the entire state. Entities would be required to disseminate, to each beneficiary who selected the entity, summary information on negotiated prices, access to such prices through pharmacy networks, and how the formulary functioned. Upon request, entities would be required to provide general coverage, utilization, and grievance information. In addition, entities would be required to have a mechanism for providing specific information upon request. The new Part D provisions relating to pharmacy access would apply to eligible entities. To the extent the

Secretary determined they could be implemented on a timely basis, entities would be required to meet the new Part D provisions with respect to development and application of formularies and the requirements to have in place an effective cost and drug utilization management program, quality assurance measures and systems, and a program to control fraud, abuse and waste. Each entity would be required to have in place meaningful procedures for hearing and resolving grievances and for expedited determinations and reconsiderations of coverage determinations. Entities would be required to provide pharmaceutical support services. They would also be required to provide for confidentiality and accuracy of enrollee records and periodic reports to the Secretary.

Entities would be required to provide beneficiaries with access to negotiated prices (including applicable discounts). Such discounts would not be taken into account in establishing "best price" for purposes of Medicaid calculations. If the entity used a formulary, negotiated prices would only be available for formulary drugs. Negotiated prices could not be limited to mail order drugs. Entities and contracting pharmacies could not charge beneficiaries for any required services. Entities would be required to disclose to the Secretary the extent to which discounts, or rebates or other remuneration or price concessions made available by a manufacturer were passed through to enrollees; such information would be confidential. Entities would be required to notify enrollees at the time of purchase of the differential between any prescribed drug and the cost of the lowest cost available generic drug that was therapeutically equivalent and bioequivalent.

The Secretary would be required to establish a prescription drug account for each enrolled individual and deposit into the account the federal contribution amount. This amount would be $800 for an accountholder with income under 135% of poverty, $500 for an accountholder with income between 135% and 150% of poverty, and $100 for all other persons. Income would be determined under the state Medicaid program or by the Social Security Administration (SSA). Such sums as may be necessary would be authorized to be appropriated to the SSA. If the program was not in effect for all of 2004, the amounts would be prorated. Persons would not be eligible for a federal contribution if they were eligible for drug coverage under Medicaid, group health plan, Medigap, medical care for members of the uniformed services, Veterans' medical care, Federal Employees Health Benefits program, or the Indian Health Care Improvement Act. The provision would authorize appropriations to the Part B trust fund of an amount equal to the amount by which benefits and administrative costs exceeded the portion of enrollment fees retained by the Secretary.

The provision would establish a new Section 1807A, Prescription Drug Accounts, that would be established for each enrolled beneficiary. Contributions to the account would include federal contributions, any state contributions, private contributions (including employer and individual contributions) and spousal rollover contributions. If the accountholder was married at the time of death, the amount in the account attributable to public contributions would be credited to the account, if any, of the surviving spouse, or if the spouse was not an Part D eligible individual, into a reserve account to be held for when the spouse became an Part D eligible individual.

Costs of the voluntary prescription drug discount card program would not be considered in calculating the Part B premium.

By March 1, 2005, the Administrator would be required to submit a report to Congress on the progress made in implementing the new prescription drug benefit, including specific steps

that had been taken, and need to be taken, to ensure timely start of the program on January 1, 2006.

Senate Bill

Section 111 would add a new Section 1807 to the Social Security Act, *Medicare Prescription Drug Discount Card Endorsement Program*. The Secretary would establish a program under which the Secretary would endorse card programs offered by prescription drug card sponsors meeting certain requirements and would make available information on such programs to beneficiaries. Eligible sponsors would be entities with demonstrated experience and expertise in operating a prescription drug discount card program or similar program that the Secretary determined to be appropriate to provide benefits to Medicare beneficiaries. Such entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers, other entities, or any combination of these.

Any individual entitled to Part A and enrolled in Part B would be eligible to enroll in an endorsed prescription drug card program. The Secretary would be required to establish procedures for identifying eligible beneficiaries. The Secretary would also be required to establish procedures under which beneficiaries could make an election to enroll and disenroll in an endorsed card program. A beneficiary could only be enrolled in one endorsed program at a time. Card sponsors could charge annual enrollment fees, not to exceed $25. The fee would be the same for all eligible Medicare beneficiaries enrolled in the program and would be collected by the card sponsor.

The Secretary would provide information, which compared the costs and benefits of various programs. This information dissemination, intended to promote informed choice, would be coordinated with the dissemination of other educational information on other Medicare options. Each card sponsor would make available to each beneficiary (through the Internet or otherwise) information that the Secretary identified as being necessary to provide for informed choice by beneficiaries among endorsed programs; this would include information on enrollment fees, negotiated prices, and services related to drugs offered under the program. The sponsor would have to provide information on how the formulary functioned. The Medicare toll-free number, 1-800-MEDICARE, would be used to receive and respond to inquiries and complaints.

Each endorsed drug card program would have to meet beneficiary protection requirements, including those relating to beneficiary appeals and marketing practices. They would also have to ensure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price. Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access (including adequate emergency access) for beneficiaries enrolled in the program. Convenient access would be determined by the Secretary and would take into account reasonable distances to pharmacy services in both urban and rural areas. Each card sponsor would be required to have in place procedures for assuring that quality service was provided to eligible beneficiaries enrolled in a prescription drug discount card program. They would also have to safeguard individually identifiable information in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Sponsors would be prohibited from charging any fees, except for the annual enrollment fee. Card sponsors could not recommend switching an Part D eligible individual to a drug with a higher negotiated price, unless a licensed health professional recommended a switch based on a clinical indication. Negotiated prices could not change more than once every 60 days.

Card sponsors would provide enrolled beneficiaries with access to negotiated prices used by the sponsor for payment for prescription drugs, provided such drugs were not excluded under the program's formulary. The term negotiated price, would include all discounts, direct or indirect subsidies, rebates, price concessions, and direct or indirect remunerations. Medicaid negotiation rules, including rebate requirements, would not apply.

Each card program would be required to provide pharmaceutical support services such as education, counseling, and services to prevent adverse drug interactions. Each card sponsor would issue a discount card to program enrollees.

Sponsors seeking endorsement of a card program would submit required information to the Secretary. The Secretary would review the information and determine whether to endorse the program. A program could not be approved unless it and the sponsor complied with the requirements of the new Section 1807.

Sponsors could use a formulary. Sponsors electing to use a formulary would be required to establish a pharmaceutical and therapeutic committee (that included at least one academic expert, at least one practicing physician and at least one practicing pharmacist) to develop and review the formulary. The committee would base clinical decisions on the strength of scientific evidence and standards of practice. The formulary would have to include drugs within each therapeutic category and class of covered drugs (as defined by the Secretary) although not necessarily for all drugs within such categories and classes. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been provided to beneficiaries, physicians, and pharmacies. The Secretary would provide appropriate oversight to ensure compliance of programs; including verification of the negotiated prices and services provided. Each program sponsor would be required to report to the Secretary on program performance, use of drugs by beneficiaries, financial information of the sponsor, and other information required by the Secretary. The Secretary could not disclose any proprietary data that was reported. The Secretary could use Parts A and B claims data for purposes of conducting a drug utilization review program.

Section 111 would add a new Section 1807A to the Social Security Act, *Transitional Prescription Drug Assistance Card Program for Eligible Low-Income Beneficiaries*. The Secretary would award contracts to prescription drug card sponsors, offering a program that was endorsed by the Secretary under the new Section 1807, to offer a prescription drug card assistance program to eligible low-income beneficiaries. The program would begin no later than January 1, 2004. The Secretary would provide for a transition and discontinuation of the drug card program and the low-income assistance card program when the new Part D program became effective. The transitional programs would continue to operate at least 6 months after the date benefits first became available under Part D.

All individuals meeting the definition of QMB, SLMB, or QI-1, or those with income below 135 percent of poverty who were not eligible to receive drug benefits under Medicaid, could receive assistance with their prescription drug costs, effective January 1, 2004. In addition, those determined to have income below 135 percent of poverty could receive assistance with their prescription drug costs. These persons would have access, through a drug discount card, to up to $600 per year. The entire $600 benefit would be available for the entire year; any balance left on the card in one year could be carried forward. Beneficiaries would be subject to

cost-sharing requirements, which could not be less than 5% of the negotiated price for a drug, or 10% for a transitional assistance eligible individual. Cost-sharing charges would not count against the $600. At a minimum, card sponsors would provide low-income enrollees with a minimum of a 20% discount from the average wholesale price for each covered drug.

In general, the enrollment procedures established for the drug discount card program would apply for this program. Each sponsor offering an assistance card program would be required to enroll any low-income person wishing to enroll if the program served the geographic area where the beneficiary resides. An individual enrolling in an assistance card program would be simultaneously enrolled in a discount card program offered by the sponsor. Enrollment fees would be waived for these individuals and would instead be paid by the Secretary.

Eligible beneficiaries would have to be provided the information required for the discount card program. In addition, sponsors would be required to notify low-income enrollees, on a periodic basis, of the amount of coverage remaining and on the grievance and appeals process under the program.

Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access for beneficiaries enrolled in the program. The Secretary would determine whether convenient access was provided; mail order pharmacies would not be included in the determination. Further, the Secretary could not make a determination that convenient access had been provided, unless an appropriate arrangement was in place for low-income persons in long-term care facilities.

The Secretary would be required to establish procedures under which benefits under the assistance card program were coordinated with coverage under a state pharmaceutical assistance program or Medicare+Choice plan.

Drug discount card managers could establish formularies. A low-income enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug was not as effective for the individual or had adverse effects for the individual. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable for a preferred drug if the prescribing physician determined that the preferred drug was not as effective for the individual or had adverse effects for the individual.

Sponsors offering assistance card programs would be required to process claims negotiate with brand name and generic manufacturers and others for price concessions, track individual beneficiary expenditures, and perform other functions specified by the Secretary. Each sponsor would receive data exchanges in a format specified by the Secretary.

Entities would be required to assure that low-income beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that was therapeutically equivalent and bioequivalent and that was available at the pharmacy or other dispenser. Entities would also be required to have meaningful procedures for hearing and resolving grievances, comparable to those established for Medicare+Choice plans. In addition, eligible entities would be required to meet Medicare+Choice requirements relating to coverage determinations.

Sponsors seeking to offer an assistance program would be required to submit information to the Secretary, in the manner specified by the Secretary. The Secretary could not approve a program unless the sponsor and program met the requirements of the new Section 1807A. Further, the Secretary would have to determine that the entity was appropriate to provide benefits to low-income beneficiaries, was able to manage the monetary assistance provided under the program, agreed to submit to audits by the Secretary, and provided other assurances require by the Secretary. There would be no limit on the number of sponsors who could be awarded contracts. The contract would be for the lifetime of the program and cover the same service area served by the sponsor under the card program under Section 1807. The sponsor could submit an application for endorsement under both programs simultaneously.

The Secretary would pay sponsors the amount agreed to in the contract between the sponsor and the Secretary. Payments would be made from the Part B trust fund but would not be considered in the calculation of the Part B premium.

The Secretary would implement New Sections 1807 and 1807A to assure that discounts and benefits were available no later than January 1, 2004. The Secretary would provide for an appropriate transition and discontinuation of the programs; such transition would ensure that benefits continue to operate until the first Part D enrollment period ended.

Conference Agreement

a. Establishment of Program. The conference agreement adds a new Section 1860D-31 to the Social Security Act, Medicare Prescription Drug Discount Card and Transitional Assistance Program. The Section requires the Secretary to establish a program to endorse prescription drug discount card programs meeting certain requirements. Discount card eligible individuals would receive access to prescription drug discounts through card sponsors throughout the U.S. The program will also provide transitional assistance for low-income persons enrolled in endorsed programs. The program is voluntary for eligible individuals.

The agreement requires the Secretary to implement the program so that discount cards and transitional assistance are available no later than 6 months after enactment. The Secretary is required to promulgate regulations to carry out the program. They could be promulgated on an interim final basis which could be effective on the date of issuance. In the case interim final regulations are promulgated, a public comment period would be provided. The Secretary could change or revise the regulations after conclusion of the comment period.

The conference agreement specifies that the new program would not, except as provided for during an individual's transition period, apply to covered discount card drugs dispensed after December 31, 2005. However, any transitional assistance for low income persons would be available after that date to the extent the assistance was for drugs dispensed on or before that date.

Special rules may apply for an individual in a transition period who is also enrolled under a card program as of December 31, 2005. The transition period to the new Part D is the period beginning January 1, 2006 and ending on the effective date of the individual's coverage under Part D or at the close of the individual's initial enrollment period for Part D. During this period, discounts may continue to apply for drugs dispensed to the individual, no annual enrollment fee would be applicable, the individual could not change the endorsed plan in which they were

enrolled, and the balance of any transitional assistance remaining on January 1, 2006 would remain available for drugs dispensed during this period.

b. Eligibility. The conference agreement specifies that persons eligible for the discount card are those entitled to or enrolled under Part A or enrolled under Part B. However individuals enrolled in Medicaid (or under any Section 1115 Medicaid waiver) who are entitled to any medical assistance for outpatient prescribed drugs would not be a discount card eligible individual.

An individual eligible for transitional assistance is a discount card eligible individual, residing in one of the 50 states or the District of Columbia, whose income is not more than 135% of the official poverty line applicable to the family size involved. Certain persons would not be eligible for transitional assistance. These are persons who had coverage for, or assistance with, covered discount card drugs under: 1) a group health insurance plan or health insurance plan (other than coverage under a plan under Medicare Part C or coverage consisting only of excepted benefits as that term is defined under Section 2791 of the Public Health Service Act); 2) Chapter 55 of the United States Code relating to medical and dental care for members of the uniformed services; and 3) a plan under the Federal employees health benefits program.

Certain transitional eligible assistance eligible individuals may also qualify as special transitional assistance eligible individuals. These are persons with incomes below 100% of the official poverty line.

The Secretary is required to provide for appropriate rules for the treatment of medically needy persons as discount eligible individuals and as transitional assistance eligible individuals.

c. Enrollment. The conference agreement requires the Secretary to establish a process through which a discount card eligible individual is enrolled and disenrolled in a discount card program. An individual not enrolled in a card program may enroll in any card program, serving residents of the state at any time beginning on the initial enrollment date and before January 1, 2006. Completion of a standard enrollment form, specified by the Secretary, is required. Each program sponsor is required to transmit to the Secretary (in a form and manner specified by the Secretary) information on persons completing the enrollment forms. They are also required to provide certain information relating to the certification as a transitional assistance eligible individual.

The conference agreement specifies that a discount eligible individual may only be enrolled in one endorsed card program at a time. An individual enrolled in one program in 2004 could change the election for 2005. The Secretary will establish a process for making this change, which will be similar to, and coordinated with, that established for annual coordinated elections for Medicare+Choice plans under Part C. The agreement requires the Secretary to permit individuals to change programs in which they were enrolled if they changed residence outside the service area of the plan or under other exceptional circumstances. The Secretary is permitted to consider a change in residential setting (such as placement in a nursing facility) as an exceptional circumstance. Also meeting this criteria would be enrollment or disenrollment from a Medicare+Choice plan through which an individual was enrolled in an endorsed program.

An individual could voluntarily disenroll from an endorsed program at any time. Such individual could not enroll under another endorsed program except during the open enrollment period or under the exceptional circumstances specified by the Secretary. An individual, who

was not a transitional assistance eligible individual, could be disenrolled by the program sponsor, if the individual failed to pay the annual enrollment fee.

A Medicare+Choice organization or organization operating under a reasonable cost contract that wishes to become a prescription drug card sponsor may elect to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in the plan. If the organization elects this option, its enrollees can only enroll in the endorsed discount card program offered by that sponsor.

A card sponsor may charge an annual enrollment fee, not to exceed $30, for each enrollee. The fee for either 2004 or 2005 could not be prorated. The sponsor will ensure that the annual enrollment fee (if any) is the same for all enrollees residing in the state. The annual enrollment fee is to be collected by the program sponsor. The annual enrollment fee for a transitional assistance eligible individual is to be paid by the Secretary on the individuals' behalf.

The Secretary will establish an arrangement under which a state could pay for some, or all, of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals. The payment would be paid directly by the state to the sponsor. No federal matching payments would be available.

The Secretary will establish special rules for individuals who change, during a year, the endorsed program in which they are enrolled.

Each card sponsor will issue, in a standard format specified by the Secretary, a discount card to each enrollee. The card will establish proof of enrollment. It may be used in a coordinated manner to identify the sponsor, program, and individual. The Secretary will specify the effective date that card enrollees will have access to negotiated prices and transitional assistance, if any.

d. Information. The conference agreement requires the Secretary to provide for activities that broadly disseminate information to discount card eligible individuals and prospective eligible individuals. These persons would receive information on enrollment in endorsed card programs and on the features of the drug discount card and transitional assistance program. In order to promote informed choice, the Secretary will provide for the dissemination of information, which compares the annual enrollment fee and other features of such programs, which could include comparative prices for covered drugs. To the extent practicable, this will be coordinated with the dissemination of educational material on other Medicare options. The required information will also include educational materials on the variability of discounts on covered drugs under an endorsed program. To the extent practicable, the Secretary will ensure the provision of required information at least 30 days prior to the initial enrollment date. The Secretary, through the use of 1-800-MEDICARE, will provide for the receipt and response to inquiries and complaints concerning the discount card program and endorsed programs.

The conference agreement requires each card sponsor to make available to discount card eligible individuals (through the Internet and otherwise) information the Secretary identifies as being necessary to promote informed choice. This includes information on enrollment fees and negotiated prices for covered drugs. Each sponsor is required to have a mechanism (including a toll free number) for providing, on request, specific information to individuals enrolled in the program. Specific information includes information on negotiated prices and the amount of transitional assistance remaining to the individual. The sponsor is required to inform transitional

assistance eligible individuals of the availability of such toll-free numbers to provide information on the amount of available assistance to the individual. Information on the balance of transitional assistance available will have to be available at the point-of-sale, either electronically or by telephone.

The conference report requires sponsors to provide that each pharmacy that dispensed a covered discount drug to inform program enrollees of any difference between the price of the drug provided to the enrollee and the price of the lowest priced generic drug covered under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy. The notice is to be provided at the time of purchase, or in the case of a mail order drug, at the time of delivery. The Secretary may waive this requirement under circumstances specified by the Secretary.

e. Discount Card Program. The conference agreement requires each card sponsor to provide each enrollee with access to negotiated prices. These negotiated prices would take into account negotiated price concessions such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations for covered drugs. Negotiated prices include any dispensing fees. Seniors currently benefit from prescription drug assistance programs offered by pharmaceutical companies. Conferees intend that these programs continue to be offered until the full implementation of the prescription drug benefit. Nothing in this conference report shall be interpreted as encouraging the discontinuation or diminution of these benefits.

Each prescription drug card sponsor must secure the participation of a sufficient number of pharmacies that dispense drugs directly to enrollees to ensure convenient access to covered drugs at negotiated prices. This requirement may only be met by entities dispensing drugs other than solely by mail order. Conferees intend for seniors to have access to a bricks and mortar pharmacy. The Secretary will establish convenient access rules that are no less favorable than standards for convenient access to pharmacies applicable under TRICARE. Applicable TRICARE standards are those specified in the statement of work solicitation (#MDA906-03-R-0002) as of March 13, 2003.

A prescription drug card sponsor (and any pharmacy contracting with the sponsor to provide covered discount card drugs) may not charge enrollees for any items and services required to be provided under the program. This prohibition would not apply to the annual enrollment fee for persons who are not transitional assistance eligible individuals or for the charge for the drug (consistent with the negotiated price) reduced by any transitional assistance.

The agreement further provides that negotiated prices will not be taken into account for purposes of making best price calculations under the Medicaid rebate program.

Each endorsed card program is required to implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

f. Eligibility Procedures. The conference agreement requires the Secretary to establish procedures for eligibility determinations for endorsed programs and for those eligible as a transitional assistance eligible individual or a special transitional eligible individual. The Secretary is to define the terms income and family size and specify the methods and period for which they are determined. If such methods provide for use of information for prior time periods, the Secretary is required to permit an individual whose circumstances changed to have

eligibility for transitional assistance determined for a more recent period. The Secretary may use a reconsideration process or other method.

An individual wishing to be treated as a transitional assistance eligible individual or special transitional eligible individual could self-certify through a simplified means as to their income, family size, and prescription drug coverage (if any). The certification could also be done by another qualified person, acting on the individual's behalf. The certification could be provided before, on or after the time of enrollment in an endorsed program. The self-certification would be deemed as consent to have the information verified by the Secretary. A verified self-certification for as a transitional assistance or special transitional assistance eligible individual would be applicable for the entire period of enrollment in any endorsed program.

The Secretary is required to establish verification methods, which could include sampling and use of information on Medicaid eligibility provided by the states, financial information from the Commissioner of Social Security, and financial information from the Secretary of the Treasury. The Secretary could find that an individual met the income requirements for transitional assistance if the individual is within a category of discount card eligible individuals who are enrolled under Medicaid (such as qualified Medicare beneficiaries, specified low-income Medicare beneficiaries, and certain qualified individuals). States will be required, as a condition of Federal Medicaid assistance to provide, on a timely basis, information that allows the Secretary to identify persons eligible for drug coverage under Medicaid, or who are transitional assistance eligible individuals, or special transitional eligible individuals. The Secretary is required to establish a reconsideration process for persons determined not to be transitional eligible or special transitional assistance eligible individuals. The results are to be communicated to the individual and drug card sponsor involved. The Secretary may enter into contracts to perform the reconsideration function.

g. *Transitional Assistance*. The conference agreement provides special provisions for low-income persons. A transitional assistance eligible individual will be entitled to have his or her discount card enrollment fee paid. Those individuals with incomes below 100% of poverty (special transitional assistance eligible individuals) would be liable for coinsurance charges of 5% of incurred costs up to $600 in both 2004 and 2005. Other transitional assistance eligible individuals (those with incomes between 100% and 135% of poverty) would be liable for coinsurance charges of 10 % of incurred costs up to $600 in both 2004 and 2005. Thus, the program will pay 95% of a special transitional eligible individual's incurred drug costs up to $600 in 2004 and 90% of other transitional eligible individual's incurred drug costs up to $600 in 2004. Similarly, payment would be made for 95% or 90%, whichever is appropriate, of the individual's incurred drug costs up to $600 in 2005. In addition, any balance left over from 2004 may be added to the amount available in 2005, except no rollover would be permitted if the individual voluntarily disenrolled from an endorsed plan. No funds will be available under this program for covered discount card drugs dispensed after December 31, 2005. The Secretary will provide a method for the reimbursement of card sponsors for transitional assistance.

The $600 annual amount is to be prorated in 2004, for persons not enrolling in an endorsed program and providing self-certification prior to the program's initial implementation date. For 2005, the amount is to be prorated for persons not enrolling in an endorsed program and providing self-certification prior to February 1, 2005.

The conference agreement permits a pharmacy to reduce the coinsurance otherwise applicable. It also permits states to pay some or all of the coinsurance for some or all transitional

assistance eligible enrollees. The payment would be made directly by the state to the pharmacy. No federal matching payments would be available for these costs; further they could not be considered as Medicare cost-sharing for purposes of the qualified Medicare beneficiary program.

The conference agreement includes provisions to ensure access to transitional assistance for qualified residents of long-tem care facilities and American Indians. It requires the Secretary to establish procedures to ensure such access for qualified residents of long-term care facilities. The Secretary could waive requirements of the new Section 1860D-31, as necessary, to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities. The Secretary is also required to establish procedures to ensure that pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 states and the District of Columbia where such a pharmacy operates. Where necessary, the Secretary could waive requirements of the new Section 1860D-31.

The availability of negotiated prices or transitional assistance could not be taken into account in determining an individual's eligibility for or benefits under any other Federal program. Any nonuniformity of benefits resulting from the implementation of the new Section 1807 (such as the waiver of an enrollment fee) would not be taken into account in calculations of any required additional benefits under Part C.

h. Qualifications for Card Sponsors. The conference agreement defines entities eligible to be card sponsors and establishes criteria that such entities would have to meet. The agreement specifies that a card sponsor could be any nongovernmental entity that the Secretary determines is appropriate to offer an endorsed discount card program. An entity which could qualify includes a pharmaceutical benefit management company, a wholesale or retail pharmacy delivery system, an insurer (including one that offered Medigap policies), an organization under Part C, or any combination of these. Each program would have to be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more organizations with demonstrated experience and expertise in operating such a program. Further, the program would have to meet business stability and integrity requirements specified by the Secretary. The sponsor will be required to have arrangements, satisfactory to the Secretary, to account for transitional assistance provided to eligible individuals.

The conference agreement requires each sponsor seeking endorsement to submit an application to the Secretary. The Secretary would review the application and determine whether to endorse the program. The Secretary could not endorse the program unless the program and sponsor comply with the applicable requirements of the new Section 1860D-31 and the sponsor enters into a contract with the Secretary to carry out such requirements. An endorsement would be for the duration of the discount card and transitional assistance program. The Secretary could make an exception for cause.

The conference agreement requires the Secretary to ensure that at least 2 endorsed programs (each offered by a different sponsor) are available to each eligible individual. The Secretary may limit (but not below 2) the number of sponsors in a state that were awarded contracts.

Card sponsors enrolling individuals in any part of a state would be required to permit eligible individuals in all parts of the state to enroll. An exception would apply in the case of a

Medicare+Choice organization, which elects to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in its Medicare+Choice plan.

Each prescription drug card sponsor will be required to pass on to discount eligible enrollees the negotiated prices for covered drugs, including discounts negotiated with pharmacies and manufacturers, to the extent such discounts are disclosed under required disclosure rules. Each card sponsor will be required to provide meaningful procedures for hearing and resolving grievances between the sponsor and enrollees in a manner similar to that required for Medicare+Choice. The operations of an endorsed card program are covered functions and a card sponsor is a covered entity for purposes of applying the administrative simplification provisions established in Part C of Title XI of the Social Security Act. Included are regulations promulgated under that Part including privacy regulations. The Secretary could waive the relevant portions of privacy regulations for an appropriate limited period of time in order to promote participation of sponsors.

The sponsor of an endorsed card program may not provide or market services under the program except if the product or service is directly related to a covered discount card drug or a discount price for a nonprescription drug. Sponsors will also be required to meet additional requirements as the Secretary identifies are needed to ensure that enrollees are not charged more than the lower of the negotiated price or the usual and customary price.

Special rules apply to Medicare+Choice organizations or organizations offering enrollment under a reasonable cost contract. An organization could elect to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in its plan. In this case, special rules would apply. The sponsor could not enroll individuals not enrolled in the plan. The pharmacy access requirements applicable to card sponsors would be deemed to be met if access is made available through a pharmacy network (and not only through mail order) and the network is approved by the Secretary. The Secretary could waive requirements applicable to card sponsors to the extent he determined they were duplicative or conflicted with a Medicare+Choice or cost contract requirement or were necessary in order to improve coordination of the card program with Medicare+Choice or cost contract benefits.

Each card sponsor will be required to disclose to the Secretary information relating to: 1) program performance; 2) use of drugs by card program enrollees; 3) extent to which negotiated price concessions made available by the manufacturer are passed through to enrollees through pharmacies or otherwise; and 4) other information specified by the Secretary. The Medicaid provision providing for the confidentiality of drug information will apply to any drug pricing information (other than aggregate data) disclosed under these requirements.

The Secretary will provide appropriate oversight to ensure compliance of card programs and sponsors with the requirements of the new Section 1860D-31. The Secretary would have the right to audit and inspect any books and records of sponsors (and any affiliated organization) that pertain to the card program, including amounts payable to the sponsor. The Secretary could impose sanctions for abusive practices.

i. Territories. The conference agreement provides federal assistance to territories, which establish a plan to provide transitional assistance for covered discount drugs to some or all eligible persons residing in the state. Eligible persons are those entitled to benefits under Part A or enrolled in Part B with incomes below 135% of the poverty line. The total amount of available federal assistance is $35 million. The amount available for each territory would be

determined using the ratio of the total number of Medicare residents in the territory to Medicare residents in all the territories.

j. Funding. The conference agreement creates a separate Transitional Assistance Account in the Part B Trust Fund. Funds in this account are to be kept separate from other funds within the Trust fund. Payments are to be made from the Account in such amounts as the Secretary certifies are necessary to make payments for transitional assistance. Appropriations are to be made to the Account equal to the amount of payments from the Account. Such sums as are necessary would be authorized to be appropriated for the Secretary's administrative expenses. Payments could not be made to sponsors for administrative expenses, except for payment of the enrollment fee for transitional eligible individuals. Costs associated with the Medicare prescription drug card and the transitional assistance program would be excluded from the calculation of the Part B premium.

Definitions; Treatment of References to Provisions in Part C (New Section 1860D-41 of Conference agreement; *New Section 1860D-10 of House bill; New* Sections 1860D, 1860D-26 and Section 110 of Senate bill**)**.

House Bill

New Section 1860D-10 would provide cross-references to other sections of the bill for definitions of covered outpatient drugs, initial coverage limit, Medicare Prescription Drug Trust Fund, PDP sponsor, qualified prescription drug coverage, and standard coverage. It would define a prescription drug plan as health benefits coverage that: 1) is offered under a policy, contract, or plan by a PDP sponsor pursuant to and in accordance with a contract between the Administrator and the sponsor; 2) provides qualified prescription drug coverage; and 3) meets the applicable beneficiary protection requirements. It would specify that the term "insurance risk" would, for a participating pharmacy, mean the type commonly assumed only by insurers licensed by a state and not payment variations designed to reflect performance-based measures of activities within control of the pharmacy, such as formulary compliance and generic drug substitution. The section would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions.

MA and EFFS plans would be required to offer drug plans pursuant to the requirements of Sections 1851 and New Section 1860e-2(d). The provision would specify that Part C requirements relating to a drug plan or sponsor would be applied (unless otherwise specified) as if: 1) any reference to a MA or other plan included a reference to a prescription drug plan; 2) any reference to a provider-sponsored organization included a reference to a PDP sponsor; 3) any reference to a contract included a reference to a drug plan contract, and 4) any reference to Part C included a reference to Part D.

Senate Bill

New Section 1860 D would define a number of terms used in the bill. The "Administrator" would be defined as the Administrator of the new Center for Medicare Choices established under the bill.

An "Part D eligible individual" would be an individual entitled to, or enrolled for, benefits under Part A and enrolled in Part B. An "eligible entity" would be any risk bearing

entity that the Administrator determined to be appropriate to provide eligible beneficiaries with benefits under a Medicare Prescription Drug Plan. Eligible entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers (including insurers that offered Medigap policies), other risk bearing entities, or any combination of these. This requirement would not preclude State pharmacy assistance programs from becoming a qualified entity if they meet the requirements.

A "Medicare Prescription Drug Plan" would offer prescription drug coverage under a policy, contract or plan by an eligible entity pursuant to and in accordance with a contract between the Administrator and the entity. The plan would have to be approved by the Administrator.

The provision would specify that Part C requirements relating to MedicareAdvantage would be applied (unless otherwise specified) as if: 1) any reference to a MedicareAdvantage plan included a reference to a Medicare Prescription Drug plan; 2) any reference to a provider-sponsored organization included a reference to an eligible entity, 3) any reference to a contract included a reference to a drug plan contract, and
4) any reference to Part C included a reference to Part D.

The provision would permit sponsors of employment-based retiree coverage that offer a prescription drug plan to restrict enrollment in the plan to eligible beneficiaries enrolled in such coverage. Sponsors could not offer enrollment in a Medicare Prescription Drug plan based on the health status of beneficiaries.

Entities offering a Medicare Prescription Drug plan or a MedicareAdvantage organization offering a MedicareAdvantage plan could enter into an agreement with a state pharmaceutical assistance program (including one established under a Section 115 waiver) to coordinate coverage.

Conference Agreement

New Section 1860D-41 provides cross references to other section of the bill for definitions of basic prescription drug coverage, covered Part D drugs, creditable prescription drug coverage, Part D eligible individual, fallback prescription drug plan, initial coverage limit, MA plan, MA-PD plan, Medicare Prescription Drug Account, PDP approved bid, PDP region, qualified prescription drug coverage, standard prescription drug coverage, state pharmaceutical assistance program; and subsidy-Part D eligible individual. It defines the term "insurance risk" as meaning for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a state and does not include payment variations designed to reflect performance-based measures of activities within control of the pharmacy, such as formulary compliance and generic drug substitution. A PDP sponsor is defined as a nongovernmental agency that is certified under Part D as meeting Part D requirements and standards. A prescription drug plan is defined as prescription drug coverage that: is offered: 1) under a policy, contract, or plan that has been approved under Part D; and 2) by a PDP sponsor pursuant to and in accordance with a contract between the Secretary and the sponsor under Part D.

The provision specifies that Part C requirements are to be applied (unless otherwise specified) as if: 1) any reference to a MA plan included a reference to a prescription drug plan; 2) any reference to a provider-sponsored organization included a reference to a PDP sponsor; 3) any reference to a contract included a reference to a drug plan contract, 4) any reference to Part C

included a reference to Part D; and 5) any reference to a Part C election period is a reference to a Part D enrollment period.

Miscellaneous Provisions (New Section 1860D-42 of conference agreement; New Section 1860D-16 of House bill; Section1860D-26 of Senate bill).

Present Law

No provision

House Bill

The Secretary would be required to submit a legislative proposal within six months of enactment containing necessary technical and conforming amendments. Not later than January 1, 2005, the Administrator would be required to submit a report containing recommendations for providing benefits under Part D for drugs currently paid for under Part B.

Senate Bill

New Section 1860D-26 would require the Secretary, within six months of enactment, to submit a legislative proposal for any necessary technical and conforming amendments.

Conference Agreement

The agreement includes miscellaneous provisions. It permits the Secretary to waive Part D requirements, including the requirement for two plans in an area, insofar as the Secretary determines it necessary to secure access to qualified drug coverage in the territories.

The agreement requires the Secretary to submit a legislative proposal within six months of enactment containing necessary technical and conforming amendments to titles I and II of the bill. Not later than January 1, 2005, the Secretary is required to submit a report to Congress containing recommendations for providing benefits under Part D for drugs currently paid for under Part B. By March 1, 2005, the Secretary is required to submit a report to Congress on the progress made in implementing the drug benefit. The report will include specific steps taken, and that need to be taken, to ensure a timely start on January 1, 2006. The report is to include recommendations regarding an appropriate transition form the discount card and transitional assistance program.

Medicare Advantage Conforming Amendments (Section 102 of Conference agreement; Section 231 of House bill; Sections 201 and 204 of Senate bill).

Present Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, made temporary changes to reporting dates and deadlines. First, CMS moved its annual announcement of M+C payment rates from no later than March 1 to no later than the 2nd Monday in May, effective only in 2003 and 2004. It also temporarily moved the deadline for plans to submit information about ACRs, M+C premiums, cost sharing, and additional benefits (if any) from no later than July 1 to no later than the 2nd Monday in September in 2002, 2003, and 2004. It also changed the annual coordinated election period from the month of November

to November 15th through December 31 in 2002, 2003, and 2004. Once the temporary provision expires, the reporting dates and deadlines would return to the pre-P.L.107-188 dates.

In addition, P.L.107-188 will continue to allow Medicare beneficiaries to make and change election to an M+C plan on an ongoing basis through 2004. Then beginning in 2005, individuals will only be able to make changes on the more limited basis, originally scheduled to be phased in beginning in 2002. Beneficiaries can make or change elections during the annual coordinated election period. Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2005 (or first 3 months of any subsequent year). Additionally, there are special enrollment rules for newly eligible aged beneficiaries as well as special enrollment periods for all enrollees under limited situations, such as an enrollee who changes place of residence.

The Secretary must provide information to Medicare beneficiaries and prospective beneficiaries on the coverage options provided under the M+C program, including open season notification, a list of plans and other general information.

House Bill

The reporting deadline for ACRs and other information would permanently move to July 1 of each year. The annual coordinated election period would be permanently changed to November 15 through December 31. The announcement of payment rates, including rates for EFFS plans, would be permanently moved to no later than the second Monday in May.

In addition to the information dissemination required under current law, the Secretary would be required to provide beneficiaries with a list of plans that are or would be available in an area, to the extent the information was available at the time the materials were prepared for mailing.

Senate Bill

Each MA organization would be required to submit information by the second Monday in September, including: 1) notice of intent and information on the service area of the plan; 2) the plan type for each plan; 3) specific information for coordinated care and PFFS plans; 4) enrollment capacity; 5) the expected mix of enrollees, by health status; and 6) other information specified by the Secretary.

Medicare beneficiaries would retain their ability to make and change elections to a Medicare+Choice plan through 2005. The current law limitation on changing elections that begins in 2005, would be delayed until 2006. Further, the annual coordinated election period for 2003 through 2006 would begin on November 15 and end on December 31. Beginning in 2007, the annual coordinated election period would be during the month of November.

In addition to the information dissemination required under current law, the Secretary would be required to provide: 1) the MA monthly basic beneficiary premium; 2) the monthly beneficiary premium for any enhanced medical benefits; 3) the MA monthly beneficiary obligation for qualified prescription drug coverage; 4) the catastrophic coverage amount (including the maximum limitation on out-of-pocket expenses) and unified deductible for the plan; 5) the outpatient prescription drug coverage benefits; 6) any beneficiary cost-sharing, including information on the unified deductible; 7) comparative information relating to

prescription drug coverage; 8) if applicable, any reduction in the Medicare Part B premium; 9) whether the MA monthly premium for enhanced benefits was optional or mandatory; and 10) quality and performance indicators for prescription drug coverage, including a comparison with FFS Medicare.

Additionally, the Secretary would conduct a special information campaign to inform MA eligible beneficiaries about plans. The campaign would begin on November 15, 2005 and ending on December 31, 2005.

Conference Agreement

The conference agreement allows Medicare beneficiaries to retain their ability to make and change elections to a Medicare+Choice plan through 2006. The current law limitation on changing elections that begins in 2005, is delayed until 2006. Further, the annual coordinated election period for 2004 and 2005 begins on November 15 and ends on December 31. For 2006, the annual coordinated election period begins on November 15 and ends on May 15, 2006. Beginning in 2007, the annual coordinated election period will begin on November 15 and end on December 31.

The Secretary is to provide for an education and publicity campaign to inform MA eligible individuals about the availability of MA plans, including MA-PD plans, offered in different areas and the election process for MA plans. If any portion of an individual's initial enrollment period for Part B occurs after the end of the annual coordinated election period, their initial enrollment period would be extended through the end of their Part B initial enrollment period.

The conference agreement will limit an individual's right to change MA plans, for plan years beginning on or after January 1, 2006. This limit will not affect an individual's opportunity to make changes during the annual coordinated election period, but it will limit changes during the continuous open enrollment and disenrollment periods in a year. Individuals enrolled in an MA plan that provides qualified prescription drug coverage, may only disenroll from their plan to get coverage through FFS Medicare or through another MA plan that does not provide qualified prescription drug coverage. They may not leave their plan to obtain coverage under an MA-PD plan or under a prescription drug plan under Part D. Conversely, individuals enrolled in an MA-PD plan, may only change to another MA-PD plan or they may get coverage under FFS Medicare with coverage under a drug plan under part D. They may not enroll in an MA plan if it does not provide qualified prescription drug coverage.

An MA-PD plan could provide for a separate or differential payment for a participating physician who prescribes covered part D drugs in accordance with an electronic prescription program meeting Part D requirements. Such payment could take into consideration the implementation costs for the physician and could also be increased for those participating physicians who significantly increased: 1) formulary compliance; 2) lower cost and therapeutically equivalent alternatives; 3) reductions in adverse drug interactions; and 4) efficiencies in filing prescriptions through reduced administrative costs. Additional or increased payment could be structured in the same manner as medication therapy management fees under section 1869(D)-4(c)(2)(E).

An MA eligible individual could elect qualified prescription drug coverage in accordance with Section 1860D-1.

Medicaid Amendments (Section 103 of Conference agreement; Section 103 of House bill; Section 104 of Senate Bill).

Present Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual eligibles" Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare, including prescription drugs. State Medicaid programs have the option to include prescription drugs in their Medicaid benefit packages. All states include drugs for at least some of their Medicaid beneficiaries and many offer it to all program recipients entitled to full Medicaid benefits.

As noted earlier, Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLIMBs), and certain qualified individuals (QI-1s). Assistance under the QI-1 program, originally available for the period January 1, 1998 to December 31, 2002, has been extended to March 31, 2004.

States make eligibility determinations for their Medicaid populations. Federal matching payments for Medicaid services in the territories is subject to an annual cap.

Current Medicaid law requires manufacturers to pay state Medicaid programs a basic rebate for single source and innovator multiple source drugs. Basic rebates are calculated by comparing the average manufacturer price for a drug (the average price paid by wholesalers) to the "best price," which is the lowest price offered by the manufacturer in the same period to any wholesaler, retailer, nonprofit, or public agency. For purposes of determining Medicaid rebates, prices paid by a number of Federal and state entities are excluded from the definition of "best price."

House Bill

Section 103 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision would require states, as a condition of receiving federal Medicaid assistance, to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the Administrator of cases where eligibility has been established, and otherwise provide the Administrator with information that may be needed to carry out Part D. The provision would provide for the phased-in federal assumption of associated administrative costs. In 2005, the federal matching rate would be increased by 6-2/3 percent and in 2006 by13-1/3 percent. In each subsequent year, the percent would be increased by 6-2/3 percentage points (but in no case could the rate exceed 100 percent). Beginning in 2019, the federal matching rate would be 100 percent. The state would be required to provide the Administrator with the appropriate information needed to properly allocate administrative expenditures that could be made for similar eligibility determinations.

The provision would provide for the federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006 - 2020 period, the federal matching rate for these costs would be increased to cover 100% of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap around to Medicare benefits for dual eligibles; states could require that these persons elect Part D drug coverage.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, beginning at $25 million in 2006 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The Administrator would be required to report to Congress on the application of the law in the territories.

Senate Bill

Section 104 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision would require states to make low-income eligibility determinations for low income subsidies. States would be required, for purposes of the transitional prescription drug card assistance program, to establish eligibility standards consistent with that program; establish procedures for providing presumptive eligibility determinations (similar to that which currently apply for low-income pregnant women and children); make eligibility determinations for the card program; and communicate to the Secretary information on eligibility determinations or discontinuations. For purposes of the low-income subsidies for the new Part D program, states would be required, beginning November 2005, to make eligibility determinations; inform the Administrator of cases where eligibility was established, and otherwise provide the Administrator with any information required to carry out Part D. States would be required to enter agreements with the Commissioner of Social Security to use all social security field offices in the state as information and enrollment sites for making eligibility determinations. As part of the eligibility determination process, states would also be required to screen for eligibility for Medicare cost-sharing assistance under the QMB, SLIMB, and QI-1 programs.

The federal government would pay an enhanced matching rate for administrative costs associated with making eligibility determinations. The rate would be 75% for the period January 1, 2004 - September 30, 2005, 70% for fiscal year 2006, 65% for FY 2007, and 60% beginning in FY 2008. Beginning November 1, 2005, the rate would be 100% for purposes of making eligibility determinations for low-income subsidies.

In addition, states would be entitled to enhanced matching for the costs associated with designing, developing, acquiring and installing improved eligibility determination systems, including hardware and software, for low-income subsidy programs. The enhanced rate would be 90% for fiscal years 2004, 2005, and 2006. The systems would be required to comply with any standards established by the Secretary for improved eligibility systems. Further, the systems would have to be compatible with the standards established under the administrative simplification provisions of Title XI of the Social Security Act.

Medicaid beneficiaries who were eligible for drug benefits under their state Medicaid program would remain in Medicaid. Beginning January 1, 2006, States agreeing to provide a

drug benefit to their dual eligible population that was at least equivalent to minimum standards would be relieved of their responsibility to pay Medicare Part B premiums for persons with incomes between the level established for the supplemental security income program and 100% of the federal poverty level. The minimum standards would be defined as follows. A state would be required to meet all current law coverage standards for dual eligibles under Medicaid, including nominal cost-sharing requirements. States would have to provide beneficiary protections equivalent to those provided under Part D. States could not place a limit on the number of prescriptions for dual eligibles. States would be permitted to cover smoking cessation drugs for this population group.

If on the date of enactment, a state provided medical assistance to aged and disabled persons up to 100% of poverty, it would be entitled to have the federal government assume the costs for Medicare Part A cost-sharing. The Part A costs would be assumed so long as the state maintained the expanded coverage. The provision would apply effective January 1, 2006.

Residents of the Puerto Rico and the territories would not be eligible for low-income subsidies. Instead, if they chose to provide assistance to their low-income residents they would receive an increase in amounts otherwise paid to them under Medicaid. The aggregate amount available would be $37.5 million for the last 3 quarters of FY2006, and $50 million for FY2007. In subsequent fiscal years, the aggregate amount would be the amount available the previous year, increased by the percentage increase in prescription drug spending.

The provision would extend the QI-1 program through December 2008 with total annual allocations of $400 million through fiscal year 2008 and $100 million for the first quarter of fiscal 2009.

The provision would expand outreach requirements for the Commissioner of Social Security to include outreach activities for low-income subsidy individuals. By January 1, 2005, the Secretary would submit a report to Congress to recommend a voluntary option for dual eligibles to enroll in Part D drug plans.

The provision would exempt negotiated prices by any qualified plan offering Medicare drug coverage from the calculation of Medicaid "best price."

Conference agreement

The conference agreement would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision establishes certain requirements, as a condition of receiving federal Medicaid assistance. States are required to provide the Secretary with Medicaid eligibility information necessary to carry out transitional prescription drug assistance verification. They are required to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the Secretary of cases where eligibility has been established, and otherwise provide the Secretary with information that may be needed to carry out Part D. Further, as part of the eligibility determination process, states are required to make determinations for Medicare cost-sharing assistance. Regular federal matching applies to these activities.

The agreement provides for the federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). The agreement provides for a phased-down state contribution. For each month

beginning in 2006, each state is required to provide for payment to the Secretary equal to the product of: 1) 1/12 of the product of the base year state Medicaid per capita expenditures for full-benefit dual eligibles and the state matching rate, and updated to the year involved by the applicable growth factor; 2) the total number of dual eligibles for such state for the month; and 3) the factor for the month. The base year is defined as the weighted average of gross Medicaid expenditures (including dispensing fees) for prescription drugs in 2003 and the estimated actuarial value of prescription drug benefits provided under a capitated care plan for full benefit dual eligibles in that year. The applicable growth factor in 2004, 2005, and 2006 is the average annual percent change in the per capita amount of prescription drug expenditures as determined based on the most recent National Health Expenditure projections. In subsequent years, the growth factor is the annual percentage increase average per capita expenditures under Part D. The factor under #3 is 90% in 2006, phasing down to 75% over 10 years. The Secretary is required to notify each state by October 15 of the amount computed under the formula for the following year, beginning in 2006. A state's failure to make required payments would result in interest charges and in an offset to amounts otherwise payable under Medicaid.

The agreement requires the Secretary when determining gross expenditures for 2003 to: 1) use data from the Medicaid Statistical Information System (MSIS) and other available data; 2) exclude expenditures for drugs that are not covered Part D drugs, and 3) reduce the portion of expenditures not attributable to dispensing fees by an adjustment ratio applied to such portion. The adjustment ratio for a state is equal to 1 minus the ratio in 2003 of aggregate payments under rebate agreements under section 1927 to gross expenditures under Medicaid for covered outpatient drugs.

The agreement specifies that Medicare is the primary payer for covered drugs for dual eligibles. Medicaid coverage is not available for such drugs or any cost-sharing for such drugs. States may provide coverage for drugs, other than Part D covered drugs in the manner otherwise provided for non-full benefit dual eligibles or through an arrangement with the prescription drug plan of MA-PD plan.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to apply for additional Medicaid funds. The total amount available is $28.125 million beginning in the last 3 quarters of 2006, $37.5 million in 2007 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to provide assurances that additional funds would be used covered drugs and administrative costs (with no more than 10 percent of the total used for administrative expenses.) The Secretary is required to report to Congress on the application of the provision in the territories.

The agreement exempts prices negotiated from manufacturers for discount card drugs under an endorsement card program and prices negotiated by a prescription drug plan under Part D, a MA-PD plan or a qualified retiree prescription plan from the calculation of Medicaid "best price."

The agreement extends the QI-1 program through September 30, 2004. It expands outreach requirements for the Commissioner of Social Security to include outreach activities for transitional assistance and low-income subsidy individuals.

Medigap Amendments (Section 104 of Conference agreement; Section 104 of House bill; Section 103 of Senate bill).

Present Law

Most beneficiaries have some health insurance coverage in addition to basic Medicare benefits. Some individuals obtain private supplementary coverage through an individually-purchased policy, commonly referred to as a "Medigap" policy. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of 10 standardized plans, though not all 10 plans are offered in all states. The 10 plans are known as Plans A through Plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. Plans H, I, and J offer some drug coverage.

The law provided for the development by the National Association of Insurance Commissioners (NAIC) of standardized benefit packages. It also provides for modifications of such packages when Medicare benefit changes are enacted.

All insurers offering Medigap policies are required to offer open enrollment for 6 months from the date a person first enrolls in Medicare Part B (generally when the enrollee turns 65). The law also guarantees issuance of specified Medigap policies for certain persons whose previous supplementary coverage was terminated. Guaranteed issue also applies to certain persons who elect to try out a managed care option under the Medicare+Choice plan program.

Medicare beneficiaries buy supplemental coverage to help pay for health care costs not covered by Medicare. Almost one-quarter (24 percent) of Medicare beneficiaries purchase this coverage as individuals through the private insurance "Medigap" market. In 1990, Congress mandated the creation of 10 standardized Medigap policies through the National Association of Insurance Commissioners (NAIC). All 10 plans are required to cover beneficiaries' coinsurance - some of the costs of Medicare services for which beneficiaries are responsible, such as 20 percent of the costs of a physician visit. Nine out of 10 of those policies, which comprise more than 90 percent of the Medigap market, are required to cover the Part A inpatient hospital deductible, and the most popular Medigap policy covers both the Part A hospital deductible and the $100 Part B deductible for physician services. Insulating beneficiaries from this cost sharing incentivizes over utilization of health services.

Numerous studies have demonstrated that covering deductibles and coinsurance has led to higher Medicare spending because beneficiaries become insensitive to costs. Beneficiaries with Medigap consume $1,400 more in Medicare services than beneficiaries without supplemental coverage, and $500 more than beneficiaries with employer-sponsored insurance. This higher utilization drives up costs for everyone -- premiums of Medicare beneficiaries without Medigap coverage and costs to taxpayers.

In addition, only the three most expensive Medigap plans cover prescription drugs, and that coverage is limited. Yet, 8 of the 10 plans are required to cover foreign travel insurance, while most beneficiaries never leave their home country.

And despite standardization, premiums continue to increase and vary widely. From 1998 to 2000, average premiums rose 16 percent for plans without drug coverage, and more than twice as fast, 37 percent, for plans with drug coverage. In addition, premiums vary dramatically for identical plans in the same location. Weiss Ratings, Inc. analyzed Medigap premiums in 2001.

A 65-year old man living in Ft. Myers, Florida would pay about $3,600 for Plan J from Physicians Mutual Insurance Company, but only $2,700 with United Healthcare Insurance Company through AARP. The same gentleman living in Las Vegas would spend about $1,500 for Plan C with United American Insurance Company, but about half that amount -- $778 B with the USAA Life Insurance Company for the same policy.

All of these factors lead conferees to believe Medigap policies should be restructured in light of changes to the marketplace since standardization. Conferees encourage the National Association of Insurance Commissioners (NAIC) to modernize the Medigap market by reforming first dollar coverage requirements that drive over utilization of services and premiums. Conferees believe that in developing the two new policies included in the conference report, NAIC should consider much broader changes to the Medigap market that will effectuate reduced premiums and more rational coverage policies that create incentives for appropriate utilization of services.

House Bill

The provision would prohibit, effective January 1, 2006, the issuance of new Medigap policies with prescription drug coverage. The prohibition would not apply to policies replacing another policy with drug coverage. Beneficiaries could keep their existing policies. Further, it would not apply to policies meeting new standards, as outlined below.

The provision would guarantee issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J. The guaranteed enrollment would be for any of the Plans A through Plan G. The guarantee would apply for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap drug Plan H, I, or J. The insurer could not impose an exclusion based on a pre-existing condition for such individuals. Further, the insurer would be prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition.

The provision would provide for the development by the NAIC of two new standardized Medigap plans and would outline the standards for these policies. The first new policy would have the following benefits (notwithstanding other provisions of law relating to core benefits): 1) coverage of 50% of the cost-sharing otherwise applicable (except coverage of 100% cost-sharing applicable for preventive benefits); 2) no coverage of the Part B deductible; 3) coverage of all hospital coinsurance for long stays (as in current core package); and 4) a limitation on annual out-of-pocket costs of $4,000 in 2006 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: 1) coverage would be provided for 75%, rather than 50%, of cost-sharing otherwise applicable; and 2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible.

Senate Bill

Effective January 1, 2006, Medigap drug policies could not be sold, issued or renewed for Part D enrollees. Persons who had such policies could obtain Medigap coverage without drug benefits. Beneficiaries who sought to enroll during the Part D open enrollment period

established for current beneficiaries would be guaranteed issuance of such non-drug policies (without an exclusion based on preexisting conditions). Medigap issuers would be required to notify individuals of these changes 60 days prior to the Part D open enrollment period.

Medigap insurers could not be required to participate as an eligible entity under the new Part D.

Conference agreement

The agreement prohibits, effective January 1, 2006, the selling, issuance, or renewal of existing Medigap policies with prescription drug coverage for Part D enrollees. The prohibition would not apply to renewal of Medigap prescription policies for persons who are not Part D enrollees. Persons enrolling under Part D during the initial enrollment period could enroll in a plan without drug coverage, or continue their previous policy as modified to exclude drugs. H, I, and J policies, modified to exclude drugs, could continue to be offered to new enrollees. Medigap issuers would be required to notify individuals of these changes 60 days prior to the initial Part D enrollment period.

The provision guarantees issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J or a pre-standard policy that included drug coverage. Evidence of enrollment and termination would be required. The guaranteed enrollment is for any of the Plans A, B, C, and F within the same carrier of issue. The guarantee applies for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap drug Plan H, I, or J. The insurer may not impose an exclusion based on a pre-existing condition for such individuals. Further, the insurer is prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition. The conferees intend that these provisions be administered in such a manner as to avoid a break in coverage.

The conference agreement requires the Secretary to request the National Association of Insurance Commissioners to review and revise standards for benefit packages taking into account the changes in benefits resulting form the enactment of this Act and to otherwise update standards to reflect other changes in law included in the Act. To the extent practicable, the revision will provide for implementation of revised standards as of January 1, 2006.

The revision is to include 2 new benefit packages. The first new package will have the following benefits (notwithstanding other provisions of law relating to core benefits): 1) coverage of 50% of the cost-sharing otherwise applicable (except coverage of 100% cost-sharing applicable for preventive benefits); 2) no coverage of the Part B deductible; 3) coverage of all hospital coinsurance for long stays and 365 extra lifetime days of coverage (as in current core package); and 4) a limitation on annual out-of-pocket costs of $4,000 in 2006 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new benefit package will have the same benefit structure as the first new package except that: 1) coverage would be provided for 75%, rather than 50%, of cost-sharing otherwise applicable; and 2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000.

Medigap issuers could not be required to participate as a PDP sponsor under the new Part D, nor could a State make such a requirement.

Additional Provisions Relating to Medicare Prescription Drug Discount Card and Transitional Assistance Program (Section 105 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes additional provisions relating to the implementation of the Medicare prescription drug discount card and transitional assistance program. It excludes program costs from the calculation of the Part B premium. It applies Medicaid confidentiality provisions to drug pricing data reported by manufacturers under the program.

The conference agreement includes additional administrative provisions. It specifies that the following sections of law would not apply to the card program: New Section 1871(a)(3) of the Social Security Act relating to time line for publication of final rules; Chapter 35 of Title 44 of the U.S. Code relating to coordination of federal information policy; Section 553(d) of Title 5 of the U.S. Code requiring at least 30 days between issuance and effective date of a substantive rule; and Section 801(a)(3)(A) of title 5 of the U.S. Code providing 60 days for congressional review of a major rule.

The contracting authority extended to the Secretary under Medicare+Choice also applies to the Secretary with respect to the discount card program. There could be no judicial review of a determination not to endorse or enter into a contract with a card sponsor. Further, an order to enjoin any provision of the new section 1807 would not affect any other provision of the section and all provisions are to be treated as severable.

The Secretary of the Treasury, upon written request from the Secretary of HHS, is required to disclose to officers and employees of HHS certain information with respect to a taxpayer for the most recent taxable year for which information is available in the Internal Revenue Service's taxpayer data information system, or if no return was filed for that year, the year before that. Required information would consist of whether the adjusted gross income (as modified by HHS regulations) of the taxpayer, and if applicable the taxpayer's spouse, exceeds amounts that are 100 percent and 135 percent of the official poverty line. Such information may only be used to determine eligibility for the transitional low income assistance program.

State Pharmaceutical Assistance Transition Commission (Section 106 of Conference agreement; Section 107 of House bill**)**.

Present Law

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

House Bill

The provision would establish a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month following enactment, would include: 1) a representative of each governor from each state with a program that the Secretary identified as having a benefit package comparable to or more generous than the new Part D; 2) representatives from other states that had pharmaceutical assistance programs, as appointed by the Secretary; 3) representatives (not exceeding the total under #1 and #2) of organizations that represented interests of participants, appointed by the Secretary; 4) representatives of MA organizations; and 5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: 1) protection of the interests of program participants in the least disruptive manner; 2) protection of the financial and flexibility interests of states so they are not financially worse off; and 3) principles of Medicare modernization outlined in Title II of the Act.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

Senate Bill

No provision.

Conference agreement

The agreement establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing State programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established as of the first day of the third month following enactment, will include: 1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the low-income assistance under the new Section 1860D-14; 2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary; 3) representatives (not exceeding the total under #1 and #2) of organizations that have an inherent interest in the participants or the program itself; appointed by the Secretary; 4) representatives of MA organizations, Pharmacy Benefit Managers and other private insurance plans; and 5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission is to develop the proposal in accordance with specified principles, namely: 1) protection of the interests of program participants in the least disruptive manner; 2) protection of the financial and flexibility interests of states so they are not financially worse off; and 3) principles of Medicare modernization outlined in Title II of the Act.

The Commission will report to the President and Congress by January 1, 2005, including specific legislative or administrative recommendations, if any. The Commission will terminate

30 days later. The Conferees intend the Commission to play an integral role in identifying potential problems and proposing creative solutions to ensure a seamless transition for States and beneficiaries in coordinating and interacting with the new Medicare plans.

Studies and Reports (Section 107 of Conference agreement; New Section 1860D-10 of House bill; Section 102, Section 106 and Section 110 of Senate bill).

House Bill

Under the new Section 1860D-10, the Secretary, within six months of enactment, would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: 1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; 2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care; and 3) recommend necessary actions. The Secretary would submit a report to the Congress on the findings and recommendations.

Senate Bill

Section 110 would require the Secretary to conduct a thorough review of the standards of practice for pharmacy services provided to patients in nursing facilities. The Secretary would assess the current standards, clinical services and other service requirements generally used in long-tern settings and evaluate the impact of these standards with respect to patient safety, reduction of medication errors, and quality of care. Within 18 months of enactment, the Secretary would be required to submit a report to Congress on the study containing: 1) a detailed description of the Secretary's plans to implement the Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients; and 2) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of care in such manner.

Section 102 would require the Administrator to conduct a study, and report to Congress by January 1, 2005, on allowing persons not entitled to Part A, but enrolled in Part B, to enroll in Part D.

Section 106 requires the Secretary, on an ongoing basis, would study variations in spending and drug utilization under Part D to determine the impact on premiums. The Secretary would examine the impact of geographic adjustments of the monthly national average premium on the maximization of competition and the ability of eligible entities to contain costs. The Secretary would submit an annual report to Congress beginning in 2007.

Conference Agreement

The agreement requires the Secretary to study variations in per capita spending for covered Part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids. The Secretary is required to submit a report to Congress on the study including information on the extent of geographic variation in per capita utilization, an analysis of the impact of direct subsidies and whether such subsidies should be adjusted to take into account such variation, and recommendations regarding the appropriateness of applying an additional geographic adjustment factor to bids.

The conference agreement requires the Secretary, within six months of enactment, to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary is to assess: 1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; and 2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care. The report is to contain a description of the Secretary's plans to implement this Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients. The report must also include recommendations regarding necessary actions.

The conference agreement requires the Secretary to enter into a contract with the Institute of Medicine to carry out a comprehensive study of drug safety and quality issues in order to provide a blueprint for system-wide change. The objectives of the study are to: 1) develop a full understanding of drug safety and quality issues through an evidence-based review of the literature, case studies, and analysis; 2) attempt to develop credible estimates of the incidence, severity and costs of medication errors; 3) evaluate alterative approaches to reducing medication errors; 4) provide guidance on high-priority strategies to achieve drug safety goals; 5) assess opportunities and key impediments to broad nationwide implementation of medication error reductions; and 6) develop an applied research agenda to evaluate the health and cost impacts of alternative interventions. The study is to be completed within an 18-month period. Such sums as may be necessary are authorized.

The agreement requires the Secretary to provide a study on the feasibility and advisability of providing multi-year contracts with PDP sponsors and MA organizations.

The agreement requires the GAO to conduct a study to determine the extent to which utilization and access to covered Part D drugs for low-income subsidy eligible individuals differs from that for persons who would qualify as subsidy eligible individuals except for application of the assets test. The report is due to Congress by September 30, 2007.

Grants to Physicians to Implement Electronic Prescription Programs (Section 108 of Conference agreement; Section 121 of Senate bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be authorized to award grants to health care providers to implement electronic prescription programs. There would be authorized to be appropriated such sums as may be necessary for each of fiscal years 2006, 2007, and 2008.

Conference Agreement

The agreement authorizes the Secretary to make grants to physicians for the purpose of assisting them to implement electronic prescription programs in complying with the standards under the new Section 1860D-(4)(e). The Secretary, in awarding the grant shall give special consideration to physicians who serve a disproportionate number of Medicare patients and give preference to physicians who serve a rural or underserved area. Grant funds may be used for purchasing, leasing, and installing hardware and software; making upgrades and other improvements; and providing education and training to eligible physician staff on the use of technology. Grant applicants are required to provide the secretary with information necessary to evaluate the project and to ensure that funding is expended only for the purposes for which it is made. The applicant must agree to make available non-Federal contributions totaling at least 50 percent of the costs. $50 million is authorized for FY 2007, and such sums as may be necessary for FY 2008 and FY 2009.

Expanding the Work of Medicare Quality Improvement Organizations to Include Parts c and D (New section 109 of the Conference agreement).

Present Law

Quality improvement organizations (QIOs) review medical necessity and quality of services provided under Medicare.

House Bill

No provision.

Senate Bill

No provision.

Conference agreement

The conference agreement expands the work of quality improvement organizations (QIOs) to include Part C and Part D. It is required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy. The secretary is to request the Institute of Medicine of the National Academy of Sciences to conduct a study of the QIO program including an evaluation of the program and the extent to which other entities could perform similar quality improvement functions as well as or better than QI0s. The Secretary will report to Congress on such study by June 1, 2006. If the Secretary finds, based on the study, that other entities could improve quality as well as or better than QI0s, the Secretary shall provide increased competition through such entities.

Conflict of Interest Study (Section 110 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Federal Trade Commission to conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers (PBMs). The study is to include an assessment of the differences in costs incurred by such enrollees and plans for drugs dispensed by mail order pharmacies owned by PBMs compared to those not owned by PBMs, and community pharmacies. The study is to examine whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees. The report is due to Congress within 18 months of enactment. It is to include recommendations regarding any legislation to insure the fiscal integrity of the Part D program. Conferees note the Secretary has the authority to accept or reject bids, based, among other factors, costs associated with delivering drug benefits.

The intent of the conferees in including this assessment by the FTC is to assess whether Medicare spending is likely to be adversely affected because of the use of mail order pharmacies that are owned and operated by a PBM under contract to a prescription drug plan or MA-PD plan. Therefore, this study should evaluate to what extent prescription drug spending is likely to be affected if a PDP or MA-PD plan approves the dispensation of covered drugs from a mail-order pharmacy owned directly or indirectly by a PBM compared to drug utilization and costs if the mail-order pharmacy were independently owned. Such assessment shall take into account the following:

(1) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) dispense fewer generic drugs compared to single source drugs within the same therapeutic class when compared to mail order pharmacies that are not owned by PBMs,

(2) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) routinely switch patients from lower priced drugs to higher priced drugs (in the absence of a clinical indication) when compared to mail order pharmacies that are not owned by PBMs,

(3) whether mail order pharmacies owned by PBMs (or entities that own PBMs) sell a higher proportion of repackaged drugs than mail order pharmacies that are not owned by PBMs,

(4) whether mail order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturer's average wholesale price,

(5) Other factors deemed relevant by the FTC.

In conducting this study, the FTC shall consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending. The FTC shall issue a written report within 18 months of the date of enactment.

Disclosure of Return Information for Purposes of Carrying Out Medicare Catastrophic Prescription Drug Program. (Section 106 of House Bill).

Present Law

Current law authorizes, under specified circumstances, the disclosure by the Secretary of the Treasury of returns and return information for purposes other than tax administration.

House Bill

The provision would permit the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS) to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. The information that could be disclosed is taxpayer identity information and the adjusted gross income for the taxpayer or, if less, the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: 1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000); or 2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would each be treated separately with each person considered to have an adjusted gross income equal to one-half of the total.

Return information disclosed, could be used by officers and employees of HHS only for administering the prescription drug benefit. They could disclose the annual out-of-pocket threshold applicable to an individual to the entity offering the individual prescription drug coverage. The sponsor could use such information only for the purposes of administering the benefit.

Senate Bill

No provision.

Conference Agreement

No provision.

Limitation on Prescription Drug Benefits of Members of Congress (Section 107 of Senate Bill**)**.

Present Law

Members of Congress are entitled to receive health benefits through the Federal Employees Health Benefits (FEHB) program.

House Bill

No provision.

Senate Bill

During calendar year 2004, the actuarial value of the drug benefit of any Member of Congress enrolled in a FEHBP plan could not exceed the actuarial value of any prescription drug benefit under Title XVIII of the Social Security Act passed by the first session of the 108th Congress and enacted into law. The Office of Personnel Management would promulgate necessary regulations.

Conference Agreement

No provision.

Protecting Seniors With Cancer (Section 108 of Senate Bill).

Present Law

Medicaid pays Part B premiums for QMBs, SLIMBs and QI-1s. It pays Medicare cost-sharing charges for QMBs.

House Bill

No provision.

Senate Bill

The cost-sharing specified under the low-income subsidy provisions would be modified for persons diagnosed with cancer. The cost-sharing specified under New Section 1860D-19 would apply except for the following changes. The QMB population would have a full premium subsidy for at least one drug plan available in the area where the beneficiary resided. For the SLIMB and QI-1 population, there would be no premium for any plan whose premium was at or below the monthly national average premium. For other persons below 160% of poverty, only a percentage of the premium otherwise applicable. Persons with incomes above 160% of the poverty line would have, in 2006, the same cost-sharing otherwise specified under the bill.

Conference Agreement

No provision.

Protecting Seniors With Cardiovascular Disease, Cancer, or Alzheimer's Disease (Section 109 of Senate Bill**)**.

Present Law

Medicaid pays Part B premiums for QMBs, SLIMBs and QI-1s. It pays Medicare cost-sharing charges for QMBs.

House Bill

No provision.

Senate Bill

The cost-sharing specified under the low-income subsidy provisions would be modified for persons diagnosed with cardiovascular disease, cancer, diabetes or Alzheimer's disease. The cost-sharing specified under New Section 1860D-19 would apply except for the following changes. The QMB population would have a full premium subsidy for at least one drug plan available in the area where the beneficiary resided. For the SLIMB and QI-1 population, there would be no premium for any plan whose premium was at or below the monthly national average premium. For other persons below 160% of poverty, only a percentage of the premium otherwise applicable. Persons with incomes above 160% of the poverty line would have, in 2006, the same cost-sharing otherwise specified under the bill.

Conference Agreement

No provision

Medication Therapy Management Assessment Program (Section 110A of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 1-year assessment program to contract with qualified pharmacists to provide medication therapy management services to fee-for-service beneficiaries. The Secretary would designate 6 geographic areas(at least 2 rural), each containing not less than 3 sites. The program would be implemented between October 1, 2004 and January 1, 2005. Beneficiaries in an area could participate if they identified a qualified pharmacist to furnish medication therapy management services. The Secretary would enter into contracts with qualified pharmacists to provide such services. The fee established under the contract would be designed to test various payment methodologies including one that applied a relative value scale and fee schedule. Payments would be made from the Part B trust fund and be budget neutral. The Secretary would be required to make data on the program available and report to Congress within 6 months of completion of the program.

Conference Agreement

No provision

Section 133. Pharmacy Benefit Managers Transparency Requirements (Section 133 of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

An eligible entity offering a Medicare prescription drug plan under Part D or a MedicareAdvantage organization offering a MedicareAdvantage plan under Part C could not enter a contract with a pharmacy benefit manager (PBM) owned by a pharmaceutical manufacturing company. PBMs would be required to provide the following information, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General for the Department of Health and Human Services: 1)aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer; 2) the amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs (as measured by volume); and 3) the percentage differential between the price PBMs pay pharmacies and the price the PBM charges the PDP or MA organization. Failure to disclose could result in civil penalties; further, the U.S. district court could order compliance. No disclosed information would be made public, except as might be relevant to any judicial action or proceeding. Nothing in the provision would be intended to prevent disclosure to either body of Congress or any duly authorized committee or subcommittee.

Conference Agreement

No provision.

Office of the Medicare Beneficiary Advocate (Section 134 of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

Within 1 year of enactment, the Secretary would be required to establish an Office of the Medicare Beneficiary Advocate within the Department of Health and Human Services. The Office would establish a toll-free number for beneficiaries to obtain information on the Medicare program, particularly with respect to Part D. It would establish a website with easily accessible information on PDPs and MA plans. From amounts appropriated to the Secretary's administrative account, $2 million could be used to establish the Office and such funds as may be necessary would be used to operate the Office.

Conference Agreement

No provision.

Title II - Medicare Advantage

Subtitle A- Implementation of Medicare Advantage Program

Sec 201. Implementation of Medicare Advantage program

Present Law

Health maintenance organizations (HMOs) and other types of managed care plans have long participated in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. In 1997, Congress passed the Balanced Budget Act of 1997 (BBA 1997, P.L. 105-33), which replaced the risk contract program with the Medicare+Choice (M+C) program. M+C plans include coordinated care plans (HMOs, preferred provider organizations or PPOs, and provider-sponsored organizations or PSOs), private fee for service (PFFS) plans, and, on a temporary basis, medical savings accounts (MSAs).

House Bill

Section 200. Title II would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of regional EFFS plans that could include preferred provider networks, beginning in 2006. It would establish the Medicare Advantage (MA) program, upon enactment, to replace the M+C program, which would continue to offer coordinated care and other plans on a county-wide basis as under current law. It would also use competitive bidding, beginning in 2010, in the same style as the Federal Employees Health Benefits program (FEHBP) for certain EFFS plans and MA plans, to promote greater efficiency and responsiveness to Medicare beneficiaries.

Senate Bill

Title II would establish the Medicare Advantage (MA) program, which would replace the M+C program, beginning in 2006. The MA program would continue to offer coordinated care and other plans on a county-wide basis as under current law. It would also establish regional PPOs, to be offered in regions. Beginning in 2008, it would establish a limited competition program, in areas designated as “highly competitive,”

Conference Agreement

Section 201. The conference agreement establishes the Medicare Advantage (MA) program under Part C of Medicare. Any reference under Part C of Medicare to the “Medicare+Choice” program is deemed to be a reference to “Medicare Advantage” and “MA”.

This title modernizes and revitalizes private plans under Medicare. The Balanced Budget Act (BBA) of 1997 altered payments for private plans and expanded the types of plans that could be offered under Medicare. Since payment rate changes were implemented, enrollment in private plans has fallen from 6.2 million beneficiaries in 1998 to 4.6 million beneficiaries in November 2003, and the number of plans has decreased from 346 risk plans in 1998 to 155 (151 coordinated care plans and 4 private FFS plans) in November 2003. This disruption has been

due, in part, to unpredictable and insufficient payments. BBA 97 fundamentally de-linked payments to plans from FFS payment growth.

To increase beneficiary choice, Title II reforms the payment system in 2004. All plans would be paid at a rate at least as high as the rate for traditional FFS Medicare, as recommended by the Medicare Payment Advisory Commission (MedPAC). After 2004, private plans' capitation rates would grow at the same rate as FFS Medicare. To increase beneficiary choice in more rural areas, Title II would establish regional plans, which would encourage private plans to serve Medicare beneficiaries in larger regions, beginning in 2006. Both local and regional MA private plans would bid competitively against a benchmark beginning in 2006.

Once private plans became established, and enrollment in private plans increased, a demonstration of comparative cost adjustment in selected sites would begin in 2010. Plan bids from private plans and rates for traditional FFS Medicare would be averaged to create a benchmark for competitive bidding. The competitive program would encourage beneficiaries to enroll in the most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs.

Subtitle B-Immediate Improvements

Section 211. Immediate improvements

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%).

A budget neutrality adjustment is made so that estimated total M+C payments in a given year will be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the direct and indirect costs of graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending, the national growth percentage. The minimum increase provides for an increase of at least 2% over the previous year's amount.

If an individual is in a short-term general hospital at the time he or she elected to enroll in an M+C plan or change from one M+C plan to another, payment for such services would be made through FFS or the original plan. Conversely, if an individual terminates enrollment in an M+C plan, that organization would be responsible for payment for such services until the date of the individual's discharge.

House Bill

Section 212(a). For 2004, a 4th payment mechanism would be added and plans would receive the highest of the four payment calculations (the floor, blend, minimum percentage increase, or the new amount). The new payment amount would be 100% of fee-for-service (FFS) costs. The FFS payment would be based on the adjusted average per capita cost for the year, for an MA payment area, for services covered under Parts A and B for beneficiaries entitled to benefits under Part A, enrolled in Part B and not enrolled in an MA plan. This payment would be adjusted to remove payments for direct medical education costs and to include the additional payments that would have been made if Medicare beneficiaries entitled to benefits from facilities of the Department of Veteran Affairs (VA) and the Department of Defense (DOD) had not used those services (VA/DOD adjustment).

Section 212(b). In 2004, no adjustment would be made for budget neutrality, which would fund the blend for that year.

Section 212(c). The calculation of the minimum percentage increase would also be revised. For 2004 and beyond, the minimum percentage increase would be the *greater* of: (1) a 2% increase over the previous year's payment rate (as under current law), or (2) the previous year's payment increased by the national per capita MA growth percentage. For purposes of calculating the minimum percentage increase, there would be no adjustment to the national growth percentage for prior years' errors before 2004. Beginning in 2005 and each subsequent year, the payments to a plan would be based on its prior year rate increased by the revised minimum percentage increase.

Section 212(d). The area-specific MA capitation rate (the local component of the blend) would be adjusted to include the VA/DOD adjustment, beginning in 2004.

Section 212(e). Beginning January 1, 2004, the payment rule for beneficiaries in a short-term general hospital at the time they either elected to enroll in or to terminate their enrollment in an M+C plan, would be extended to a beneficiary in an inpatient rehabilitation facility.

Section 212(f). No later than 18 months after enactment of this Act, the Medicare Payment Advisory Commission would report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report would examine the variation in costs between different areas, including differences in input prices, utilization and practice patterns; the appropriate geographic area for payment; and the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care to different groups of beneficiaries.

Section 212(g). No later than July 1, 2006, the Administrator would submit a report to Congress that described the impact of additional financing provided under this Act and other Acts, (including the Balanced Budget Refinement Act of 1999 - BBRA and the Benefits Improvement and Protection Act of 2000 - BIPA) on the availability of MA plans in different areas and the impact on lowering premiums and increasing benefits under such plans.

Section 212(h). The Secretary would calculate and announce the new MA capitation rates within 6 weeks of enactment of this legislation.

Senate Bill

Section 203. [§1853(c)]. For payments before 2006, the payment would be calculated in the same manner as under current law — the highest of the blend, minimum payment (floor) rate, or minimum percentage increase. However the calculation of the minimum percentage increase would change for 2005. The minimum percentage increase for 2005 would be a 3% increase over the rate for the area for 2003. For 2006 and subsequent years, it would be a 2% increase over the previous year (but calculated as though the increase in 2005 was 2%.) Additionally, beginning in 2014, the minimum amount (floor) would be increased by the percentage increase in the CPI for all consumers, for the 12-month period ending in June of the previous year.

Section 204(b). The Secretary would conduct a study to determine the extent to which M+C cost-sharing discourages access to covered services or discriminates based on the health status of M+C eligible beneficiaries. The Secretary would submit a report to Congress, providing recommendations for legislation and administrative action, no later than December 31, 2004.

Section 210. The costs of DOD and VA military facility services would be included in the area specific M+C payment and the local fee for service rates beginning in 2006.

Conference Agreement

Section 211(a). The conference agreement makes several changes to the payments for MA plans. In some MA payment areas, the MA payment rate is lower than the costs of providing FFS care to enrollees in traditional Medicare in some parts of the country. Many private plans have seen their Medicare payment rates rise much less rapidly than the costs of FFS Medicare, as they have been held to increases of two percent annually every year since 1998, except for 2001 when a three percent increase was paid due to the BIPA. Health costs in general are running much higher than the two percent payment increases that most plans are receiving in the areas where most of the beneficiaries are enrolled in Medicare+Choice. Plans find it difficult—if not impossible—to contract with providers if FFS Medicare can reimburse providers at higher rates than private plans may offer, given their Medicare payments. If paid less than FFS Medicare, private plans may be forced to increase enrollee premiums or cost-sharing, or decrease supplemental benefits, such as prescription drug coverage. Since 1998, the number of plans participating in M+C has declined from 346 to 155.

To encourage plan entry, all private plans would be paid at a minimum of the FFS rate. In addition, private plan rates would increase at the same rate as growth in FFS Medicare. The goal is to increase beneficiary choice, by increasing private plan participation in Medicare.

For 2004, a 4th payment mechanism will be added and plans will receive the highest of the four payment calculations (the floor, blend, minimum percentage increase, or the new amount). The new payment amount is 100% of fee-for-service (FFS) costs. The FFS payment is based on the adjusted average per capita cost for the year, for an MA payment area, for services covered under Parts A and B for beneficiaries entitled to benefits under Part A, enrolled in Part B and not enrolled in an MA plan. The 4th payment mechanism, 100% fee-for-service, will be rebased no less than once every 3 years. This payment will be adjusted to: (1) remove payments for direct medical education costs, and (2) include the additional payments that would have been made if Medicare beneficiaries entitled to benefits from facilities of the Department of Veteran

Affairs (VA) and the Department of Defense (DOD) had not used those services (VA/DOD adjustment).

Section 211(b). In 2004, no adjustment will be made for budget neutrality, in order to fund the blend for that year.

Section 211(c). The calculation of the minimum percentage increase will also be revised. For 2004 and beyond, the minimum percentage increase will be the *greater* of: (1) a 2% increase over the previous year's payment rate (as under current law); or (2) the previous year's payment increased by the national per capita MA growth percentage. For purposes of calculating the minimum percentage increase, there will be no adjustment to the national growth percentage for prior years' errors before 2004. Beginning in 2005 and each subsequent year, the payments to a plan will be based on its prior year rate increased by the revised minimum percentage increase.

Section 211(d). The area-specific MA capitation rate (the local component of the blend) will be adjusted to include the VA/DOD adjustment, beginning in 2004.

Section 211(e). Beginning January 1, 2004, the payment rule for beneficiaries in a short-term general hospital at the time they either elected to enroll in or to terminate their enrollment in an MA plan, will be extended to a beneficiary in an rehabilitation hospital, a distinct part rehabilitation unit, or a long-term care hospital. For beneficiaries leaving their MA plan while receiving these inpatient hospital services, this provision will expand the rule that disallows payment for such services under fee-for-service payments for inpatient hospitals. Under the expansion, payments will be prohibited from any type of payment provision under Medicare for inpatient services, for the type of facility, hospital, or unit involved.

Section 211(f). No later than 18 months after enactment of this Act, the Medicare Payment Advisory Commission (MedPAC) will submit a report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report will examine the variation in costs between different areas, including differences in input prices, utilization and practice patterns; the appropriate geographic area for payment of local MA plans; and the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care to different groups of beneficiaries.

Section 211(g). No later than July 1, 2006, the Secretary will submit a report to Congress that describes the impact of additional financing provided under this Act and other Acts, (including the Balanced Budget Refinement Act of 1999 - BBRA and the Benefits Improvement and Protection Act of 2000 - BIPA) on the availability of MA plans in different areas and the impact on lowering premiums and increasing benefits under such plans.

Section 211(h). The Medicare Payment Advisory Commission (MedPAC) will conduct a study to determine the extent to which MA cost-sharing affects access to covered services or selects enrollees based on the health status of MA eligible beneficiaries. MedPAC will submit a report to Congress, providing recommendations for legislation and administrative action, no later than December 31, 2004.

Section 211(i). Within 6 weeks after enactment, the Secretary will determine and announce the revised MA capitation rates. The revised payment rates will be subject to the same transition rules that applied to revised payments after the passage of the Benefits Improvement and Protection Act of 2000 (BIPA, P.L. 106-554), including the requirement that

plans that previously announced their intention to terminate their contract or reduce their service area could rescind their notice, among other transition rules. Also for 2004, any changes to payments made under this Act will be effective beginning in March 2004, and would be adjusted to include any additional amounts plans would have received if the new payment system had been effective January 1. If a plan revises its submission of information to the Secretary, and it includes changes in beneficiary premiums, beneficiary cost-sharing, or benefits under the plan, then the plan is required to notify each enrollee in writing, within 3 weeks after the date that the Secretary approves the changes. There will be no administrative or judicial review of any determination made by the Secretary for application of this section or payment rates.

In order to clarify current law, if a private fee-for-service plan has contacts and agreements with a sufficient number and range of providers within a category of health care professionals and providers, it may charge higher beneficiary copayments to providers in that category who do not have such contracts or agreements (other than deemed contracts or agreements).

Subtitle C- Offering Medicare Advantage (MA) Regional Plan; Medicare Advantage Competition

Section 221. Establishment of MA regional plans

Present Law

M+C plans include coordinated care plans (HMOs, preferred provider organizations or PPOs, and provider-sponsored organizations or PSOs), private fee for service (PFFS) plans, and, on a temporary basis, medical savings accounts (MSAs).

Enrollment in any individual M+C plan is open only to those beneficiaries living in a specific service area. An M+C payment area is defined as a county, or equivalent area as specified by the Secretary. Plans define a service area as a set of counties and county parts, identified at the zip code level. At a state's option, the service area could be defined as the entire state; however, to date, no state has done so.

House Bill

Section 201(a). [§1860E-1(a)] Beginning January 1, 2006, the Administrator would establish the EFFS program for EFFS eligible individuals in EFFS regions. Plans would be offered on a regional basis, in at least 10 regions established by the Administrator. Before establishing the regions, the Administrator would conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. Regions would be established to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas.

[§1860E-1(b)]. EFFS plans would be required to provide either fee-for-service (FFS) or preferred provider coverage. Under FFS coverage, plans would: (1) reimburse hospitals, physicians and other providers at a rate determined by the plan on a FFS basis, without placing providers at risk, (2) not vary rates based on the provider's utilization, and (3) not restrict the selection of providers from among those who were lawfully authorized to provide covered services and agreed to accept the plan's terms and conditions. Under preferred provider coverage, plans would: (1) have a network of providers who agreed to a contractually-specified

reimbursement for covered benefits with the organization, and (2) provide for reimbursement for all covered benefits regardless of whether they were provided within the network.

[§1860E-1(c)]. EFFS plans would have to comply with existing eligibility, election, and enrollment provisions (under §1851) including guaranteed issue and renewal, but could offer cash rebates, reduced premiums, or supplemental benefits to beneficiaries if plan bids were below a specified benchmark.

[§1860E-3(a)]. The Administrator may enter into contracts with up to three EFFS organizations in any region.

Senate Bill

Section 211. [§1858(a)]. Beginning January 1, 2006, a preferred provider organization (PPO) plan would be offered to MA eligible individuals in preferred provider regions. A PPO would be an entity with a contract that met other requirements of this Act. A PPO would have a network of providers that agreed to contractually specified reimbursements for covered benefits under Parts A and B. The PPO would pay for all covered services an enrollee received, whether provided in or out of network.

[§1858(a)(3)]. There would be at least 10 regions. Each region would have to include at least one state, and could be the entire United States. The Secretary could not divide states so that portions of the state were in different regions. To the extent possible, the Secretary would include multi-state metropolitan statistical areas (MSAs) in a single region, except that he or she could divide an MSA where necessary to establish a region of such size and geography to maximize the participation of PPOs. The Secretary could use the same regions established for the prescription drug program, under Part D. The service area of a PPO would be the region.

Each plan would be offered to any MA eligible individual residing in the service area.

Section 211. [§1858(b)]. PPOs would be required to establish a sufficient number and range of health care professionals and providers willing to provide services under the plan's terms. The Secretary would consider this requirement to be met if the organization had a sufficient number of contracts and agreements with a sufficient number and range of providers. These arrangements would not restrict enrollee access to other providers for covered services. Additionally, if the plan was in a state where 25% or more of the population resided in a health professional shortage area, these arrangements would also not restrict the categories of licensed health professionals or providers from whom the enrollee could obtain covered benefits. The Secretary could disapprove any PPO believed to attract a population that is healthier than the average population of the region serviced by the plan.

Section 211. [§1858(d)]. If there were bids for more than three plans in a preferred provider region, the Secretary would limit the number of plans to the three lowest-cost credible plans that met or exceeded the quality or minimum standards.

Conference Agreement

The conference agreement establishes a new regional plan program beginning in 2006. The Secretary will establish between 10 and 50 regions across the nation. Plans wishing to participate in this program will be required to serve an entire region. By requiring plans to serve

larger service areas that bring together both urban and rural areas, the program will bring greater health plan choices to areas not previously served by the Medicare+Choice program, particularly rural areas.

In establishing Medicare Advantage regions (MA regions), the Secretary will conduct a market study to determine how regions should best be constructed to maximize plan participation and availability of plans to beneficiaries. The conference agreement includes a number of provisions to provide incentives for plans to participate in the regional program. These provisions include risk corridors for plans during the first 2 years of the program, 2006 and 2007; a stabilization fund to encourage plan entry and limit plan withdrawals; a blended benchmark that will provide greater responsiveness to the market by allowing plan bids to influence the benchmark amount; and a network adequacy fund to assist plans in forming adequate networks, particularly in rural areas. While private plans have experience in serving Medicare beneficiaries at a local level, such plans have not previously operated on a region-wide basis. These provisions will assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger regions.

Section 221(a). This provision establishes a 2-year moratorium on new local preferred provider organizations in order to encourage PPOs to operate at the regional level. PPOs that are in operation as of December 31, 2005, including demonstration projects, will be allowed to continue operations and expand enrollment in their existing service areas during this period; however they will not be allowed to expand their service areas. PPOs will be able to enter new or expanded service areas again beginning January 1, 2008.

Section 221(b). The conference agreement allows MA regional coordinated care plans under the MA program. An MA regional plan: (1) has a network of providers who agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan, (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers, and (3) has a service area of one or more MA regions. A local MA plan is an MA plan that is not an MA regional plan, and local MA areas are defined, as under current law, as a county or equivalent area specified by the Secretary. MSA and PFFS plans are defined as local plans, although nothing prevents an MSA plan or an MA PFFS plan from serving one or more regions, or the entire nation.

Section 221(c). [§1858(a)(1)]. The service area for an MA regional plan will consist of an entire MA region and may not be segmented.

[§1858(a)(2)]. No later than January 1, 2005 the Secretary will establish and publish a list of MA regions. There will be between 10 and 50 regions within the 50 states and the District of Columbia. Before establishing the MA regions, the Secretary will conduct a market survey and analysis, including an examination of current insurance markets. The regions should maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially beneficiaries residing in rural areas. To the extent possible, each region should include at least one State, should not divide States across regions, and should include multi-State Metropolitan Statistical Areas in a single region. The Secretary may periodically review MA regions and, based on the review, revise the regions to be more appropriate. An MA regional plan may be offered in more than one region including all regions.

Single Deductible and Catastrophic Limit

Present Law

Medicare does not have a catastrophic limit on beneficiary out-of-pocket expenses, although some M+C plans offer an out-of-pocket limit as an added benefit. The original Medicare FFS program includes is a Part B deductible and a separate Part A deductible for hospital stays.

House Bill

Section 201(a). [§1860E-2(b and c)]. EFFS plans could only be offered in a region if the plan, among other requirements, included a single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses.

Senate Bill

Section 202. [§1852(a)]. Each MA plan would have to offer a maximum limitation on out-of-pocket expenses and a unified deductible.

Conference Agreement

Section 221(c). [§1858(b)]. In order to ensure that MA regional plans are structured more like existing private market plans for the under-65 population, the conference agreement requires MA regional plans to include a single deductible for benefits under Parts A and B. The single deductible may be applied differentially for in-network services and may be waived for preventive or other items and services. MA regional plans will also be required to include two catastrophic limits – one for out-of-pocket expenditures for *in-network* Part A and B benefits and one for out-of-pocket expenditures for *all* Part A and B benefits. Payment rates to these plans are not increased to provide this coverage.

Risk Corridors

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 211. [§1858(e)]. The PPO would notify the Secretary of the total amount of costs incurred during 2007 and 2008 in providing covered benefits under Part A and B of Medicare, except that certain expenses would not be included (administrative expenses over the amount determined appropriate by the Administrator and amounts expended for enhanced medical benefits).

The Secretary would be required to establish risk corridors for the regional PPO plans for 2006 and 2007. Medicare would share risk with PPO organizations after costs fell above or below a risk corridor of 5% as follows: 1) Medicare would share 50% of the losses or profits

between 105% and 110% of a target which consists of Medicare's MA payment plus the beneficiaries' contributions; and 2) Medicare would share 90% of the losses or profits above 110% of the target. PPOs would be at full risk for all enhanced medical benefits. A beneficiary's liability would not be affected by these risk corridors in the given years.

Conference Agreement

Section 221(c). [§1858(c)]. In order to encourage plans to enter the regional market and to provide assistance to these plans during the start-up phase of their business, Medicare will share risk with MA regional plans if costs fall above or below a specific risk corridor. These risk corridors will be available to plans during 2006 and 2007. The conference agreement provides that MA regional plans notify the Secretary of: (1) the total costs of providing Part A and B benefits and the portion attributable to allowable administrative expenses, and (2) the costs of providing rebatable integrated benefits and the portion of these costs attributable to allowable administrative expenses. Allowable cost is defined, with respect to an MA regional plan for a year, as the total amount of costs incurred in providing benefits under the original Medicare FFS program, and rebatable integrated benefits, reduced by administrative expenses. Rebatable integrated benefits are defined as non-drug supplemental benefits provided by a plan, as part of its required rebate to beneficiaries, that are integrated with the benefits under the original Medicare fee-for-service program. The Secretary will have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations.

[§1854(c)(2)(D)]. The target amount is defined as an amount equal to the sum of: (1) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original Medicare FFS program; (2) the total of the MA monthly basic beneficiary premium, collectable for the enrollees for the year; and (3) the total amount of rebatable integrated benefits that the Secretary determines are appropriate for inclusion in the risk corridor calculation. The target amount does not include the cost of administrative expenses for FFS benefits or for rebatable supplemental benefits.

[§1854(c)(2)]. There will be no payment adjustment if the allowable costs for the plan are at least 97 percent, but do not exceed 103 percent of the target amount for the plan. If allowable costs for the plan are more than 103 percent but less than 108 percent of the target amount for the plan for the year, the Secretary will increase the total monthly payments made to the organization by 50 percent of the difference between 103 percent and allowable costs. If allowable costs for the plan are greater than 108 percent of the target amount, the Secretary will increase the total monthly payments to the plan by an amount equal to the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between allowable costs and 108 percent of the target. Conversely, if the allowable costs for the plan are less than 97 percent, but greater than or equal to 92 percent of the target amount, the Secretary will reduce the total monthly payment to the plan by 50 percent of the difference between 97 percent of the target amount and the allowable cost. If the allowable costs for the plan are below 92 percent of the target, the Secretary will reduce the total monthly payments to the organization by the sum of: (1) 2.5 percent of the target amount, and (2) 80 percent of the difference between 92 percent of the target and the allowable cost.

[§1854(c)(3)]. Each contract under the MA program will provide the information the Secretary deems necessary to carry out this subsection. While the Secretary has the right to inspect and audit all books and records pertaining to information provided under this section, the information disclosed or obtained may only be used to carry out this section.

Organizational and Financial Requirements

[§1854(d)]. In order to facilitate the offering of MA plans in regions that may encompass multiple states, the conference agreement establishes rules for applying licensing requirements across states. If an MA organization offering an MA regional plan is organized and licensed under State law in a state in the region but does not meet the requirements in other states in the region, the Secretary may waive such requirement for an appropriate period of time. Such a waiver can only be granted if the organization demonstrates to the Secretary's satisfaction that it has filed the necessary application to meet the other state's requirements. If an MA organization is organized and licensed under more than one state in the region, and the organization does not meet the requirements of each state, the organization may select the rules of one State and apply those rules to the entire service area until such time as the organization meets a state's requirements, in a manner specified by the Secretary.

Stabilization Fund

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 231. If an area was designated as highly competitive, benchmarks would not apply. Instead, a plan would bid the total payment it was willing to accept (not taking into account risk adjustment) for providing required Parts A and B benefits to plan enrollees residing in the service area. The Secretary would substitute the second lowest bid for the benchmark. If there were fewer than three bids, the Secretary would be required to substitute the lowest bid for the benchmark. Total funding for this provision is limited to $6 billion over 2009 through 2013.

Conference Agreement

Section 221(c). [§1858(e)]. During the past several years a number of plans have pulled out of the Medicare+Choice program due to changing market conditions and an inflexible payment formula. Plans were held to 2 percent annual payment increases while costs in the fee-for-service program were rising at a much faster rate. Under current law, the Secretary had no ability to respond quickly to these market changes, resulting in plan withdrawals which have affected millions of beneficiaries. In order to promote greater stability in the regional program and provide the Secretary with a tool to respond to market fluctuations, the conference agreement establishes an MA Regional Plan Stabilization Fund. The Fund can be used to provide incentives for plan entry in each region and plan retention in MA regions with below-average MA penetration. Initially, $10 billion will be available for expenditures from the Fund beginning on January 1, 2007 and these start-up funds will only be available until December 31, 2013. Funds will be drawn from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a proportion that reflects the relative weight that the benefits under Parts A and B represent of the actuarial value of the total benefit. Additional

funds will be available in an amount equal to 12.5% of average per capita monthly savings from regional plans that bid below the benchmark. The additional funds will be deposited on a monthly basis into a special account in the Treasury.

The Fund is designed to allow the Secretary to respond to market conditions on a temporary basis. If the Fund is used for either plan entry or retention for 2 consecutive years, the Secretary must report to Congress on the underlying market conditions in the regions. These reports will give Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

[§1858(e)(2)]. The funds will be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. [§1854(e)(5)]. The total amount projected to be expended from the Fund in any year may not exceed the amount available in the Fund as of the first day of that year. If the use of the stabilization fund results in increased expenditures under this title, the increased expenditures shall be counted as expenditures from the Fund. The Secretary will only obligate funds if the Secretary, the Chief Actuary of CMS, and the appropriate budget officer certifies that there are sufficient funds at the beginning of the year to cover all such obligations for that year. The Secretary will take steps to ensure that sufficient funds are available to make such payments for the entire year, which may include computing additional payment amounts or limitations on enrollment in MA regional plans receiving such payments. [§1858(e)(2)(D)]. Expenditures from the Fund will first be made from amounts made available from the initial funding.

[§1858(e)(3)]. Plan entry incentives are available for either a one-year national bonus payment or multi-year adjustments in regional payments; however in no case can there be a regional payment adjustment if there is a national bonus for that year. In order to encourage the offering of plans in all regions, the national bonus payment will be available to an MA organization that elects to offer a regional plan in each MA region in a year, but only if one of the regions did not have a plan available in the previous year. Funding is only available for a single year, but more than one organization can receive the incentive in the same year. The national bonus payment will: (1) be available to an organization only if it offers plans in every MA region; (2) be available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization, subject to funding limitations.

[§1858(e)(3)]. If a national bonus payment is not made, a regional payment adjustment can be made. The regional payment adjustment is an increased payment for an MA regional plan offered in an MA region that did not have any MA regional plans offered in the previous year. The Secretary will determine the adjusted payment amount based solely on plans' bids in the region, and the adjusted payment amount will be available to all plans offered in the region. The amount can be based on the mean, mode, median or other measure of such bids and may vary from region to region, but the payment amount cannot be determined through a method that limits the number of plans or bids in the region. Such a payment adjustment will be treated as a change to the benchmark amount in that region for purposes of calculating individual plan payments and beneficiary rebates.

[§1858(e)(3)(C)(ii)]. Subject to funding limitations, the Secretary will determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding will be provided for a second consecutive year under this provision, the Secretary is

required to submit a report to Congress describing the underlying market dynamics in the region and recommending changes to the payment methodology. Multi-year funding may be made available to all MA plans offered in a region. If this multi-year increased amount is made available to MA plans in a region, funding will not be available for plan retention in the region in the following year. Regional payment adjustments will not be taken into account when computing the underlying benchmark for the subsequent year.

[§1858(e)(4)]. In addition to using the Fund to encourage plans to enter regions that might otherwise go unserved, the Secretary may also use the fund to encourage plans to remain in regions if market conditions are causing plan withdrawals. Incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements. The requirements are: (1) one or more plans inform the Secretary that they will discontinue service in the region in the succeeding year; (2) the Secretary determines that if those plans were not offered, fewer than 2 MA regional plans, each offered by a different organization, would be offered in the region in the year; (3) for the previous year, the Secretary determines that the proportion of beneficiaries enrolled in MA regional plans in the region is less than national average of MA regional plan enrollment; (4) funds have not already been awarded for 2 consecutive years. Any additional payment amount will be treated as if it were an addition to the benchmark amount otherwise applicable, but will not be taken into account in the computation of the benchmark for any subsequent year. If plans receive funding under this part for a second year, the Secretary will submit a report to Congress that describes the underlying market dynamics in the region and includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

[§1858(e)(4)]. The incentive for plan retention payment will be an amount determined by the Secretary, that does not exceed the greater of: (1) 3 percent of the benchmark amount applicable in the region; or (2) an amount that, when added to the benchmark, results in a ratio such that the additional amount plus the benchmark for the region divided by the adjusted average per capita cost (AAPCC) equals the weighted average of benchmarks for all regions divided by the AAPCC for the United States.

[§1858(e)(6)]. Not later than April 1 of each year beginning in 2008, the Secretary will submit a report to Congress and the Comptroller General of the United States that includes: (1) a detailed description of the total amount expended as a result of the Stabilization Fund in the previous year (and the projections for the current year) compared to the total amount that would have been expended under this title in each year if this subsection had not been enacted; (2) amounts remaining within the funding limitations; and (3) the steps the Secretary will take to ensure that the expenditures from the Stabilization Fund will not exceed the amount available. The report will include certification from the Chief Actuary of CMS that estimates are reasonable, accurate and based on generally accepted actuarial principles and methodologies.

[§1858(e)(7)]. Not later than January 1 of 2009, 2011, 2013 and 2015, the Comptroller General of the United States will submit a report to the Secretary and Congress on the application of payments from the Stabilization Fund. The reports will include an evaluation of: (1) the quality of care provided to individuals for which additional payments were made from the Stabilization Fund; (2) beneficiary satisfaction; (3) the cost of Stabilization Fund payments to the Medicare program; and (4) any improvements in service delivery. The report will also include a comparative analysis of the performance of MA regional plans receiving payments to MA regional plans not receiving Stabilization Fund payments, and recommendations for legislation or administrative action as the Comptroller General determines would be appropriate.

Regional Blended Benchmark

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee reduced by any Part B premium reduction, and adjusted for risk.

House Bill

Section 201. [§1860E-3(b)]. The EFFS region-specific non-drug monthly benchmark amount means an amount equal to 1/12 of the average (weighted by the number of EFFS eligible individuals in each local payment area in the region) of the annual MA payment rate for payment areas within the region.

Senate Bill

Section 211. [§1858(c)(2)]. Beginning in 2006, the Secretary would calculate a benchmark amount for required services for each region equal to the average of each benchmark amount for each MA payment area within the region, weighted by the number of MA eligible individuals residing in the payment area for the year. Each year, beginning in 2005, the Secretary would publish (at the time of publication of the risk adjustors under Part D — no later than April 15) the benchmark amount for each region, factors to be used for adjusting payments under the comprehensive risk adjustment methodology and methodology used for adjustments for geographic variations within a region.

Conference Agreement

Section 221(c). [§1854(f)]. Beginning in 2006, the Secretary will compute a "blended benchmark" amount for each MA region. The blended benchmark is designed to be responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount. The MA region-specific non-drug monthly benchmark amount is defined as the sum of a statutory component and a plan-bid component for the year. The statutory component is the product of the statutory region-specific non-drug amount for the region and the year, and the statutory national market share percentage. The statutory region-specific non-drug amount, the first part of the statutory component, is an amount equal to the sum, (for each local MA area within the region) of the product of the MA area-specific non-drug monthly benchmark amount for the area and the year, and the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region. The statutory national market share percentage, the second part of the statutory component, is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the most recent month during the previous year for which data are available.

The plan-bid component is the product of the weighted average of MA plan bids for the region and the year and the non-statutory market share percentage. The weighted average of plan bids for an MA region is calculated as the sum across MA regional plans, of (for each plan) the products of the unadjusted MA statutory non-drug monthly bid for the plan, and the plan's share of MA enrollment in the region. Or, in the first year in which any regional plan is offered in a region, if more than one MA regional plan is offered in that year, the plan's share of MA enrollment in the region is replaced in the formula either by 1) one divided by the number of plans in the region, or 2) a share estimated by the Secretary. The non-statutory market share percentage is one minus the statutory national market share percentage.

Uniform Coverage Determination

Present Law

An M+C organization may elect to have a single local coverage policy apply to its plan when the plan's service area includes more than one local coverage policy area. The Secretary will identify the local coverage policy that is most beneficial to M+C enrollees.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 221(c). [§1854(g)]. The organization offering an MA regional plan may elect to have a local coverage determination for the entire MA plan based on the local coverage determination applied for any part of the region, as selected by the organization. These local coverage determination are may be appealed under the applicable provisions of section 1869(f) (BIPA, sec. 522).

Assurance of Network Adequacy

Present Law

An M+C organization may select the providers in its network, so long as: (1) the organization makes the benefits available and accessible to each individual within the service area with reasonable promptness and in a manner which assures continuity in the provision of benefits; (2) when medically necessary, the organization makes benefits available and accessible 24 hours a day and 7 days a week; and (3) the plan provides reimbursement for services provided outside of the network when services are medically necessary and immediately required, when the services are renal dialysis and the beneficiary is temporarily out of the plan's service area, or when the services are maintenance care or post-stabilization. The organization must provide access to appropriate providers including credentialed specialists, and must provide emergency services without regard to prior authorization.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 221(c). [§1854(h)]. All current law network adequacy requirements will remain in place under the new regional program. However, because regions may encompass areas served by a single hospital, plans may have difficulty meeting their network adequacy requirements if they are unable to reach an agreement with such a hospital. In order to facilitate the meeting of these network adequacy requirements across large regions, the conference agreement allows the Secretary to provide payment to an essential hospital that provides services to enrollees in an area, in cases in which the MA organization offering the plan was unable to reach an agreement with the hospital regarding provision of services to plan enrollees. The Secretary will make the plan payment available only if the organization makes satisfactory assurances to the Secretary that it will pay the hospital an amount not less than the Medicare Part A payment for such services, and, with respect to specific services provided to an enrollee, the hospital demonstrates that its costs exceed the Medicare Part A payment. The agreement makes $25 million available in 2006, increased each year by the growth in the market basket percentage. Subject to that limit, the payment, if any, would be the amount by which the payment for inpatient hospital services if the hospital were a critical access hospital exceeds the payment for the same service that the hospital would otherwise receive. An essential hospital would be defined as a general acute care hospital that demonstrates to the Secretary that its costs exceed the Medicare Part A payment and is determined by the Secretary to be necessary for the plan to meet its network adequacy requirements.

Section 222. Competition program beginning in 2006

Submission of bidding and rebate information

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee, reduced by any Part B premium reduction, and adjusted for risk.

Each year a coordinated care plan of an M+C organization submits an adjusted community rate (ACR) proposal, estimating its proposed cost to serve Medicare beneficiaries for the following contract year and comparing such costs to the estimated costs of providing Medicare services to a commercial population. To the extent that a plan's ACR is below the administered payment amount, the plan must provide additional benefits to its enrollees or reductions in the Part B premium. In submitting its proposal, the organization must include information on: (1) the ACR; (2) the M+C monthly basic beneficiary premium; (3) a description

of the deductible, coinsurance and copayments under the plan (including the actuarial value of each); and (4) a description of any required additional benefits. For supplemental benefits, the organization must also include: (1) the ACR, (2) the M+C monthly supplemental beneficiary premium, and (3) a description of the deductible, coinsurance and copayments, including the actuarial value of each.

House Bill

Section 221(a). Beginning in 2006, an MA organization would be required to provide the following information: (1) the monthly bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the area and the actuarial bases for determining such amount; (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted MA statutory non-drug monthly bid" amount), statutory prescription drug benefits, and non-statutory benefits (including the actuarial basis for determining these proportions); and (3) additional information as the Administrator may require.

Senate Bill

Section 204. [§1854(a)]. Each MA organization would be required to submit information by the second Monday in September, including: (1) notice of intent and information on the service area of the plan; (2) the plan type for each plan; (3) specific information for coordinated care and PFFS plans; (4) enrollment capacity; (5) the expected mix of enrollees, by health status; and (6) other information specified by the Secretary. For coordinated care plans and PFFS plans, the plans would also be required to submit the plan bid (the total amount that the plan was willing to accept for required Parts A and B benefits not taking into account the application of comprehensive risk adjustment), the assumptions used in preparing the bid with respect to the number of enrollees in each payment area and the mix by health status, and any required information for prescription drug coverage. The plan bid would also have to be based on actuarial equivalence.

For any enhanced medical benefit package a plan chooses to offer, it would be required to provide the following information: 1) the ACR, 2) the portion of the actuarial value of such benefits package, if any, that would be applied toward satisfying the requirement for additional benefits, 3) the MA monthly beneficiary premium for enhanced benefits, 4) cost-sharing requirements, 5) the description of whether the unified deductible had been lowered or if the maximum out-of-pocket limitation had been decreased, and 6) other information required by the Secretary.

[§1854(a)(5)]. Each plan bid would be required to reasonably and equitably reflect the cost of benefits provided under that plan.

Conference Agreement

Section 222 (a). Under the current Medicare+Choice system, plans are paid a fixed administrative amount regardless of their efficiency or their actual costs of providing services to the Medicare population. Beginning in 2006, an MA organization (other than an MSA) will be required to submit a bid to provide services to Medicare beneficiaries on either a local or a regional level. In submitting its bid, the plan will provide the following information: (1) the monthly aggregate bid amount for the provision of all required items and services, based on average revenue requirements (as applied under Title XIII of the Public Health Service Act for

Health Maintenance Organizations) in the payment area for an enrollee with a national average risk profile (including demographic risk factors and health status); (2) the proportion of the bid attributable to the provision of benefits under the original Medicare fee-for-service program, basic prescription drug coverage, and supplemental health care benefits; (3) the actuarial basis for determining the amounts and proportions, and additional information as the Secretary may require to verify such actuarial basis; (4) a description of deductibles, coinsurance and copayments applicable under the plan and their actuarial value; and (5) for qualified prescription drug coverage, the information required under Title I of this Act. In order to facilitate regional plans being offered in more than one MA region, the Secretary will establish procedures to reduce paperwork for bids in multiple regions. Use of the term "required revenue" is intended to make clear that the bids of health plans incorporate all their revenue needs, both the medical costs of providing benefits and associated administrative costs (including profits or retained earnings).

The changes made in the bidding process under Part C do not apply to PACE programs, which operate outside of Part C. However, if they wish to offer qualified prescription drug coverage, they will be treated as a MA-PD local plan and must submit a bid for drug coverage.

Plan bids for supplemental benefits, for which plans charge a premium may include reductions in the cost sharing that would otherwise apply under the plan for Part A and B services. Benefits in each of the three areas (A/B benefits, prescription drug benefits, and supplemental benefits) will be integrated together in a way that is seamless to the beneficiary and paid for through a single premium.

Acceptance and Negotiation of Bid Amounts

Present Law

The Secretary reviews the information submitted by plans and approves or disapproves the premiums, cost-sharing amounts, and benefits. The Secretary does not have the authority to review the premiums for either MSA plans or PFFS plans.

House Bill

Section 221(a)(3)(C). The Administrator would have the same authority to negotiate bid amounts that the Director of the Office of Personnel Management has with respect to the Federal Employee Health Benefits Plan. The Administrator could negotiate the bid amount and could also reject a bid amount or proportion of the bid, if it was not supported by the actuarial basis. PFFS plans would be exempt from this negotiation.

Senate Bill

Section 204 (a)(5). Each bid amount would have to reasonable and equitably reflect the cost of benefits provided by the plan.

Conference Agreement

Section 222 (a). The conference agreement provides the Secretary with the authority to negotiate the monthly bid amount and the proportions, including supplemental benefits. The Secretary has similar authority to negotiate bid amounts to that of the Director of the Office of Personnel Management with respect to the Federal Employees Health Benefits Program. The

Secretary may only accept such a bid amount and proportion if they are supported by the actuarial bases, and reasonably and equitably reflect the revenue requirement (as applied under Title XIII of the Public Health Service Act for Health Maintenance Organizations) of benefits provided under the plan. As under current law, the Secretary does not have the authority to review the bid amounts for PFFS plans.

The Secretary may not require: (1) any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title; or (2) a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority.

Benefits under the original Medicare fee-for-service program option

Present Law

M+C plans are required to include all Medicare-covered services (Parts A and B benefits) except hospice care. In some circumstances, plans may also be required to offer additional benefits or reduced cost-sharing to their beneficiaries. The *basic* benefit package includes all of the required Medicare-covered benefits (except hospice services) as well as the additional benefits, as determined by a formula which is set in law. The adjusted community rate (ACR) mechanism is the process through which health plans determine the minimum amount of additional benefits, if any, they are required to provide to Medicare enrollees and the cost-sharing they are permitted to charge for those benefits. Medicare does not have a catastrophic limit on beneficiary out-of-pocket expenses although some M+C plans offer an out-of-pocket limit as an added benefit. The original Medicare FFS program includes a Part B deductible and a separate Part A deductible for inpatient hospital stays.

House Bill

MA organizations, other than PFFS plans, will be required to offer at least one plan in their service area that provides drug coverage as outlined in Title I. However, if an organization offers one such plan with drug coverage, they may offer alternative plans without such drug coverage. MA plans would be required to pay rebates to beneficiaries – in the form of additional benefits, reduced premiums, or cash payments – to the extent that program payments to MA plans exceeded bid amounts. MA plans would also be able to offer supplemental benefits for additional premiums.

Senate Bill

Section 202. [§1852(a)]. In addition to offering Medicare Parts A and B benefits (except hospice) and any additional required benefits, each MA plan (except MSAs, and in the case of prescription drug coverage, PFFS plans) would be required to offer: (1) qualified prescription drug coverage under Part D to beneficiaries residing in the area, and (2) a maximum limitation on out-of-pocket expenses and a unified deductible.

[§1852(a)(7)]. The unified deductible would be defined as an annual deductible amount applied in lieu of the inpatient hospital deductible and the Part B deductible. This would not prevent an MA organization from requiring coinsurance or a copayment for inpatient hospital services, after the unified deductible was satisfied, subject to statutory limitations.

[§1852(a)(2)(D)]. A PFFS plan could choose not to offer qualified prescription drug coverage under part D. Beneficiaries enrolling in such a PFFS plan could choose to enroll in an eligible entity under part D to receive their prescription drug coverage. [§1852(d)(4)]. A PFFS plan entirely meeting the access requirement for a category of providers through contracts or agreements (other than deemed contracts) could require higher beneficiary co-payments for providers who did not have such contracts or agreements.

Conference Agreement

Section 222 (a). Beginning in 2006, plan bids will be compared to a benchmark amount. For MA local plans, the benchmark amount will be the MA payment rates. For MA regional plans, the benchmark amount will be the regional blended benchmark. Plans that submit bids below the benchmark will be paid their bids, plus 75 percent of the difference between the benchmark and the bid, which must be returned to beneficiaries in the form of additional benefits or reduced premiums. For plans that bid above the benchmark the government will pay the benchmark amount, and the beneficiary will pay the difference between the benchmark and the bid amount as a premium. When for an MA regional plan, in determining the actuarially equivalent level of cost-sharing for required benefits, only expenses for in-network providers will be taken into account for the application of the catastrophic limit. Supplemental benefits can include reductions in cost-sharing for A and B benefits below the actuarial value of the deductible, coinsurance and copayments that would be applicable, on average, to individuals in the original fee-for-service program.

MA organizations, other than PFFS plans, will be required to offer at least one plan in their service area that provides drug coverage as outlined in Title I. However, if an organization offers one such plan with drug coverage, it may offer alternative plans without such drug coverage.

Beneficiary Savings

Present Law

To the extent that a plan's ACR is below the administered payment amount, plans must provide reduced cost-sharing, additional benefits, or reduced Part B premiums to their Medicare enrollees. Such benefits must be valued at 100 percent of the difference between the projected cost of providing Medicare-covered services to its commercial population and the expected revenue for Medicare enrollees. Plans can choose which additional benefits to offer, however, the total cost of these benefits must at least equal the "savings" from Medicare-covered services. Plans may also place the additional funds in a stabilization fund or return funds to the Treasury.

House Bill

Section 221(b). An MA plan would be required to provide an enrollee a monthly rebate that equaled 75 percent of any average per capita savings (the amount by which the risk-adjusted benchmark exceeded the risk-adjusted bid). The rebate could be: 1) credited toward the MA monthly supplemental beneficiary premium or the prescription drug premium; 2) paid directly to the beneficiary; 3) provided by another means approved by the Administrator; 4) or any combination of the above. The remaining 25 percent of the average per capita savings would be retained by the federal government.

Benchmarks would equal one-twelfth of the annual MA capitation rate for an enrollee in that area, and would be calculated by updating the previous year's capitation rate by the annual increase in the minimum percentage increase.

Senate Bill

[§1854(c)]. If the weighted service area benchmark exceeded the plan bid, the Secretary would require the plan to provide additional benefits, and if the plan bid exceeded the weighted service area benchmark, the plan could charge an MA monthly basic beneficiary premium equal to the amount the bid exceeded the benchmark.

Section 204. [§1854(g)]. If the plan bid was lower than the weighted service area benchmark, the plan could, in addition to benefits allowed under current law, also lower the amount of the unified deductible and decrease the maximum limitation on out-of-pocket expenses. However, plans would be restricted from specifying any additional benefits that provided for the coverage of any prescription drug, other than that relating to covered drugs under Part D.

Conference Agreement

Section 222 (b). The conference agreement requires an MA plan to provide an enrollee with a monthly rebate equal to 75 percent of any average per capita savings (the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid). In calculating such savings, and in order to ensure that savings are uniform for all enrollees in a plan, the benchmark and the bid will be risk adjusted according to a statewide (for local plans) or region-wide (for regional plans) risk adjuster. Alternatively, the Secretary has the discretion to risk adjust the benchmark and bid on a plan-specific basis for the purpose of calculating such savings. The beneficiary rebate can be credited toward the provision of supplemental health care benefits (including a reduction in cost-sharing, additional benefits or a credit toward any MA monthly supplemental beneficiary premium), the prescription drug premium, or the Part B premium. The plan will inform the Secretary about the form and amount of the rebate, or the actuarial value, in the case of supplemental health care benefits. The remaining 25 percent of the average per capita savings will be retained by the federal government.

Revision of Premium Terminology

Present Law

The M+C monthly basic beneficiary premium is the amount authorized to be charged for the plan based on the application of the "limitation on enrollee liability". The "limitation on enrollee liability" requires that the actuarial value of the premium, deductibles, coinsurance, and copayments applicable on average to enrollees in an M+C plan for required services does not exceed the actuarial value of deductibles, coinsurance, and copayments on average for beneficiaries in traditional Medicare. However, this average may be achieved by having higher copayments for some M+C services and lower copayments for other services. The supplemental beneficiary premium is amount authorized to be charged for the plan, such that the actuarial value of supplemental beneficiary premium, deductibles, coinsurance, and copayments for such benefits does not exceed the ACR for such benefits. These requirements do not apply to PFFS plans.

House Bill

Section 221 (d). For plans with a bid amount below the benchmark, the basic premium would be zero. For plans with bids above the benchmark, the basic premium would be equal to the amount by which the bid exceeded the benchmark.

Senate Bill

Section 204. If the weighted service area benchmark exceeded the plan bid, the plan would have to provide additional benefits. If the bid exceeded the weighted service area benchmark, the amount of the excess would be the MA monthly basic beneficiary premium.

Conference Agreement

Section 222 (b). For plans providing rebates (plans that bid below the benchmark), the MA monthly basic beneficiary premium will be zero. For plans with bids above the applicable benchmark, the MA monthly basic beneficiary premium will equal the amount by which the bid exceeds the benchmark. The MA monthly prescription drug beneficiary premium is the portion of the aggregate monthly bid amount that is attributable to the provision of prescription drug benefits under Title I of this Act, less the amount of any rebate. The MA monthly supplemental beneficiary premium is the portion of the aggregate monthly bid amount that is attributable to the provision of supplemental health care benefits, less the amount of any rebate. The unadjusted MA statutory non-drug monthly bid is the portion of the bid submitted by a plan attributable to the provision of required benefits under Medicare fee-for-service.

Collection of Premiums

Present Law

Medicare beneficiaries may have their Part B premiums deducted directly from their Social Security benefits.

House Bill

Section 221(b). Enrollees would be permitted to have their MA premiums deducted directly from their Social Security benefits or through an electronic funds transfer. The Administrator would be required to provide a mechanism whereby a beneficiary who joined an MA plan and elected Part D coverage through the plan would be able to pay one consolidated premium amount.

Senate Bill

No provision.

Conference Agreement

Section 222 (c). The conference agreement allows enrollees to have their MA premiums deducted directly from their Social Security benefits, through an electronic funds transfer, or such other mean as specified by the Secretary, including payment by an employer or under

employment-based retiree coverage on behalf of an employee, a former employee, or a dependent. All premium payments deducted from Social Security benefits will be credited to the appropriate Trust Fund as specified by the Secretary (in consultation with the Commissioner of Social Security and the Secretary of the Treasury) and shall be paid to the MA organization involved. The MA plan may not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments.

For individuals electing to have premiums deducted directly from Social Security benefits, the Secretary will transmit to the Commissioner of Social Security, by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium owed by the enrollee for each month during the year, and other information determined appropriate by the Secretary. Information will be periodically updated throughout the year. The Secretary will be required to provide a mechanism for the consolidation of any MA monthly basic beneficiary premium, any MA monthly supplemental beneficiary premium, and any MA monthly prescription drug beneficiary premium.

Computation of MA Benchmark and Payments of Plans Based on Bid Amounts

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee, reduced by any Part B premium reduction, and adjusted for risk.

House Bill

Section 221(c). For payments before 2006, the monthly payment amount would equal 1/12 of the annual MA capitation rate, for an enrollee for that area, reduced by any Part B premium reduction and adjusted for risk factors such as age, disability status, gender, institutional status and other factors the Administrator determines to be appropriate, including an adjustment for health status.

Beginning in 2006, MA payment rates would be determined by the Administrator by comparing plan bids to the benchmark. Non-drug benefits: Beginning in 2006, for plans with bids below the benchmark, the payment would equal the unadjusted MA statutory non-drug monthly bid amount, with adjustments for demographic factors (including age, disability, and gender) and health status and the monthly rebate. Conversely, for plans with bids at or above the benchmark, the payment amount would equal the MA area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments. Drug benefits: Additionally, for an MA enrollee who enrolled in Part D and elected prescription drug coverage through the plan, the plan's payment would include a direct and a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income beneficiaries, as outlined in Title I of this bill.

Senate Bill

Section 203. [§1853(a)]. Each MA organization would receive a separate monthly payment for: (1) benefits under FFS Medicare Parts A and B, and (2) benefits under the prescription drug program, Part D. The Secretary would ensure that payments for each enrollee would equal the MA benchmark amount for the payment area, as adjusted. The adjustments would include both a risk adjustment and an adjustment based on the ratio of the payment amount to the weighted service area benchmark.

Section 203. [§1853(c&d)]. Beginning in 2006, payments to MA plans would be determined differently, based on a comparison between plan bids and the weighted service area benchmark. The Secretary would however, continue to calculate the annual M+C capitation rates.

Plans would submit bids to the Secretary by the second Monday in September.

The Secretary would calculate the benchmark amounts as the greater of the minimum amount (floor) or the local FFS rate for the area. The local FFS rate would be calculated similarly to the adjusted average per capita cost (AAPCC), adjusted to remove the costs of indirect and direct graduate medical education.

The Secretary would calculate the weighted service area benchmark amount equal to the weighted average of the benchmark amounts for required services for the payment areas included in the service area of the plan.

The Secretary would determine the difference between each plan's bid and the weighted service area benchmark amount. For plan bids that equal or exceed the weighted service area benchmark, the MA organization would be paid the weighted service area benchmark amount. For plan bids below the weighted service area benchmark, the plan would be paid the weighted service area benchmark reduced by the amount of any premium reduction elected by the plan. The Secretary would adjust payments using the comprehensive risk adjustment methodology.

Section 205. This provision would establish the additional payments that would be made to the MA plans for the prescription drug coverage under Part D.

Conference Agreement

Section 222 (d). The conference agreement defines the term MA area-specific non-drug monthly benchmark amount, for a month in a year, for a service area that is entirely within an MA local area, as an amount equal to 1/12 of the annual MA capitation rate for the area. For a service area within more than one MA local area, the amount is equal to the average of the local amounts, weighted by the projected number of enrollees in the plan residing in the respective local area. For an MA region, the MA region-specific benchmark amount for the region for the year is defined as the sum of the statutory component and the plan-bid component. The statutory component is a weighted average of the local MA benchmarks in the region.

Section 222 (e). For payments before 2006, the conference agreement sets the monthly payment amount to equal 1/12 of the annual MA capitation rate, for an enrollee for that area, reduced by any Part B premium reduction and adjusted for demographic factors such as age, disability status, gender, institutional status and other factors the Secretary determines to be appropriate, including an adjustment for health status.

Beginning in 2006, MA payment rates will be determined by the Secretary by comparing plan bids to the benchmark. Non-drug benefits: Beginning in 2006, for plans with bids below the benchmark, the payment will equal the unadjusted MA statutory non-drug monthly bid amount, with adjustments for demographic factors (including age, disability, and gender) and health status, adjustments for intra-regional variation (if applicable), adjustments relating to risk adjustment, and the monthly rebate. To adjust for intra-regional variation, the Secretary will adjust the amounts to take into account variation in MA local payment rates among the different MA local areas included in a region. For adjustments relating to risk, the Secretary will adjust payments to MA plans to ensure that the sum of the monthly payment and any basic beneficiary premium equals the unadjusted MA statutory non-drug monthly bid amount, with demographic adjustments, and for an MA regional plan, adjustments for intra-regional variations. For plans with bids at or above the benchmark, the payment amount will equal the MA area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments, adjustments for intra-regional variation (if applicable), and adjustments relating to risk adjustment. The use of a risk adjustment methodology that uses demographic factors and health status factors will continue as under current law, and the Secretary will continue to have the flexibility to develop and implement new risk adjustment methodologies. Drug benefits: Additionally, for an MA enrollee in an MA-PD plan, the plan's payment will include a subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income beneficiaries, as outlined in Title I of this bill.

In the case of an MSA plan, the payment equals the MA area-specific non-drug monthly benchmark amount, adjusted for demographics and health status.

Annual Announcement Process

Present Law

The Secretary annually determines and announces, no later than May 1 for 2003 and 2004 and March 1, thereafter (for the following year), the annual M+C capitation rate for each M+C payment area and the risk and other factors to be used in adjusting these rates.

House Bill

Section 221(e). For years before 2006, for the calendar year concerned, the Secretary would announce the annual MA capitation rate for each MA payment area for the year and the risk and other factors to be used to adjust these rates. Beginning in 2006, the Secretary would announce yearly the MA area-specific non-drug benchmark and the adjustment factors relating to demographics, end stage renal disease (ESRD), and health status in each MA plan in the area.

Senate Bill

Section 203. [§1853(a)]. Beginning April 15, 2005 (at the same time as risk adjusters for prescription drug coverage were announced), the Secretary would annually announce the benchmark for each MA payment area and the risk adjustment factors.

Conference Agreement

Section 222 (f). For payments in 2005, the conference agreement requires the Secretary to determine and announce the MA capitation rates for each MA payment area for 2005, and the risk and other adjustment factors, by the 2nd Monday in May of 2004. For 2006 and subsequent years, the Secretary will determine and announce, not later than the 1st Monday in April before the calendar year concerned, the MA capitation rate for each payment area, and the risk and other factors to be used in adjusting such rates. The Secretary will determine and announce, on a timely basis before the calendar year concerned, for each MA region and MA regional plan for which a bid is submitted, the MA region-specific non-drug monthly benchmark amount.

Protection Against Beneficiary Selection

Present Law

The M+C monthly basic and supplemental beneficiary premium cannot vary among individuals enrolled in a the same plan.

House Bill

Section 221 (d). The MA monthly bid amount, the MA monthly basic, prescription drug, and the supplemental beneficiary premium would not vary among enrollees in the plan. Additionally, the MA monthly MSA premium would not vary within an MSA plan.

Senate Bill

Section 204. The provision would establish the requirement that the MA monthly basic beneficiary premium, the MA monthly beneficiary obligation for qualified prescription drug coverage, and the MA monthly beneficiary premium for enhanced medical benefits could not vary among beneficiaries enrolled in the plan. Also, the MA MSA premium would not vary among beneficiaries enrolled in the MSA plan.

Conference Agreement

Section 222 (g). Except as permitted to facilitate the offering of MA plans under contracts between MA organizations and employers, labor organizations or the trustees to a fund established by one or more employers or labor organizations (as currently allowed under sec. 1857(i)), the MA monthly bid amount, the MA monthly basic, prescription drug, and the supplemental beneficiary premium may not vary among enrollees in the plan.

Adjusted Community Rates

Present Law

Each year an M+C organization submits an ACR proposal, estimating their proposed cost of serving Medicare beneficiaries for the following contract year as compared to the estimated cost of providing the same services to a commercial population. The ACR process is a mechanism through which health plans determine the minimum amount of additional benefits they are required to provide to Medicare enrollees and the cost-sharing they are permitted to charge for those benefits.

House Bill

Plan bids would replace ACRs beginning in 2006.

Senate Bill

No provision.

Conference Agreement

Plan bids will replace ACRs beginning in 2006.

Plan Incentives

Present Law

A M+C organization may not operate a physician incentive plan unless it meets the following requirements: (1) no specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided to an enrollee; or (2) if the plan places a physician or group at substantial financial risk, it must provide stop-loss protection and conduct periodic surveys of current and former enrollees to determine the degree of access and satisfaction with the quality of services. The organization must provide the Secretary with sufficient information regarding the plan, to determine whether or not the plan is in compliance with these requirements.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222 (h). An MA organization may not operate a physician incentive plan unless it provides assurances satisfactory to the Secretary. Requirements that the organization: (1) conduct periodic surveys, and (2) provide the Secretary with sufficient information regarding the plan, to determine whether or not the plan is in compliance with these requirements are replaced. Instead, the plan must provide such information as the Secretary requires on any physician incentive plan.

Continuation of treatment of enrollees with End-Stage Renal Disease

Present Law

The Secretary established a separate rate of payment to an M+C organization for individuals with ESRD who are enrolled in an M+C plan.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222 (i). The conference agreement requires payment rates to be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provision of this section in effect before the enactment of this Act. The Secretary may apply the competitive bidding methodology of this section, with appropriate adjustments to account for the risk adjustment methodology applied to ESRD payments.

Facilitating employer participation

Present Law

Employers may sponsor an M+C plan or pay premiums for retirees who enroll in an M+C plan. If an M+C plan contracts with an employer group health plan (EGHP) that covers enrollees in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP benefits supplementing the M+C plan benefits. The Secretary may waive or modify requirements that hinder the ability of employer or union group health plans to offer an M+C plan option.

House Bill

No provision.

Senate Bill

Section 206. The Administrator could permit an MA plan to establish a separate premium amount for enrollees in an employer or other group health plan that provides employment-based retiree health coverage. This provision would also apply the current law requirements to regional PPOs.

Conference Agreement

Section 222 (j). The conference agreement allows the Secretary to waive or modify requirements that hinder the design of, offering of, or enrollment in an MA plan offered by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (to furnish benefits to any combination of current or former employees, or current or former members of the labor organization.) The MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan.

Expansion of Medicare Beneficiary Education and Information Campaign

Present Law

The Secretary is authorized to collect a user fee from each M+C organization for use in carrying out enrollment information dissemination activities for the program as well as the health insurance and counseling assistance program. The fee is based on the ratio of the organization's number of Medicare enrollees to the total number of Medicare beneficiaries. There are authorized to be appropriated $1 million each year, reduced by any fees collected by the Secretary, to carry out these activities.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222(k). The conference agreement allows the Secretary to also charge a PDP sponsor under Part D for its share of fees related to enrollment information dissemination activities. The authorization for appropriated amounts will be increased to $2 million each year, beginning in 2006.

Protection against Beneficiary Selection

Present Law

No provision.

House Bill

Section 221(d). The Administrator would not approve a plan if benefits were designed to substantially discourage enrollment by certain MA eligible individuals.

Senate Bill

Section 204. [§1854(a)]. The Secretary could disapprove a plan bid if he or she determined that the deductibles, coinsurance or copayments discouraged access to covered services or were likely to result in favorable selection of MA eligible beneficiaries.

Conference Agreement

Section 222 (l). The Secretary may not approve a plan if the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals.

Section 223. Effective date

Present Law

No provision.

House Bill

Section 211(e). The MA program would be effective January 1, 2004. Section 21 (g). The competition program would be effective January 1, 2006.

Senate Bill

Section 209. Generally effective January 1, 2006. However, the Secretary would apply payment and other rules for MSA plans, as if this title had not been enacted.

Conference Agreement

The conference agreement makes the amendments of Title II effective for plan years beginning on or after January 1, 2006, unless otherwise provided. The Secretary shall revise previously promulgated regulations for the changes due to the provisions of this Act, to carry out Part C of Medicare.

Subtitle D- Additional Reforms

Section 231. Specialized MA plans for special needs beneficiaries

Present Law

One model for providing a specialized M+C plan, EverCare, operates as a demonstration program. EverCare is designed to study the effectiveness of managing acute-care needs of nursing home residents by pairing physicians and geriatric nurse practitioners. EverCare receives a fixed capitated payment, based on a percentage of the AAPCC, for all nursing home resident Medicare enrollees.

House Bill

Section 233. A new MA option would be established — specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA eligible beneficiaries who were institutionalized, entitled to Medicaid, or met requirements determined by the Administrator. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. Interim final regulations would be required within 6 months of enactment. The Secretary would be permitted to offer specialized MA plans for plans that disproportionately serve beneficiaries with special needs who are the frail elderly. No later than December 31, 2005, the Administrator would be required to submit a report to Congress that assessed the impact of specialized MA plans for special needs beneficiaries on the cost and quality of services provided to enrollees.

Senate Bill

Section 222. A new M+C option would be established — specialized M+C plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those M+C eligible beneficiaries who were institutionalized, entitled to Medicaid,

or met requirements determined by the Secretary. Enrollment in specialized M+C plans could be limited to special needs beneficiaries until January 1, 2008. No later than December 31, 2006, the Secretary would be required to submit a report to Congress that assessed the impact of specialized M+C plans for special needs beneficiaries on the cost and quality of services provided to enrollees. No later than 1 year after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

Conference Agreement

Section 231. The establishment of a specialized plan designation provides health plans the authority and incentives to develop targeted clinical programs to more effectively care for high-risk beneficiaries who have multiple chronic conditions or have complex medical problems. This provision designates two specific segments of the Medicare population as special needs beneficiaries, but also provides the Secretary the authority to designate other chronically ill or disabled beneficiaries as "special needs beneficiaries" to allow plans to serve additional high risk groups who would benefit from enrollment in plans that offer targeted geriatric approaches and innovations in chronic illness care. The Secretary should consider Medicare demonstrations for guidance regarding other potential special needs beneficiary designations.

The provision would establish a new Medicare Advantage option – Specialized Medicare Advantage plans for Special Needs Beneficiaries. Specialized Medicare Advantage plans are plans that exclusively serve special needs beneficiaries such as the Evercare and Wisconsin Partnership demonstrations and, at the discretion of the Secretary, those that serve a disproportionate number of such beneficiaries. Special needs beneficiaries are defined as Medicare Advantage enrollees who are institutionalized, or entitled to Medicaid, or individuals with severe and disabling conditions that the Secretary deems would benefit from a specialized plan. Specialized Medicare Advantage plans can limit enrollment to special needs beneficiaries until January 1, 2009. No later than 1 year after enactment of this act, the Secretary is required to issue final regulations to establish requirements for special needs beneficiaries. No later than December 31, 2007, the Secretary is required to submit a report to Congress that assesses the impact of Specialized Medicare Advantage plans on the cost and quality of care. The provision does not change current Medicare+Choice quality, oversight or payment rules.

The legislation also allows the Secretary to define as Specialized Medicare Advantage plans those that "disproportionately" serve special needs beneficiaries. Since there is no existing standard for measuring "disproportionate," the provision gives the Secretary discretion in promulgating this part of the regulation with a view toward establishing quantitative criteria for defining "disproportionate." The Secretary may identify such means of measuring "disproportionate" as are feasible to capture appropriate risk levels for designation as a "Specialized Medicare Advantage Plan for Special Needs Beneficiaries." The Secretary may wish to require further validation that "disproportionate" plans are 'specialized" by requiring evidence of processes or clinical programs designed to address the unique needs of the special needs beneficiaries served.

Section 232. Avoiding duplicative State regulation

Present Law

Medicare law currently preempts state law or regulation from applying to M+C plans to the extent they are inconsistent with federal requirements imposed on M+C plans, and

specifically, relating to benefit requirements, the inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

House Bill

Section 232. Federal standards established by this legislation would supersede any state law or regulation (other than state licensure laws and state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

Senate Bill

No provision.

Conference Agreement

Section 232. The conference agreement clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus, it would not affect previous and ongoing litigation.

Additionally, no state may impose a premium, or similar, tax on premiums paid to MA organizations under this bill.

Section 233. Medicare Medical Savings Accounts (MSAs)

Present Law

BBA1997 authorized a demonstration for M+C MSAs. The M+C option combined a high-deductible health insurance plan with an M+C MSA. New enrollment was not allowed after January 1, 2003 or after the number of enrollees reached 390,000. No private plans have established an M+C MSA for Medicare beneficiaries. M+C plans (including MSAs) must have an ongoing quality assurance program for health care services provided to Medicare beneficiaries. The required elements of the program are specified in statute.

House Bill

Section 234. The requirement that MSAs report on enrollee encounters for an ongoing quality assurance program would be eliminated because MSAs are not plans but bank accounts. The Medicare MSA demonstration would be made a permanent option, the capacity limit would be removed and the deadline for enrollment would be eliminated. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

Senate Bill

Section 201. The deadline for enrollment in an MSA would be extended until December 31, 2003.

Conference Agreement

Section 233. Medicare MSAs are not being offered in the Medicare program today, despite the legislative authority granted in 1997 and despite the fact that non-Medicare MSAs are being offered. The Medicare MSA demonstration will be made a permanent option, the capacity limit will be removed and the deadline for enrollment will be eliminated. The requirement that MSAs report on enrollee encounters for an ongoing quality assurance program would be eliminated because MSAs are not plans but bank accounts. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans. The Conferees hope to encourage this additional choice for seniors through these changes.

Section 234. Extension of reasonable cost contracts

Present Law

Cost-based plans are those plans that are reimbursed by Medicare for the actual cost of furnishing covered services to Medicare beneficiaries, less the estimated value of beneficiary cost-sharing. The Secretary cannot extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

House Bill

Section 235. Reasonable cost contracts could be extended or renewed indefinitely, with an exception that would begin in 2008. Beginning January 1, 2008, cost contracts could not be continued if during the entire previous year, the service area had two or more coordinated care MA plans or two or more EFFS plans, each of which met the following minimum enrollment requirements: 1) at least 5, 000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area, and 2) at least 1,500 enrollees for any other portion of such area.

Senate Bill

Section 221. Reasonable cost contracts could be extended or renewed until December 31, 2009. Beginning in 2004, these plans would have to comply with certain requirements of the M+C program (and beginning in 2006 the MA program), including ongoing quality assurance programs, physician incentive plan limitations, uniform premium amount requirements, premium tax restrictions, federal preemption, authority of an organization to include supplemental health care benefits, benefit filling deadlines, contract renewals and beneficiary notifications, and proposed cost-sharing subject to the Secretary's review.

The Secretary would be required to approve a new application for a group practice HMO to enter into a reasonable cost contract if the group met certain requirements of the Public Health Service Act. The requirements would be that the group practice HMO, as of January 1, 2004, provided at least 85% of the services of a physician (which are provided as basic health services) through a medical group (or groups), and met other requirements for such entities specified in statute.

Conference Agreement

Section 234. The conference agreement ends the uncertainty about the continuation of cost contracts, allowing these plans to operate indefinitely, unless two other plans of the same

type (i.e., either 2 local or 2 regional plans) enter the cost contract's service area. These other plans must meet the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area, and (2) at least 1,500 enrollees for any other portion of such area. The Conferees believe that if other private plans are willing to enter the cost contract's service area, then the cost contract should be required to operate under the same provisions as these other private plans.

Section 235. 2-year extension of Municipal Health Service demonstration projects

Present Law

The Municipal Health Services Demonstration Project operates in four cities. These cities use their existing public health programs as the nucleus of a coordinated system to provide community-based health care for the underserved urban poor. The project provides comprehensive health services, including a prescription drug benefit and dental services.

BBA 97 extended the program through 2000. The BBRA extended it through 2002, and the BIPA extended it through December 31, 2004.

House Bill

Section 236. Demonstration projects would be extended through December 31, 2009, for beneficiaries who reside in the city in which the project is operated.

Senate Bill

Section 618. Demonstration projects would be extended through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

Conference Agreement

Section 235. The conference agreement extends demonstration projects through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

Section 236. Payment by Program of All-Inclusive Care for the Elderly (PACE) providers for Medicare and Medicaid services furnished by non-contract providers

Present Law

PACE was created as a demonstration project in the Omnibus Budget Reconciliation Act (OBRA 86). The Secretary was required to grant waivers of certain Medicare and Medicaid requirements to a maximum of 10 (expanded to 15 in OBRA90) community-based organizations to provide health and long-term care services on a capitated basis to frail elderly persons at risk of being institutionalized. The Balanced Budget Act 97 (BBA97) made PACE a permanent part of Medicare and a state option for the Medicaid program.

House Bill

No provision.

Senate Bill

Section 223. For the Medicare program, protections against balance billing to PACE providers and beneficiaries enrolled with such PACE providers would apply in the same manner as applies to M+C. For the Medicaid program, with respect to services covered under the State plan (but not under Medicare) that were furnished to a beneficiary enrolled in a PACE program, the PACE program would not be required to pay a provider an amount greater than required under the state plan.

Conference Agreement

Section 236. For the Medicare program, protections against balance billing to PACE providers and beneficiaries enrolled with such PACE providers apply in the same manner as applies to M+C (MA). For the Medicaid program, with respect to services covered under the State plan (but not under Medicare) that are furnished to a beneficiary enrolled in a PACE program, the PACE program is not required to pay a provider an amount greater than required under the state plan.

Section 237. Reimbursement for Federally Qualified Health Centers (FQHCs) providing services under MA plans

Present Law

Services provided by FQHCs to Medicare enrollees are reimbursed at no more than 80% of the reasonable costs of providing such services less any beneficiary cost sharing amounts collected.

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

House Bill

No provision.

Senate Bill

Section 615. FQHCs would receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision would raise reimbursements to FQHCs, so that when they are combined with M+C payments and cost-sharing payments from beneficiaries, they would equal 100% of the reasonable costs of providing such services.

This provision would extend the safe harbor to include any remuneration between a FQHC (or entity control by and FQHC) and an MA organization.

Conference Agreement

Section 237. FQHCs will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision raises reimbursements to FQHCs, so that when they are combined with MA payments and cost-sharing payments from beneficiaries, they equal 100% of the reasonable costs of providing such services.

This provision extends the safe harbor to include any remuneration between a FQHC (or entity control by an FQHC) and an MA organization.

Section 238. Study of performance-based payment systems

Present Law

No provision.

House Bill

Section 237. The Secretary would request that the IOM conduct a study to review and evaluate public and private sector experiences in: 1) establishing performance measures and payment incentives under the Medicare program, and 2) linking performance to payment. The Secretary would also request that no later than 18 months after enactment, the Institute submit a report to the Secretary and the Congress that included a review and evaluation of incentives to encourage quality performance, as specified in the statute. The study would also examine how these measures and incentives might be applied in the Medicare MA, EFFS, and FFS programs. The report would include recommendations regarding appropriate performance measures for use in assessing and paying for quality and would identify options for updating performance measures.

Senate Bill

Section 224. Within 2 months of enactment, the Secretary would be required to enter into an arrangement with IOM to evaluate leading health care performance measures and options to implement policies that align performance with payment under the Medicare program. The information that would be catalogued, reviewed and evaluated by IOM would be specified in statute. A report would be due to the Secretary and the congressional committees of jurisdiction within 18 months of enactment. There would be $1 million authorized to be appropriated to conduct the evaluation and prepare the report.

Conference Agreement

Section 238. The conference agreement requires that within 2 months of enactment, the Secretary shall enter into an arrangement with IOM to evaluate leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program. The information examined by IOM includes the validity of leading health care performance measures, the success and utility of alternative performance incentive programs, and options to implement policy that aligns performance with payments. The Institute shall consult with MedPAC. A report is be due to the Secretary and the congressional committees of jurisdiction within 18 months of enactment. There will be authorized to be appropriated such sums as may be necessary to conduct the evaluation and prepare the report.

Subtitle E- Demonstration of Comparative Cost Adjustment

Establishment of Demonstration

Present Law

No provision.

House Bill

Section 241. Beginning in 2010, FEHBP-style competition would begin nationwide in competitive areas. Competitive areas would be defined as areas in which Medicare beneficiaries have access to two private plans – either two MA or two EFFS plans – along with traditional FFS Medicare; and private plan enrollment in the area that is at least as great as private plan enrollment nationwide, or 20 percent, whichever is lower. Competitive MA (CMA) areas would be limited to metropolitan statistical areas, or areas with substantial numbers of MA enrollees. To be considered a competitive area, the two private plans must be offered during the open season by different organizations, each meeting minimum enrollment requirements as of March of the previous year.

In competitive areas, private plans would submit bids and traditional FFS would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by the VA and DoD military facilities. In addition, payments would be adjusted for health status and other demographic factors.

The competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the competitive area. In order to provide traditional FFS disproportionate influence in competitive areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the competitive area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the regional proportion if lower.

The competitive benchmark would be blended with the older, pre-2010 benchmark for the area over a 5-year period to allow for transition to a more competitive system.

Beneficiaries enrolling in plans with bids or FFS amounts below the competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 5-year period for beneficiaries remaining in traditional FFS in competitive areas. The traditional FFS beneficiary premium would be unaffected in non-competitive areas or regions.

Beginning in 2010, the MBA Administrator would announce the MA area-specific non-drug benchmark yearly. If applicable, the MBA Administrator would also announce, for the year and CMA area: the competitive MA non-drug benchmark; the national FFS market share percentage; the demographic, end-stage renal disease, and health status adjustment factors; the

MA area-wide non-drug benchmark amount; the FFS area-specific non-drug amount; and MA enrollment.

To carry out this section, the MBA Administrator would transmit the name, social security number, and adjustment amount to the Commissioner of SSA at the beginning of each year and at periodic times throughout the year.

Senate Bill

No provision.

Conference Agreement

Section 241 [§1860 C-1]. In order to test whether direct competition between private plans and the original Medicare FFS program will enhance competition in Medicare, improve health care delivery for all Medicare beneficiaries, and provide for greater beneficiary savings and reductions in government costs, the conference agreement requires the Secretary to establish a demonstration for the application of comparative cost adjustment (CCA). The 6-year demonstration will begin on January 1, 2010. The first 4 years include a phase-in. Upon completion of the demonstration, the Secretary will submit a report to Congress that includes an evaluation of: (1) the financial impact on Medicare, (2) changes in access to physicians and other health care providers, and (3) beneficiary satisfaction under the demonstration and original Medicare fee-for-service. Based upon the results of the evaluation, the Secretary will provide recommendations for any extension or expansion of the demonstration. The demonstration cannot be extended unless there is a reauthorization from Congress.

Allowing for competition for enrollees, between private plans and original FFS Medicare, will level the playing field between all options available to Medicare beneficiaries. If traditional FFS Medicare is able to provide benefits at a lower cost than some or all private plans in a competitive area, then beneficiaries remaining in traditional FFS will see their premiums decline. In this case, beneficiaries enrolling in higher-cost private plans will be required to pay the extra price stemming from that decision. Likewise, if a private plan is able to offer Medicare beneficiaries coverage at a lower cost, then beneficiaries will be encouraged to enroll in the private plan by lowering the beneficiaries' costs of coverage under the private plan. In any case, beneficiaries will be entitled to the same defined benefit package and payments to plans will be fully adjusted for health and other demographic factors.

Without this stage of competition, private plans will have an incentive to shadow price their benchmarks. A floating benchmark rewards more efficient plans, and it allows these more efficient plans to lower the benchmark in future years, as their market share rises.

Several features were added in the Chairman's amendment in the nature of a substitute to allow for a smooth transition to a more competitive system in 2010 in competitive areas/regions, and to prevent shock to the current system. The competitive benchmark, based on private plan bids and traditional FFS rates, would be calculated based on the relative enrollment in FFS versus private plans nationwide (or the area/region if FFS enrollment is a larger proportion in the area/region). This feature ensures that the competitive benchmark is closer to the traditional FFS rate than would otherwise occur. Premium changes for beneficiaries remaining in traditional FFS in competitive areas would be phased-in over five years to prevent oscillations. In addition, the competitive benchmark would be phased-in over a 5-year period for private plans. This would

allow for a more gradual change from the benchmarks under the pre-2010 system to the new competitive benchmark in competitive areas.

The Secretary will select CCA demonstration areas from among qualifying Metropolitan Statistical Areas (MSAs). To qualify, an MSA must have: (1) at least 25 percent of eligible Medicare beneficiaries enrolled in a local coordinated care MA plan; and (2) at least 2 coordinated MA local plans offered by different organizations, both of which meet minimum enrollment criteria. The total number of CCA areas may not exceed 6, or 25% of the total number of qualifying MSAs, whichever is lower.

To maximize the opportunity for a successful demonstration, the Secretary will select CCA demonstration areas to provide for geographic diversity and not seek to maximize the number of beneficiaries affected by the demonstration. At least one of the selected MSAs must be chosen from the 4 largest that qualify (based on the eligible MA population). At least one selected MSA must be chosen from among the 4 with the lowest population density. At least one must include a multi-State area. No more than 2 CCA areas may be located within the same geographic region. In addition, the Secretary willl also grant priority to qualifying MSAs that have not had a Medicare preferred provider organization (PPO) plan demonstration.

In order to ensure that all beneficiaries residing in a CCA demonstration area have sufficient choice, a county within the MSA will be included only if it has at least 2 MA local coordinated care plans, each of which is offered by a different MA organization. An area will continue to be included as long as there is at least one MA local plan offered in the local area.

To minimize any possible disruption, the demonstration will be phased in over a four-year period between 2010 and 2013. Both the benchmark and changes to the Part B premiums under the original FFS program will be phased-in over this 4-year period.

In CCA areas, private plans would submit bids and traditional FFS would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by the VA and DoD military facilities. In addition, payments would be adjusted for health status and other demographic factors.

The CCA competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the CCA area. In order to provide traditional FFS disproportionate influence in CCA areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the CCA area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the CCA proportion if lower.

The CCA competitive benchmark would be blended with the older, pre-2010 benchmark for the area over a 4-year period to allow for transition to a more competitive system.

Beneficiaries enrolling in plans with bids or FFS amounts below the CCA competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium

adjustments would be moderated over a 4-year period for beneficiaries remaining in traditional FFS in CCA areas.

In order to test whether application of the CCA benchmark to the traditional FFS program will improve efficiency of the program, an individual residing in a CCA demonstration area who is enrolled in Part B of Medicare, but not enrolled in an MA plan, can have an adjustment to their Part B premium, either as an increase or a decrease. No premium adjustment would be made for individuals, for a month that they were eligible for a prescription drug subsidy, as defined in Title 1 of this Act. That is, individual with incomes below 150 percent of poverty and who also meet the assets requirements would continue to pay the Part B premium amount.

The Part B premium adjustment for FFS beneficiaries in CCA demonstration areas would be made as follows: (1) if the FFS area-specific non-drug amount for the month *does not exceed* the CCA non-drug benchmark, the Part B premium is reduced by 75% of the difference; and (2) if the FFS area-specific non-drug amount for the month *exceeds* the CCA non-drug benchmark, the Part B premium is increased by the full amount of the difference. This adjustment will be phased-in over 4 years. There is also a 5% limit to the adjustment, irrespective of whether it is an increase or a decrease.

The premium adjustment will not affect any late enrollment penalties or income-related adjustments to the Part B premiums as established under Title VIII of this Act. The Secretary will transmit to the Commissioner of Social Security at the beginning of each year, the name, social security account number and the amount the any adjustment for each individual, and periodically through the year, update the information.

Nothing in the demonstration project in any way changes the entitlement to defined benefits under Parts A and B of the Medicare program. Throughout the demonstration, beneficiaries will have complete freedom to choose either a private plan or the traditional Medicare fee-for-service program.

Other Provisions

Expanding the work of Medicare Quality Improvement Organizations (QIOs) to include parts C and D

Present Law

QIOs, formerly known as Peer Review Organizations (PROs), are responsible for working with consumers, physicians, hospitals, and other care-givers to refine care delivery.

House Bill

No provision.

Senate Bill

Section 225. The responsibilities of the QIOs would be expanded to include M+C and MA organizations, prescription drug card sponsors, and eligible entities beginning January 1, 2004. Quality improvement assistance relating to prescription drug therapy would be provided

to providers, practitioners, prescription drug card sponsors, eligible entities under Part D, M+C plans, and MA plans beginning January 1, 2004.

Conference Agreement

The conference agreement does not include this provision.

Extension of demonstration for end-stage renal disease (ESRD) managed care

Present Law

Medicare beneficiaries with ESRD cannot enroll in a managed care plan. If they develop ESRD while a member of a plan they can continue their enrollment in the plan. The Deficit Reduction Act of 1984 established a demonstration project for ESRD managed care, which was subsequently extended by the Omnibus Budget Reconciliation Act of 1993.

House Bill

No provision.

Senate Bill

Section 226. The Secretary would be required to extend the demonstration project for ESRD managed care through December 31, 2007. The terms and conditions in place during 2002 would apply. The monthly capitation rate for enrollees would be set based on the reasonable medical and direct administrative costs of providing the benefits to participants.

Conference Agreement

The conference agreement does not include this provision.

MA annual coordinated election period

Present Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188 changed the annual coordinated election period from the month of November to November 15th through December 31 in 2002, 2003, and 2004. Once the temporary provisions expired, the reporting dates and deadlines return to the pre-P.L.107-188 dates.

In addition, P.L.107-188 continues to allow Medicare beneficiaries to make and change election to an M+C plan on an ongoing basis through 2004. Then beginning in 2005, individuals may only make changes on the more limited basis, originally scheduled to be phased in beginning in 2002. Since the beginning of the M+C program, beneficiaries have been able to make and change election to an M+C plan on an ongoing basis. Beginning in 2005, elections and changes to elections will be available on a more limited basis. Beneficiaries can make or change elections during the annual coordinated election period. Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2005 (or first 3 months of any subsequent year). Additionally, there are special enrollment rules for newly eligible aged

beneficiaries as well as special enrollment periods for all enrollees under limited situations, such as an enrollee who changes place of residence.

House Bill

Section 231. The annual coordinated election period would be permanently changed to November 15 through December 31.

Senate Bill

Section 201. [§1851(e)]. Medicare beneficiaries would retain their ability to make and change elections to an M+C plan through 2005. The current law limitation on changing elections that begins in 2005, would be delayed until 2006. Further, the annual coordinated election period for 2003 through 2006 would begin on November 15 and end on December 31. Beginning in 2007, the annual coordinated election period would be during the month of November.

[§1851(e)(3)]. Additionally, the Secretary would conduct a special information campaign to inform MA eligible beneficiaries about plans. The campaign would begin on November 15, 2005 and ending on December 31, 2005.

Conference Agreement

The conference agreement does not include this provision.

Cause for intermediate sanctions

Present Law

The Secretary is authorized to carry out specific remedies in the event that an M+C organization: (1) fails substantially to provide medically necessary items and services required to be provided, if the failure adversely affects the Medicare enrollee; (2) imposes premiums on enrollees that are in excess of those allowed; (3) acts to expel or refuses to re-enroll an enrollee in violation of Federal requirements; (4) engages in any practice that would have the effect of denying or discouraging enrollment (except as permitted by law) of eligible beneficiaries whose medical condition or history indicates a need for substantial future medical services; (5) misrepresents or falsifies information to the Secretary or others; (6) fails to comply with rules regarding physician participation; or (7) employs or contracts with any individual or entity that has been excluded from participation in Medicare.

House Bill

No comparable provision.

Senate Bill

Section 208. In addition to specifications included in current law, the Secretary could also carry out remedies if an organization charged any Medicare enrollee an amount in excess of

the MA monthly beneficiary obligation for qualified prescription drug coverage, provided coverage that was not qualified prescription drug coverage, offered prescription drug coverage but did not make standard prescription drug coverage available, or provided coverage for drugs other than that relating to prescription drugs covered under Part D, as an enhanced or additional benefit.

Conference Agreement

The conference agreement does not include this provision.

Evaluate fee-for-service modernization projects

Present Law

No provision.

House Bill

No explicit provision. H.R. 1 would establish chronic care improvement benefits under fee-for-service (Section 721) and under MA and EFFS (Section 722).

Senate Bill

Section 232. The Secretary would be required to review the results of the demonstrations required under Sections 442, 443, and 444 of this bill and report to Congress by January 1, 2008. [These demonstrations are the Medicare health care quality demonstration, the Medicare complex clinical care management payment demonstration, and the Medicare fee-for-service care coordination demonstration.] Beginning in 2009, the Secretary would be required to establish projects to provide Medicare beneficiaries in traditional Medicare coverage of enhanced benefits or services (preventive services not already covered under Medicare, chronic care coordination services, disease management services or other benefits determined by the Secretary). The purpose of the projects would be to evaluate whether the enhanced benefits or services improved the quality of care, improved health care delivery systems, and reduced expenditures under the Medicare program. The projects would be conducted in regions comparable to the regions designated as "highly competitive." The Secretary would be required to submit annual reports to Congress and the GAO beginning no later than April 1, 2010. The GAO would be required to report by January 1, 2011 and biennially thereafter for as long as the projects were being conducted.

Conference Agreement

The conference agreement does not include this provision.

Establish MA enrollment goal

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 241. This provision would establish an MA enrollment goal of at least 15% of Medicare beneficiaries by January 1, 2010. If the goal were not met, a bipartisan commission would be established as provided for in Section 242.

Conference Agreement

The conference agreement does not include this provision.

Establish national bipartisan commission on Medicare reform

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 242. If the enrollment goal described in Section 241 were not met, the National Bipartisan Commission on Medicare Reform would be established. The Commission would review and analyze the long-term financial condition of the Medicare program; identify problems that threaten the financial integrity of the Medicare Trust Funds; and analyze potential solutions to the identified problems. The Commission would be required to make recommendations, including issues facing Medicare, such as solvency, financing of the Medicare Trust Funds, and benefits. The Commission would have 17 members — four appointed by the President, 12 appointed by Congressional leaders, and one appointed jointly by the President and Congressional leaders to serve as Chairperson. The Commission would be required to submit a report and an implementation bill to the President and Congress no later than April 1, 2014.

Conference Agreement

The conference agreement does not include this provision.

Establish congressional consideration of reform proposals

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 243. Congressional leaders would be required to introduce the implementation bill required by Section 242. Hearings would be required by appropriate committees as well as floor consideration.

Conference Agreement

The conference agreement does not include this provision.

Authorize appropriations

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 244. Appropriations would be authorized for such sums as necessary to carry out the provisions regarding the National Bipartisan Commission on Medicare Reform for fiscal years 2012 through 2013.

Conference Agreement

The conference agreement does not include this provision.

Enhanced benefits

Present Law

M+C plans may offer supplemental benefits in addition to any required benefits under Parts A and B of Medicare and any additional required benefits.

House Bill

Section 221 (a). Plans could include supplemental benefits in their bids. The Secretary's authority to negotiate bids would include these supplemental benefits.

Senate Bill

Section 202. [§1852(a)(3)]. MA plans could choose to provide beneficiaries with enhanced medical benefits that the Secretary could approve. The Secretary could deny any submission for enhanced benefits believed to discourage enrollment by MA eligible individuals. The Secretary could not approve any enhanced medical benefit that provided for the coverage of any prescription drug, other than those relating to covered prescription drugs under Part D.

Conference Agreement

The conference agreement does not include this provision.

Incentive for Enrollment

Present Law

M+C plans cannot offer cash or monetary rebates as an inducement for enrollment.

House Bill

Section 221 (d). For MA plans, the ability to offer cash or monetary rebates would be limited to the rebates (based on the calculation of average per capita monthly savings) established under this bill.

Senate Bill

No provision.

Conference Agreement

The conference agreement does not include this provision.

TITLE III -COMBATTING WASTE, FRAUD AND ABUSE

Medicare Secondary Payor (MSP) Provisions (Section 301 of the Conference Agreement, Section 301 of the House Bill, and Section 461 of the Senate Bill)**.**

Present Law

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under workmen's compensation law or plan, under automobile or liability insurance (including a self-insured plan) or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers compensation plan or no-fault insurance claim but Medicare determines that the payment will not be made promptly, as determined in accordance with regulations).

House Bill

The Secretary would be able to make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional payment would be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369)(which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made would be clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified. This provision clarifying the conditional payment provisions would be effective upon enactment.

Senate Bill

Identical provision.

Conference Agreement

The conference agreement clarifies that the Secretary may make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment is contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional payment is effective as if included in the enactment of title III of

the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369) (which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made is also clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, is required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also is clarified. This provision clarifying the conditional payment provisions is effective as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980.

Payment for Durable Medical Equipment; Competitive Acquisition of Certain Items and Services (Section 302 of the Conference Agreement, Section 302 of the House Bill, and Section 430 of the Senate Bill)**.**

Present Law

Medicare pays for durable medical equipment (DME), using a different fee schedule for each class of covered items. Under the fee schedule, covered items are classified into six major categories, one of which is prosthetics and orthotic devices. In general, fee schedule payments are a weighted average of either local or regional prices, subject to national limits (both floors and ceilings), that are updated each year by the consumer price index for urban consumers (CPI-U) for the 12-month period ending with June of the previous year.

Medical devices are classified into three categories: Class I devices represent minimal potential for harm, and are subject to the least regulatory control (e.g., elastic bandages and enema kits). Class II devices are moderate risk (e.g., some surgical lasers). Class III devices are devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval, the most stringent regulatory control.

BBA 97 authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for Part B services other than physician services. The Secretary was required to establish up to three competitive acquisition areas for this purpose. Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were implemented, two in Polk County, Florida and one in the San Antonio, Texas area.

House Bill

The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, medical supplies, home dialysis supplies, blood products, parental nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Enteral nutrients and class III devices, those that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and

are subject to premarket approval by the Food and Drug Administration would not be covered by the program.

In starting the programs, the Secretary would be required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs would be phased-in over 3 years with at least one-third of the areas implemented in 2005 and two-thirds of the areas implemented in 2006. High-cost items and services would be required to be phased-in first. The Secretary would be able to exempt items and services for which competitive acquisition would not be likely to result in significant savings. The Secretary would be required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items. Also, the Secretary may establish a process where a physician would be able to prescribe a particular brand or mode of delivery of an item or service if such item is clinically more appropriate than other similar items.

Certain requirements for the competitive acquisition program would be established. Specifically, the Secretary would be allowed to award contracts in an area only when the following conditions were met: entities met quality and financial standards specified by the Secretary or the Program Advisory and Oversight Committee; total amounts paid under the contracts would be expected to be less than would otherwise be paid; beneficiary access to multiple suppliers would be maintained; and beneficiary liability would be limited to 20% of the applicable contract award price. Contracts would be required to be re-competed at least every three years. The Secretary would be required to award contracts to multiple entities submitting bids in each area for an item or service and would also have the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services. The similarity of the clinical efficiency and the value of specific products would be considered when establishing the categories and products that would be subject to bidding. The Secretary would not be able to pay for items furnished by a contractor unless the contractor has submitted a bid to supply the item and the contract has been awarded. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary would also be able to contract with an appropriate entity to address beneficiary complaints, provide beneficiary outreach and education services, and monitor the quality of items and services provided. The Secretary would be required to report to Congress annually on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary would be established. The Committee would be required to provide advice and technical assistance to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act would not apply to this Committee.

The Secretary would be required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the test. The same quality and financial conditions specified for the DME competitive acquisition program would

apply for clinical laboratory test competitive acquisition. An initial report to Congress would be required of the Secretary not later than December 31, 2005 with progress and final reports as the Secretary would determine appropriate.

The covered items and services included in the competitive acquisition program would be paid as determined under this program. The Secretary would be able to use this payment information to adjust the payment amounts for DME not in a competitive acquisition area. In this instance, the inherent reasonableness rule would not be applied. Orthotics in a competitive acquisition program would also be paid the amounts determined by this program. The Secretary would be able to use this payment information to adjust the payment amounts for such items. The provision would be effective upon enactment.

Senate Bill

Medicare would not increase the DME fee schedule amounts in any of the years from 2004 through 2010 and would update the amounts by the CPI-U in each subsequent year. Payments for orthotic devices that have not been custom-fabricated would be similarly affected. Class III medical devices would be exempt from the freeze in DME payments. Prosthetics, prosthetic devices, and custom-fabricated orthotics would be updated by the percentage change in the CPI-U. The provision would also subject DME companies to an accreditation and quality assurance process. The Secretary would be required to designate independent accreditation organizations no later than 6 months from enactment after consultation with an expert outside advisory panel. The application of quality standards would be phased in over a 3-year period. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary to establish and implement quality standards for suppliers of: items and services of durable medical equipment, prosthetics and orthotics, and certain other items and services. Suppliers of the following items and services are included in the conference agreement: items of durable medical equipment, prosthetic devices, orthotics and prosthetics, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion machines. The Secretary is explicitly authorized to establish the quality standards by program memorandum on a prospective basis after consultation with representatives of relevant parties. The standards are required to be posted on the Internet website of CMS. The Secretary is required to designate one or more independent accreditation organizations not later than one year after the date the quality standards are implemented. The quality standards may not be less stringent than the quality standards otherwise in place.

The Secretary is required to establish standards for clinical conditions for payment for covered durable medical equipment that include the specification of types or classes of covered items that require, as a condition of payment, a face-to-face examination and a prescription for the item. Standards are required to be established for those covered items for which there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items. Beginning with the date of enactment, payment may not be made for motorized or power wheelchairs unless a physician, physician assistant, nurse practitioner, or a clinical nurse specialist has conducted a face-to-face examination of the individual and written a

prescription for the item. Medicare payment is not permitted unless the item meets the standards established for clinical condition of coverage.

The conference agreement also establishes competitive acquisition programs for durable medical equipment (including items used in infusion and drugs), medical supplies, home dialysis supplies, therapeutic shoes, enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Exclusions from the competitive acquisition are: inhalation drugs; parenteral nutrients, equipment, and supplies; and class III devices, that is those that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval by the Food and Drug Administration.

In starting the programs, the Secretary is required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs will be phased-in so that competition under the programs occurs in 10 of the largest metropolitan statistical areas in 2007; 80 of the largest metropolitan statistical areas in 2009; and remaining areas after 2009. The Secretary is permitted to phase-in first items and services with the highest cost and highest volume, or those items and services that the Secretary determines have the largest savings potential. The Secretary may exempt items and services for which competitive acquisition would not be likely to result in significant savings. The Secretary is required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items. Also, the Secretary may establish a process where a physician would be able to prescribe a particular brand or mode of delivery of an item or service within a particular healthcare procedure code (HCPCS) if the physician determines that use of the item or service would avoid an adverse medical outcome on the beneficiary, as determined by the Secretary, although this could not affect the amount of payment otherwise applicable.

Certain requirements for the competitive acquisition program are established by the conference agreement. Specifically, the Secretary cannot award contracts in an area unless the following conditions were met: (1) entities meet quality standards established by the Secretary; (2) entities meet financial standards specified by the Secretary, taking into account the needs of small providers; (3) total amounts paid under the contracts are expected to be less than would otherwise be paid; and (4) beneficiary access to multiple suppliers would be maintained. Contracts are subject to terms and conditions that the Secretary may specify and are required to be re-competed at least every 3 years. The Secretary is required to award contracts to multiple entities submitting bids in each area for an item or service and has the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services.

Payment for competitively priced items and services will be based on bids submitted and accepted. The Secretary is required to determine a single payment amount for each item or service in each competitive acquisition area. Medicare payment is required to be equal to 80 percent of the payment amount determined, with beneficiaries paying the remaining 20 percent (after meeting the Part B deductible). Payment for any item or services can be made only on an assignment-related basis that is the supplier bills Medicare and accepts Medicare payment as payment in full. The use of advanced beneficiary notices is not precluded by this program.

In establishing the categories and products that would be subject to bidding, the Secretary is permitted to consider the clinical efficiency and the value of specific items within HCPCs codes, including whether some items have a greater therapeutic advantage to individuals. The Secretary is required to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in this program. The Secretary cannot pay for items furnished by a contractor unless the contractor has submitted a bid to supply the item and the contract has been awarded. The Secretary is permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary is permitted to contract with an appropriate entity to address beneficiary complaints, provide beneficiary outreach and education services, and monitor the quality of items and services provided. The Secretary is also permitted to contract with entities to implement the competitive bidding program. The conference agreement prohibits administrative or judicial review of the establishment of payments amounts, the awarding of contracts, the designation of competitive acquisition areas, the phased-in implementation, the selection of items and services for competitive acquisition or the bidding structure and number of contractors. The Secretary is required to report to Congress by July 1, 2009, on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary is required to be established. The Committee is required to provide advice to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, the establishment of quality standards, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act do not apply to this Committee. The Committee is required to end on December 31, 2009.

The Secretary is required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the test. The terms and conditions of the demonstration are to include the application of CLIA quality standards. An initial report to Congress is required of the Secretary no later than December 31, 2005, with progress and final reports as the Secretary determines appropriate.

For durable medical equipment, prosthetic devices, prosthetics and orthotics, the update will be 0 percentage points in 2004 through 2008. After 2008, for those items not included in competitive bidding the update will be the consumer price index (CPI). For 2005, the payment amount for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses, will be reduced. The Secretary will take the payment amount otherwise determined and reduce it by the percentage difference between the amount of payment otherwise determined for the specific item for 2002 and the amount of payment for the specific item and HCPC code under chapter 89 of title 5, United States Code (which was identified in the column entitled a median FEHBP Price in the table entitled A SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS that was included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002). An OIG report on oxygen will be available in the spring of 2004.

For class III medical devices the update in 2004, 2005, and 2006 is equal to the percentage increase in the consumer price index for all urban consumers (CPI-U) for the 12-month period ending with June of the previous year. In 2007 the percentage change for class III medical devices is to be determined by the Secretary after taking into account recommendations made by the Comptroller General in a report on class III medical devices. In 2008 the update is determined by the amount paid in 2007 updated by the CPI. In subsequent years the CPI is the update.

For covered items and services furnished beginning January 1, 2009, items and services included in the competitive acquisition program would be paid as determined under that program and the Secretary would be able to use this payment information to adjust the payment amounts for DME, off-the-shelf orthotics, and other items and services that are supplied in an area that is not a competitive acquisition area. The inherent reasonableness authority for DME, off-the-shelf orthotics, medical supplies, home dialysis supplies, therapeutic shoes, enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine is not eliminated but, if the Secretary uses the competitive acquisition program information to adjust payments, then inherent reasonableness authority cannot be used.

The Inspector General of the Department of Health and Human Services (the Inspector General) is required to study the extent to which (if any) suppliers of covered items of DME that are subject to the competitive acquisition program are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. The report is due to Congress no later than July 1, 2009.

The provision is effective upon enactment.

Competitive Acquisition of Covered Outpatient Drugs and Biologicals (Section 303 of the Conference Agreement, Section 303 of the House Bill, and Section 432 of the Senate Bill)**.**

Adjustment to the Physician Fee Schedule (Section 303(a) of the Conference Agreement, Section 303(a) of the House Bill and Section 432(b) of the Senate Bill)**.**

Present Law

The relative value associated with a particular physician service is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense includes both direct costs (such as clinical personnel time and medical supplies used to provide a specific service to an individual patient) as well as indirect costs such as rent, utilities, and business costs associated with running a practice). When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (PL. 103-432) required the Secretary to develop a methodology for a resource based system for calculating practice expenses for use in CY1998. BBA 1997 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on

relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

House Bill

The Secretary would be required to increase the practice expense relative value for the physician fee schedule in CY2005 using survey data that includes information on the expense associated with administering drugs and biologicals. The supplemental data provided by entities and organizations would be included if consistent with the Secretary's criteria for acceptable survey data and submitted by December 31, 2004. Using existing processes for coding considerations, the Secretary would be required to promptly evaluate existing codes for the administration of covered outpatient drugs and biologicals to ensure accurate reporting and billing for these services. Any payment increase in CY2005 that resulted from using supplemental survey data or reevaluating codes would not be subject to budget neutrality provisions, would be exempt from administrative and judicial review, and would be treated as a change in law and regulation in the sustainable growth rate determination. Nothing in this section would prevent the Secretary from providing for practice expense adjustments in subsequent years, subject to the budget neutrality provisions. The Secretary would be required to consult with the Comptroller General of the United States (GAO) and groups representing the affected physician specialties before publishing the notice of proposed rulemaking. Also, the Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to establish the practice expense relative value for the physician fee schedule in CY2004 using the survey data collected from a physician specialty organization as of January 1, 2003 if the data cover the practice expenses for oncology administration services and meet the Secretary's criteria for acceptable survey data. The Secretary would also be required to review and appropriately modify Medicare's payment policy for the administration of more than one anticancer chemotherapy agent to an individual patient on a single day. The increase in expenditures resulting from this provision would be exempt from the budget-neutrality requirement. Also, the Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes. The provision would be effective upon enactment.

The Secretary would not be able to revise payment amounts for a category of outpatient drugs or biologicals unless the Secretary concurrently adjusts the payment amounts for administration of such category of drug or biological. The provision would be effective upon enactment.

The provisions affecting the practice expense relative values, multiple chemotherapy agents administered on a single day, and treatment of other services currently in the non-physician work pool would not be subject to administrative or judicial review under Sections 1869 and 1878 of the Social Security Act (SSA) or otherwise. The provision would be effective upon enactment.

Conference Agreement

Beginning in 2004, the Secretary is required to make adjustments in practice expense relative value units for certain drug administration services when establishing the physician fee schedule. The Secretary is required to use the survey data submitted by the American Society of Clinical Oncology (ASCO) in 2002 because it meets criteria established under the BBRA for use.

The Secretary is required to add work relative value units to certain drug administration services, equal to the work relative value units for a level 1 office medical visit for an established patient. These services are classified, as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy), chemotherapy administration services, and therapeutic, prophylactic or diagnostic injections. Only those services for which national relative value units, but no work relative value units have been assigned by October 1, 2003 are included. These specified drug administration services are intended to be those classified as of October 1, 2003, within HCPCs codes 90780-90781, 96400, 96408-96425, 96520, 96530 and 90782-90788, and as subsequently may be modified by CMS, to provide work relative value units for CPT code 99211 for a level 1 office medical visit for an established patient.

Starting in 2005, the Secretary is required to use supplemental survey data to increase practice expense relative values for other drug administration services in the physician fee schedule if that supplemental survey data include information on the expense associated with administering drugs and biologicals, the survey meets criteria for acceptance, and the survey is submitted by March 1, 2004, for 2005, or March 1, 2005 for 2006. This provision will apply only to a specialty that received 40% or more of its Medicare payments in 2002 from drugs and biologicals and would not apply to the ASCO survey submitted in 2002.

The Secretary is also required to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for these services. These codes should take into account levels of complexity of the administration and resource consumption. The Secretary is required to use existing processes for considering coding changes and for incorporating appropriate changes in the relative values for such services. As part of this process, the Secretary is required to consult with representatives of physician specialties affected by the changes in payment for drugs under this section and, within the scope of existing authority, expedite appropriate conclusions resulting from these coding evaluations.

The adjustments in practice expense relative value units for certain drug administration services based on the ASCO survey data are exempt from the budget neutrality requirements in 2004. Adjustments in practice expense relative value units for other drug administration services in 2005, 2006, or 2007 based on the surveys or coding changes described above are also exempt. Nothing in this section shall prevent the Secretary making these practice expense adjustments in subsequent years, subject to the budget neutrality provisions.

The Secretary is required to make adjustments to the non-physician work pool methodology so that the practice expense relative values for other services in the pool are not affected by the changes to practice expenses for drug administration. This provision is intended to protect the services in the non-physician work pool from payment reductions resulting from changes made to the AWP payment methodology. The budget neutrality waiver was included in this section to ensure that the increase in practice expense relative value units for drug

administration services (resulting from the use of new supplemental survey data) would not be offset by decreases in the other non-physician work pool services. The Secretary is further required to review and appropriately modify Medicare's payment policy in effect on October 1, 2003, for the administration of more than one drug or biological to an individual on a single day through the push technique. The increase in expenditures resulting from this provision will be exempt from the budget-neutrality requirement in 2004. The Conferees strongly urge the Secretary to make payment for these multiple pushes.

A transitional adjustment or additional payment for services furnished from April 1, 2004, through December 31, 2005 will be made for drug administration services. This Part B payment is to be made to the physician and equals a percentage of the payment otherwise made. The percent is 32 in 2004, and 3 in 2005.

MedPAC is required to review the payment changes as they affect payments for items and services furnished by oncologists and for drug administration services furnished by other specialists. This review will also include an examination of the effect of such changes on the quality of Part B services and beneficiary satisfaction with such care. The Commission is required to submit a report to the Secretary and Congress by January 1, 2006 on oncologists' payments and by January 1, 2007 on drug administration services furnished by other specialists. The reports may include recommendations for further adjustments. The Secretary could make appropriate adjustments to payments as part of the rulemaking for physician payments for 2007.

Section 303 exempts all physician specialties, other than oncology, from the payment adjustments made to both physicians' services and expenses for the administration of drugs and biologicals in this section, and does not apply to inhalation drugs in Section 305. Section 304 requires the Secretary to disregard this exemption and apply the adjustments in section 303 to these other specialties. The intent in drafting the two sections in this manner is to segregate the savings achieved from adjustments to payments to oncologists from savings derived from other physician specialties. The specialties to which the provisions apply are the specialties as used by the carriers in administering Medicare.

Application of Market based Payment Systems (Sections 303(b) through Sections 303(d) of the Conference Agreement, Section 303(b) of the House Bill and Section 432(a) of the Senate Bill)**.**

Present Law

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are generally calculated using the average wholesale price (AWP).

The AWPis intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on prices reported by drug manufacturers, that are published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. AWP has never been defined in either statute or regulation, but it is used to set reimbursement amounts for drugs and biologicals covered under the Medicare Part B benefit

The Balanced Budget Act of 1997 (BBA 97, P.L.105-33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Current Medicare payment rates are 95% of AWP for brand name drugs produced by a single manufacturer (referred to single source drugs.) Medicare pays 95% of the lower of (a) the median AWP of all generic drugs or (b) the lowest brand-name product AWP for drugs with 2 or more competing brand names drugs (referred to as multisource or multiple source drugs) or those drugs with available generic equivalents. Although Medicare uses a Healthcare Common Procedure Coding System (HCPCS) code to identify and pay for physician administered drugs, AWPs are reported on the basis of national drug codes (NDC), which are maintained by the Food and Drug Administration (FDA). Every drug sold in the United States has a unique NDC that provides information on its chemical molecule, drug manufacturer, dosage, dosage from and package size. In addition, there may be several multiple source or generic drugs within a specific HCPCS code.

There is substantial evidence that indicates that AWPs for many Medicare-covered products far exceed the acquisition cost paid by suppliers and physicians. Reliance on AWP (instead of a market based price) has caused significantly increased payments, as some use AWP to inflate payments made for drugs to influence physician prescribing practices. This has resulted in Medicare paying more than $1 billion per year in excess overpayments for these products. Because Medicare beneficiaries are also required to pay coinsurance amounts equal to 20 percent of the Medicare payment amount, the increased Medicare payment amounts resulting from inflated AWPs cause Medicare beneficiaries to pay hundreds of millions of extra dollars in inflated co-payments every year.

Some physicians assert that the overpayment for drugs covers underpayment for practice expenses. They contend that Medicare does not adequately reimburse them for the practice expenses associated with providing care in outpatient settings. This section reduces the overpayment for drugs and biologics, while increasing physician practice expenses.

Since 1992, the HHS Office of the Inspector General OIG (OIG) has raised concerns about how certain drug manufacturers have established AWPs for certain of their Medicare-covered drugs that were much higher than the prices generally paid by the health care providers to those drug companies. This difference – commonly referred to by the industry and the health care community as the “spread” – B results in a profit to providers each time they administer such drugs to Medicare patients. For example, in 1999, an oncologist could purchase 10 mgs of doxorubicin, a chemotherapy agent, for $10.08, while Medicare’s reimbursement for that same dose was $42.92, resulting in a profit to the providers of $32.84. The OIG, based on a review of 24 of the Medicare-covered drugs, estimate that such practices result in Medicare making $750 million each year in overpayments to these providers.

Subsequently, the findings of this report were updated with more current drug pricing. This updated report found that, of the $3.7 billion Medicare spent for 24 drugs in 2000, if

Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would have saved $887 million a year.

In addition to the financial toll on the U.S. Treasury, these large spreads also affect Medicare beneficiaries, who are often required to pay dramatically inflated co-payments for the drugs they receive. These co-payments sometimes even exceed the actual price that the provider has paid for the drug. For example, leucovorin calcium, a chemotherapy agent, had a beneficiary co-payment of $3.60 per dosage, while the OIG estimated a provider could buy the same drug for $2.94, and would receive a total reimbursement (including beneficiary co-payment) of $18.02 per dose. OIG estimated that if Medicare had paid reimbursements equal to widely available wholesale prices, beneficiaries would have paid $175 million less in coinsurance.

A September, 2001, GAO report found that physicians can obtain Medicare-covered drugs at prices significantly below current Medicare payments. GAO found that the average discount from AWP ranged from 13 percent to 34 percent, and that two drugs had discounts of 65 percent and 86 percent.

Evidence also suggests that certain types of health care providers may also be making treatment decisions based at least in part upon the amount of profit they can reap from the use of certain drugs. In one particularly disturbing example, a respiratory therapy drug, ipratropium bromide, saw its utilization skyrocket after certain drug manufacturers began to build a large spread in its price. In 1995, Medicare reimbursed providers $14 million dollars for their use of ipratropium bromide. After the spread was created, utilization increased dramatically, to the point where Medicare paid $250 million for the same drug in 1999, and over $300 million in 2000 and 2001.

In its recommendations to the Congress, the GAO urged CMS to take steps to begin reimbursing providers for Part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. The GAO also recommended that CMS should evaluate expanding competitive bidding approaches to setting payment levels, and that CMS should monitor beneficiary access to covered drugs in light of any changes to reimbursement.

The GAO also debunked some common myths generally held by many in the health care community. Specifically, the GAO found that despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, physicians with low volumes reported that their purchase prices were the same or less than the widely available prices GAO documented. GAO also believes that Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. The Committee shares this view, and believes the legislation achieves this goal.

The Committee on Ways and Means, the Committee on Energy and Commerce and the Senate Finance Committee have all conducted independent investigations and held public hearings on the problems associated with using AWP as a reimbursement benchmark. All three Committees have also examined the reimbursement for drug administration through the Medicare physician payment structure. Both reimbursement systems were found to have serious flaws in methodology and application.

More recently, the Centers for Medicare and Medicaid Services issued a proposed rule on August 20, 2003, to improve the way that Medicare pays for covered drugs and asked for public input on the best way to achieve that goal. The rule solicited comments on four differing approaches:

Medicare would pay the same amounts for covered drugs that private insurers pay;
Medicare would apply a discount of 10 to 20 percent from the inflated average wholesale price in 2004 and then establish more reasonable payment updates in future years;
Medicare would use existing sources of market-based prices and would develop additional sources to monitor market changes over time, such as drug price catalogs; or
Medicare would establish a competitive bidding process for drugs and would also require drug companies to report their average sales prices.

Because of the serious flawed reimbursement methodology in the current system, and absent a change in the statute, CMS has indicated they will move forward with the rule.

House Bill

New sections 1847A and 1847B would be established. Under 1847A, the Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least 2 contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be able to select a contractor who would deliver covered drugs and biologicals to the physician; alternatively, a physician would be able to elect payment under the use of the average sales price payment methodology established by 1847B.

Under the competitive acquisition program, there would be 2 categories of drugs under this program: the oncology category (which would include drugs determined by the Secretary as typically primarily billed by oncologists or are otherwise used to treat cancer) which would be implemented beginning in 2005 and the non-oncology category which would be implemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o) of the SSA which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, drugs and biologicals furnished as treatment for end-stage renal disease (ESRD), radiopharmaceuticals, and vaccines would not be considered covered drugs under the competitive acquisition program. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce savings.

Certain contractor selection and contracting requirements for the competitive acquisition program would be established. Specifically, the Secretary would be required to establish an annual selection process for a contractor in each area for each of the 2 categories of drugs. The Secretary may not award the 2-year contract to any entity that does not have the capacity to supply covered outpatient drugs within the applicable category or does not meet quality, service, and financial performance and solvency standards established by the Secretary. Specifically the entity would be required to have (1) arrangements to ship covered drugs at least 5 days of the week and on an emergency basis; (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries; (3) grievance resolution procedures, including review by the Medicare Provider Ombudsman established in this legislation. The Secretary would not be able to contract with an entity that has had its license for distributing

drugs (including controlled substances) suspended or revoked by the Federal or a State government or that has been excluded from program participation. A contractor would be required to comply with a specified code of conduct, including conflict of interest provisions as well as all applicable provisions relating to the prevention of fraud and abuse. A contract would be able to include the specifications with respect to secure facilities, safe and appropriate storage of covered drugs, examination of drugs, record keeping, written policies and procedures, and compliance personnel. Those contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. Contracts would be able to be terminated by either the Secretary or the entity with appropriate advance notice. The Secretary would make the list of the available contractors accessible to physicians on an ongoing basis, through a directory posted on the Internet and provided by request.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below two. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to ensure product integrity, customer service, past experience with drug distribution, and other factors. This bid price would include all costs related to the delivery of the drug or biological to the selecting physician or other delivery point as well as all dispensing and shipping costs. Costs relating to the administration of the drug or biological or waste, spillage or spoilage would not be included. As part of the awarded contract, the selected contractor would be required to disclose the reasonable, net acquisition costs regularly (but not more often than once a quarter) as specified by the Secretary. The selected contractor would also be required to disclose appropriate price adjustments over the period of the contract to reflect changes in reasonable, net acquisition costs.

The Secretary would be able to reject the contract offer of an entity for a category of drugs and biologicals if the Secretary establishes that the aggregate average bid price exceeds the average sales price (as determined under Section 1847B discussed subsequently). Nothing in the section would prevent a bidder from submitting a contract offer to cover all areas of the United States; nothing would prevent requiring a bidder to submit a contract offer to cover all areas of the United States. The amount of the bid price submitted under a contract offer would be required to be the same for all portions of the area. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information.

The Secretary would be required to compute an area average of the bid prices submitted, in contract offers accepted for the category and the area, for each year or other contract period. The Secretary would apply special rules and alternative payment amounts to establish a price for specific covered drugs including new drugs and biologicals, oral anti-cancer and immunosuppressive drugs. Generally, the Secretary would not be able to adjust payments for drugs under this section unless supplemental data is used to adjust the practice expense payment adjustment. Also, if the Secretary excludes a class of drugs or biologicals or a specific item from the competitive acquisition program, Medicare's payment would be based on the average sales price methodology discussed subsequently. Beneficiary liability would be limited to 20% of the payment basis for the covered drug or biological

The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts would only be made to the contractor; would only be made upon the administration of the drug; and would be based on the average bid of prices for the drug and biological in the area. The Secretary would be required to

establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered. The Secretary would be required to establish an appeals process for physicians that is comparable to those provided to a physician who prescribes durable medical equipment or a laboratory test

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home. The Secretary would be able to specify other non-physician office settings where a beneficiary would be able to receive a covered drug directly. However, the contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. A physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements, including adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain a supply of drugs that may be needed in emergency situations. In order to maintain such an inventory, a physician would be required to demonstrate that the drugs would be immediately required, not reasonably foreseen as immediately required, not able to be delivered by the contractor in a timely manner, and administered in an emergency situation. No applicable State requirements relating to the licensing of pharmacies would be waived.

The Secretary would be able to establish an advisory committee to assist in the implementation of this program. The Secretary would be required to report to Congress on savings, reductions in cost-sharing, access to items and services, the availability of contractors as well as beneficiary and satisfaction under the competitive acquisition program. These reports would be due each year from 2005, 2006, and 2007.

Alternatively, physicians would be able to elect payment for covered outpatient drugs under a separate methodology established in Section 1847B. Subject to the applicable beneficiary coinsurance and deductible amount, a single and multiple source drugs would be paid 112% of the applicable price in 2005 and 2006 and 100% of the price subsequently. The applicable price for all the products within multiple source drug codes would be the reported volume-weighted average of the average sales price; the applicable price for a single a single source drug would be the lesser of the manufacturer's average sales price for the NDC code or the reported wholesale acquisition cost. The payment amount would be determined without regard to any special packaging, labeling or identifiers on the dosage form or product or package.

Starting for calendar quarters on or after April 1, 2004, the average sales price would be calculated by NDC code each calendar quarter by dividing a manufacturer's total sales by the total number of units sold in that quarter. Certain sales would be exempt from the calculation: (1) those sales that are exempt from the Medicaid drug rebate program including those to the Indian Health Service, the Department of Veterans Affairs, a state Veterans home, the Department of Defense, or the Public Health Services as well as any price charged under the Federal Supply Schedule or used under a state pharmaceutical assistance program; and (2) those sales that do not reflect market prices, as determined by the Secretary. The average sales price would take into account volume discounts, prompt pay discounts, cash discounts, chargebacks and certain rebates. The Secretary would be able to disregard the average sales price during the first quarter of a new drug's sales if the price data is not sufficient to determine an average amount payable. The average sales price would be determined by the manufacturer on a quarterly basis; to the extent that data on rebates and chargebacks is reported on a lagged basis, the manufacturer would apply the 12-month rolling average methodology to estimate the amount

of such discounts, as specified by the Secretary. The wholesale acquisition cost would be the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States for the most recent available month, not including discounts or other price reductions, as reported in wholesale price guides or other pricing publications. Payment rates would be updated on a quarterly basis and based on the most recent calendar quarter. The Secretary would be able to use carriers, fiscal intermediaries or other contractors to determine the payment amounts. Certain standards would be established with respect to the definition of multiple source and single source drugs. Certain determinations of pharmaceutical equivalence and bioequivalence would be established. There would be no administrative or judicial review of the determination of the manufacturer's average sale price.

The Secretary would be able to use the wholesale acquisition cost or other reasonable measure of drug price instead of the manufacturer's average sale price in the case of certain public emergencies where there is a documented inability to access covered outpatient drugs and a related increase in price. The alternative price would be used until the price and availability of the drug or biological has stabilized and is substantially reflected in the manufacturer's average sale price.

The Secretary would be required to submit an annual report to the Committees of jurisdiction on the trends in average sales prices, the administrative costs, and total value of payment as well as a comparison of the average manufacturer's sale price with the price established under the Medicaid drug rebate program. The provision would be effective upon enactment.

Senate Bill

Drugs or biologicals furnished before January 1, 2004 would be paid at 95% of the AWP. In 2004, existing drugs and biologicals would be paid the lower of the AWP or 85% of the listed AWP as of April 1, 2003. In subsequent years, this price would be increased by change the consumer price index (CPI) for medical care for the previous year ending in June. Existing drugs and biologicals are those first available for payment on or before April 1, 2003. After January 1, 2004, payments for influenza virus, pneumococcal pneumonia, and hepatitis B vaccines would be equal to the AWP.

The Secretary would be required to establish a process to determine whether the widely available market price to physicians and suppliers for drugs and biologicals furnished in a year is different from the AWP amounts. This determination would be based on: (1) any report on market price published by the Inspector General (IG) of the Department of Health and Human Services (HHS) or GAO after December 31,1999; (2) a review of market prices by the Secretary including information from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers or any other appropriate source as determined by the Secretary; (3) data submitted by the manufacturer of the drug or biological or by another entity; and (4) other appropriate information as determined by the Secretary. If the market price for a drug or biological determined through this process differs from the AWP amount, that market price shall be treated as the AWP amount when determining Medicare's payment for a drug or biological in 2004 and subsequently. The Secretary would be able to make subsequent determinations with respect to the widely available market price for a given drug or biological. If not, the prior market price determination will be considered as the basis for Medicare's payment amount for such an item.

If, however, the first market price determination for a given drug or biological would result in a payment amount that is 15% less than would otherwise be made, the Secretary would provide for an appropriate transition period where the price is reduced in annual increments equal to 15% of Medicare's payment amount in the previous year. At the end of the transition period, the market price (as determined) would serve as basis for Medicare's payment amount. This transition period would not apply to a drug or biological where a generic version of that drug or biological first enters the market on or after January 1, 2004. The generic version would not be required to be marketed under the chemical name of the given drug or biological.

New drugs and biologicals, those that are first available for Medicare payment after April 1, 2003, would be subject to certain requirements in order to obtain a code and receive Medicare payment. A manufacturer would be required to provide the Secretary with necessary and appropriate information on the estimated price that the manufacturer expects physicians and suppliers to pay to routinely obtain the drug or biological; the manufacturer would be able to provide the Secretary with other appropriate information as well. During the first year that the drug or biological is available for Medicare payment, the manufacturer would be required to provide the Secretary with updated information on the actual market prices paid by physicians or suppliers for such drugs and biologicals. These market prices would be equal to the lesser of the average wholesale price for the drug or biological or the amount determined by the Secretary based on information originally submitted by the manufacturer supplemented by other appropriate information. The market price of the drug or biological during the second year after becoming available for Medicare payment is subject to the same conditions as in the first year. In subsequent years, the market price would be equal to the lesser of the average wholesale price or the widely available market price as determined by the Secretary in the same fashion as for existing drugs. If no market price determination occurs, then Medicare's payment for drug or biological in the prior year is updated by the change in the CPI for medical care for the previous year ending in June.
The provision would be effective upon enactment.

With respect to home infusion drugs and biologicals, the Secretary would be able to make separate payments for these drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. Total amount of payments for the infusion drugs in the year could not exceed the total amount of spending that would have occurred without enactment of this legislation. The provision would be effective upon enactment.

Conference Agreement

Certain categories of drugs and biologicals will continue to be paid at 95 percent of the AWP; these include a drug or biological furnished before January 1, 2004; blood clotting factors furnished during 2004; a drug or biological furnished during 2004 that was not available for Part B payment as of April 1, 2003; pneumococcal, influenza, and hepatitis B vaccines; and a drug or biological (other than erythropoietin) furnished in connection with renal dialysis services that are separately billed by renal dialysis facilities; and radiopharmaceuticals and blood products. In general, payments for other drugs furnished in 2004 will equal 85 percent of the average wholesale price (determined as of April 1, 2003). Beginning in 2005, drugs and biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services, will be paid using either the average sales price methodology or through the competitive acquisition program. Infusion drugs furnished through covered durable medical equipment starting January 1, 2004 will be paid 95% of the AWP in effect on October 1, 2003;

those infusion drugs which may be furnished in a competitive acquisition area starting January 1, 2007 will be paid on the competitive price. Intravenous immune globulin will be paid at 95% of AWP in 2004 and paid according to the average sales price method beginning in 2005.

The Secretary is authorized to substitute a different percent of the April 1, 2003 AWP, based on the Secretary's NPRM, but not less than 80%. Also, the Secretary may adjust the price based on data submitted by the manufacturer of the drug or biological by October 15, 2003.

New sections 1847A and 1847B are established in the Social Security Act. New Section 1847A establishes the use of the average sales price methodology for payment for drugs and biologicals (except for pneumococcal, influenza, and hepatitis B vaccines, or drugs or biologicals furnished in connection with certain renal dialysis services, blood or blood products or radiopharmaceuticals) furnished starting January 1, 2005. This methodology does not apply in the case of a physician who elects to participate in the newly established competition acquisition program established in new Section 1847B; payments for drugs and biologicals will be paid under that section instead.

Medicare's payment under the average sales price methodology will equal 106% of the applicable price for a multiple source drug or single source drug, subject to the applicable beneficiary deductible and coinsurance requirements. The manufacturer will be required to specify the unit associated with each National Drug Code (NDC) as part of its Medicaid reporting requirements. Unit is defined as the lowest identifiable quantity of the drug or biological by NDC (including package size) that is dispensed, exclusive of any diluents without reference to volume measures pertaining to liquids. After 2004, the Secretary may establish the counting method and unit for the manufacturer to report.

The applicable price for all drug products within the same multiple source drug billing and payment code is the volume-weighted average of the sales prices. The applicable price for single source drugs is the lesser of the manufacturer's average sales price for an NDC or the wholesale acquisition cost (WAC). A limited number of single source drugs and biologicals are currently included in the same HCPCs codes, along with other similar single source products. The Conferees intend to exempt these products from the definition of single source drugs or biologicals, and continue to allow these products to be treated as multiple source drugs and be included within the same HCPCs code. The payment amount is determined without regard to any special packaging, labeling or identifiers on the dosage form or product or package. In the section, the term "payment and billing code" shall mean the HCPCs code for such drug or biological.

A manufacturer's average sales price is calculated by NDC code for each calendar quarter by dividing a manufacturer's total sales by the total number of units sold in that quarter. Certain sales are exempt from the calculation: (1) certain sales that are exempt from the Medicaid drug rebate program including those to the Indian Health Service, the Department of Veterans Affairs, a state Veteran's home, the Department of Defense, or the Public Health Services; and (2) sales that are nominal in amount, as used in the Medicaid rebate program. The average sales price will take into account volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and certain rebates (not including Medicaid rebates). After 2004, the Secretary may include other price concessions that result in a price reduction to the purchaser as may be recommended by the Inspector General.

The Secretary will be able to disregard the average sales price during the first quarter of a new drug's sales if the price data is not sufficient to determine an average amount payable. The average sales price will be calculated by the manufacturer on a quarterly basis; to the extent that data on rebates and chargebacks is reported on a lagged basis, the manufacturer will apply the 12-month rolling average methodology to estimate the amount of such discounts, as specified by the Secretary. After 2004, the Secretary may establish a uniform methodology to estimate and apply such costs. Payment rates will be updated on a quarterly basis. The Secretary may contract with appropriate entities to determine the payment amounts. The Secretary may implement any provision of this section by program instruction or otherwise.

To monitor market prices, the Inspector General will conduct studies, which may include market surveys, to determine market prices of drugs and biologicals paid under this section. The Inspector General will compare average sales price under Medicare with the widely available market price and the average manufacturer price. The Secretary may disregard the average sales price reported by a manufacturer if this price exceeds the market price or average manufacturer price by a threshold percentage. In 2005 the threshold is 5%; in 2006 and subsequent years, the percentage threshold will be specified by the Secretary. If the Inspector General finds that the average sales price for a drug or biological exceeds the widely available market price or average manufacturer price by the applicable threshold, the Inspector General will inform the Secretary at specified times, and the Secretary will substitute a payment amount equal to the lesser of the widely available market price or 106 percent of the average manufacturer price.

The section requires that in order to have a drug covered under both Medicare and Medicaid, a manufacturer must submit information quarterly on the manufacturer's average sales price, total number of units, wholesale acquisition cost and sales made at nominal price. The Conferees intend that if a manufacturer knowingly (as defined by section 3729(b) of the False Claims Act) submits false information, that such submission be considered a "false record or statement" made or used "to get a false or fraudulent claim paid or approved by the government" for purposes of section 3729(a)(2) of title 31, United States Code, known as the False Claims Act. Thus if a manufacturer knowingly submits any false information, the manufacturer would be fully subject to liability under the False Claims Act.

The Conferees intend that that the Secretary, in making determinations to use the widely available market price, rather than the ASP, would provide a number of procedural and substantive safeguards to ensure the reliability and validity of the data used to make such determinations. These safeguards would include notice and comment rulemaking, identification of the specific sources of information used to make such determinations, and explanations of the methodology and criteria for selecting such sources.

If the Secretary determines that a manufacturer has misrepresented the average sales price of a drug, the Secretary may apply a civil monetary penalty of up to $10,000 for each price discrepancy and for each day in which the price misrepresentation was applied. In this subsection for drugs furnished in a year after 2004, the widely available market price is the price that a prudent physician or supplier would pay for a drug or biological, taking into account discounts, rebates and other price concessions routinely made available. The Secretary will consider information from one or more of the following sources including manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physician and supplier surveys as well as information on market prices from insurers and private health plans.

The Secretary will be able to use the wholesale acquisition cost or other reasonable measure of drug price instead of the manufacturer's average sale price in the case of certain public emergencies where there is a documented inability to access covered outpatient drugs and a related increase in price (which is not reflected in the manufacturer's average sale price for one or more quarters). The alternative price will be used until the price and availability of the drug or biological has stabilized and is substantially reflected in the manufacturer's average sale price.

There will be no administrative or judicial review of determinations of payment amounts including the assignment of NDCs to billing and payment codes; the identification of units and package size; the method to allocate rebates, chargebacks, and other price concessions to a quarter, the manufacturer average sales price when it is used for Medicare's price determinations, and the disclosure of the average manufacturer price under certain situations.

The Secretary will conduct a study on the sales of drugs and biologicals to large volume purchasers such as pharmacy benefit managers to determine whether the price at which drugs and biologicals are sold to these purchasers represents the price made available to physicians. The Secretary will submit a report to Congress, including recommendations, on whether sales to large volume purchasers should be excluded from the computation of the manufacturer's average sale price. Upon completion of this report, the Secretary may require that manufacturers separately report these prices, which may also then be excluded from future calculations of ASP, if the Secretary determines that doing so would be better reflect prices available to prudent physicians.

Under the new Section 1847B, the Secretary would be required to establish a competitive acquisition program to acquire and pay for competitively biddable drugs and biologicals. Under the program, competitive acquisition areas (defined as an appropriate geographic region) will be established throughout the United States. Each year, a physician would be able to select a contractor who would deliver covered drugs and biologicals to the physician; alternatively, a physician would be able to elect payment using the methodology established by Section 1847A. Conferees intend this choice to be completely voluntary on behalf of the physician. Use of this system should reduce administrative and inventory costs for physicians. In addition, because physicians do not take title to the drug, their liability is reduced.

Under the competitive acquisition program, categories of competitively biddable drugs under this program will be established, and the program will be phased in beginning in 2006. In order to promote competition and the efficient operation of the program, the Secretary would be able to waive provisions of the Federal Acquisition Regulation, other than those relating to confidentiality of information and other provisions deemed appropriate by the Secretary.

Competitively biddable drugs and biologicals exclude pneumococcal, influenza, and hepatitis B vaccines or drugs or biologicals (other than erythropoietin) furnished in connection with renal dialysis services furnished starting January 1, 2006, radiopharmaceuticals, IVIG products and blood products. Conferees do not intend to exclude therapeutic vaccines, such as new vaccines used to treat cancer that may be in development. The Secretary will be able to exclude competitively biddable drugs and biologicals including classes of such drugs and biologicals that are not appropriate for competitive bidding, if such inclusion is not likely to result in significant savings or is likely to have an adverse impact on access to the drugs and biologicals. The Secretary may provide for payment of these excluded drugs and biologicals (or class of same) using the average sale price methodology established in Section 1847A. Conferees intend the

use of the exclusion authority to apply in exceptional cases. Such authority is not intended to be a system wide replacement for competitive bidding.

The contractor supplying the physician in the area will submit the claim for the drugs and biologicals and will collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts will only be made to the contractor and will only be made upon the administration of the drug or biological. The Secretary is required to establish a process for recovery of payments billed at the time of dispensing of drugs or biologicals that were not actually administered as well as a process by which physicians submit information to contractors for the purposes of collection of any applicable deductible or coinsurance amounts. Payment could only be made to the contractor, provided the contractor has a contract and the physician elects that contractor for such category of drug or biological for the area. Alternatively, the physician may elect Section 1847A to apply.

Certain contractor selection and contracting requirements for the competitive acquisition program are established. Specifically, the Secretary is required to establish an annual selection process for a contractor in each area for each category of drugs and biologicals. The selection of the contractor will be made at the time the physician elects to participate in the program established under Section 1847B. The Secretary will make a list of contractors in the different competitive acquisition area who are available to physicians on an ongoing basis through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services, and through the annual CMS "Dear Doctor" campaign.

The Secretary will conduct a competition among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area. The competition within a HCPCS code for multiple source drug products is intended to produce competitive forces that will lower bid prices for drugs. Because multiple source drugs and generics within a HCPCS code are therapeutically equivalent, such competition will ensure access to appropriate therapeutic products. The Secretary may not award the 3-year contract to any entity that does not have the capacity to supply competitively biddable drugs or biologicals within the applicable category or does not meet quality, service, and financial performance and solvency standards established by the Secretary. Specifically, the entity would be required to have (1) sufficient arrangements to ship competitively biddable drugs and biologicals at least 5 days of the week in order for the timely delivery (including for emergency situations) of such drugs and biologicals; (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of these drugs; and (3) a grievance and appeals process. Review of complaints by the Medicare Provider Ombudsman has been established in Section 923 of this legislation. The Secretary will not be able to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the federal or a state government or that has been excluded from program participation.

The Secretary will be able to limit the number of qualified entities in each category and area, but not below 2 for any category and area. The Secretary is required to base selection on bid prices for competitively biddable drugs and biologicals, bid prices for distribution of those drugs and biologicals, ability to ensure product integrity, customer service, past experience with drug and biologic distribution, and other factors.

The contract is subject to terms and conditions that the Secretary may specify. The contract will be for a term of 3 years, but may be terminated by either the Secretary or the entity with appropriate notice. The Secretary must require that all drugs and biological products distributed by a contractor be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer. Nothing in this provision relieves or exempts any contractor from the requirements of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals. Conferees want to ensure the safe distribution of drugs and to ensure counterfeiting and adulteration is minimized. Such measures include includes the safe and appropriate storage of drugs and biologicals, disposition of damaged and outdated drugs and biologicals and appropriate record keeping and compliance personnel.

Contractors will be required to comply with a code of conduct and fraud and abuse rules. Specifically, the contractor will comply with standards relating to conflicts of interest and all applicable provisions and guidelines relating to the prevention of fraud and abuse established by the Department of Justice and the Inspector General.

The appropriate contractor, as selected by the physician, will supply competitively biddable drugs and biologicals directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home or other non-physician office settings as the Secretary may provide. The contractor shall not deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. However, a physician would not be required to submit a prescription for each individual treatment or change a physician’s flexibility in terms of writing a prescription for a single treatment or course of treatment. Conferees do not intend contractors to mix drug products prior to a patient's visit, but may do so should it be clinically advised. If specialty pharmacies mix products under the program for a specific patient, it should be done only to the benefit of the patient. Such cases may include a physician office that lacks the ability to mix Part B drugs in compliance with medical, clinical and environmental standards. In no way do conferees intend the requirements for the competition program to impair a patient's access to health treatment as a result of changes in the patient's health status, including pre-mixed drugs or biologics.

The Secretary is required to establish rules allowing physicians to use drugs or biologics from their own inventories in emergency situations consistent with safe drug practices and with adequate safeguards against fraud and abuse. In order to resupply such an inventory, a physician will be required to demonstrate that the drugs are immediately required; that the immediate need could not reasonably have been foreseen, that the drugs could not be delivered by the contractor in a timely manner, and that the drugs were administered in an emergency situation. No applicable State requirements relating to the licensing of pharmacies are waived.

The Secretary is required to base selection of the contractors on several factors including bid prices. Bid prices are those in effect and available through the entity for the contract period and includes all costs related to the delivery of the drug or biological to the selecting physician or other delivery point as well as all dispensing and shipping costs. Costs relating to the administration of the drug or biological or waste, spillage or spoilage are not included. As part of the awarded contract, the selected contractor will be required to disclose the reasonable, net acquisition costs regularly (but not more often than once a quarter) as specified by the Secretary. The selected contractor will also be required to disclose appropriate price adjustments over the period of the contract to reflect changes in reasonable, net acquisition costs.

Payments would be based upon bids submitted and accepted, and the Secretary would determine a single payment amount for each drug in an area. The Secretary will apply special rules and alternative payment amounts to establish a price for specific competitively biddable drugs and biologicals, including new drugs and biologicals (for which an average bid price has not been previously determined) and other exceptional cases specified in regulations. Medicare's payment for these drugs equals 80% of the payment amount after the Medicare beneficiary meets the applicable deductible. Generally, these coinsurance and deductible amounts will be collected by the contractor that supplies the drug or biological which may be collected in a similar manner as those collected for durable medical equipment.

Nothing in the section prevents a bidder from submitting a contract offer to cover all areas of the United States. Similarly, nothing would require a bidder to submit a contract offer to cover all areas of the United States. The amount of the bid price submitted under a contract offer is required to be the same for all portions of the area.

The Secretary will establish a procedure under which a prescribing physician has certain appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a clinical diagnostic laboratory test. Certain provisions specified in Section 1842(o) (3) with respect to assignment will also apply to claims for competitively biddable drugs and biologicals. Certain protections against liability in case of adverse medical necessity determination will apply to Medicare beneficiaries. There shall be no administrative or judicial review with respect to the establishment of payment amounts, contract awards, establishment of competitive acquisition areas, the phased in implementation, the selection of categories of competitively biddable drugs and biologicals for competitive acquisition or the bidding structure or number of contractors who are selected.

No later than July 1, 2008, the Secretary is required to report to Congress on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to providers as well as beneficiary and provider satisfaction under the competitive acquisition program. The report will also examine the information comparing prices for drugs in the competitive acquisition program and under the application of the average sales price methodology under Section 1847A.

In developing rules to implement this section, the Secretary should seek public comment on factors that disadvantage certain covered drugs based on drug forms and delivery and dispensing modes, and which may result in increased Medicare expenditures.

Items and Services Relating to Furnishing of Blood Clotting Factors (Section 303(e) (1) of the Conference Agreement and Section 303(f) of the House Bill)**.**

Present Law

Medicare will pay for blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision, as well as the items related to the administration of such factors.

House Bill

MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors and its administration in its 2004 annual report. The provision would be effective upon enactment.

Senate Bill

The Secretary is required to review the GAO report on payment for blood clotting factors and provide a separate payment for the administration of these factors. The total amount of payments for blood clotting factors furnished in CY2004 would not exceed the amount that would have otherwise been expended. In CY2005 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to review the GAO report on payment for blood clotting factors and provide a separate payment for the administration of these factors. The payment amount may take into account the mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements as well as ancillary supplies and patient training necessary for self-administration. The total amount of payments for blood clotting factors furnished in CY2005 can not exceed the amount that would have otherwise been expended. In CY2006 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June.

Pharmacy Supplying Fee for Certain Drugs and Biologicals (Section 303(e) (2), Section 303(g) of the House Bill and Section 432(b) (8) of the Senate Bill)**.**

Present Law

Medicare pays for certain outpatient prescription drugs and biologicals. For instance, Medicare pays a dispensing fee in conjunction with inhalation therapy drugs used in nebulizers. Medicare does not pay a dispensing fee to pharmacists or providers who supply oral drugs.

House Bill

The Secretary would be required to provide for separate payments in the physician fee schedule to cover the administration and acquisition costs associated with covered drugs and biologicals furnished by a contractor under the competitive acquisition program. The provision would be effective upon enactment.

Senate Bill

Medicare would pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. Medicare would be able to pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for other drugs and biologicals. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to pay a supply fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. Such fee is not meant to be a dispensing fee. The intent of the Conferees is to not to include in such fee, amounts for cognitive services.

Linkage of Revised Drug Payments and Increases for Drug Administration (Section 303(f) of the Conference Agreement and Section 432(b) (1) of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision

Senate Bill

A linkage of revising drug payments to incorporate market prices and payment increases for drug administration would be established.

Conference Agreement

The Secretary cannot implement the revision in payment amount for categories of drug or biological administered by physicians unless the Secretary concurrently makes the practice expense payment adjustment on the basis of survey data as specified earlier.

Prohibition of Administrative and Judicial Review (Section 303(g) of the Conference Agreement and Section 432(d) of the Senate Bill)**.**

Present Law

Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal adverse determinations regarding claims for benefits under Part A and Part B. Section 1869 of the SSA allows these parties who have been denied coverage of an item or service the right to appeal that decision through a series of administrative appeals and then into federal district court under certain circumstances. Section 1878 of the SSA allows providers who are dissatisfied with certain cost reporting determinations that affect their reimbursement amounts the right to appeal that decision in front of the Provider Reimbursement Review Board and then into federal district court if certain thresholds regarding the amount in dispute are met at each step of the appeals process.

House Bill

No provision.

Senate Bill

The provisions concerning Medicare's determination of payment amounts for existing and new drugs and biologicals including the administration of blood clotting factors, home infusion drugs and inhalation drugs would not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise. The provision would be effective upon enactment.

Conference Agreement

The provisions concerning Medicare's determination of payment amounts, methods or adjustments including those with respect to a drug's widely available market price in 2004, the administration of blood clotting factors, and pharmacy supplying fees will not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise. The provision would be effective upon enactment.

The provisions concerning Medicare's determination of the budget neutral adjustments, adjustments to the practice expense relative value units for certain drug administration services and other drug administration services will not be subject to administrative or judicial review under Section 1869 of the SSA or otherwise. The provision would be effective upon enactment.

The provisions concerning Medicare's treatment of other services currently in the non-physician work pool, payment for multiple chemotherapy agents furnished on a single day through the push technique, and the transitional adjustment will not be subject to administrative or judicial review under Sections 1869 and Section 1878 of the SSA or otherwise. The provision would be effective upon enactment.

Continuation of Payment Methodology for Radiopharmaceuticals (Section 303(h) of the Conference Agreement and Section 303(c) of the House Bill)**.**

Present Law

Under certain circumstances, Medicare makes a separate payment for supplies furnished in connection with a procedure. Medicare will pay separately for pharmaceutical or radiopharmaceutical supplies when procedures such as diagnostic radiolologic procedures or other diagnostic tests requiring a pharmacological stressing agent.

Although Medicare uses the Healthcare Common Procedure Coding System (HCPCS) codes to identify and pay for physician administered drugs, the AWPs are established for national drug codes (NDC) codes that are maintained by the Food and Drug Administration (FDA). Until January 1, 2003, each Medicare carrier would convert NDC codes into HCPCS codes in order to develop AWP-based payments for physicians in its area. To address the variation in carrier-established drug pricing methods, CMS implemented a single drug pricer (SDP), a centrally administered fee schedule for covered outpatient drugs on January 1, 2003. The SDP excludes radiopharmaceuticals, outpatient hospital drugs, and drugs paid by the durable medical equipment regional carriers (DMERCs).

House Bill

These provisions would not affect the existing carrier invoice pricing method used to pay for radiopharmaceuticals. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement will not change the Part B payment methodology for radiopharmaceuticals including the use by carriers of the invoice pricing method.

Conforming Amendments (Section 303(i) of the Conference Agreement and Section 303(d) of the House Bill)**.**

Present Law

No provision.

House Bill

The provisions in this section would not affect the existing coverage for outpatient drugs. The collection of data to calculate the manufacturer's average sales price and the manufacturer's wholesale acquisition cost would be included as part of the Medicaid drug rebate program for calendar quarters beginning on or after April 1, 2004. Information on sales that were made at a nominal price would also be submitted and be subject to audit by the HHS Inspector General. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes conforming amendments to the existing statutory language. A pharmacy-dispensing fee will not be paid when payment for a drug is made under the average sales price or competitive acquisition program. The provisions in this section will not affect the existing coverage for outpatient drugs. The list of services paid for under Part B will be amended to include drugs paid for under Sections 1847, 1847A, and 1847B. Information by NDC (including package size) on the manufacturer's average sales price and total number of units; the manufacturer's wholesale acquisition cost; sales that were made at a nominal price will be included as part of the Medicaid drug rebate program for calendar quarters beginning on or after January 1, 2004. This information will be subject to audit by the Inspector General. The Secretary will be able to survey wholesalers and manufacturers that directly distribute covered outpatient drugs to verify average sales price (including wholesale acquisition cost) under the Medicaid drug rebate program. The provisions with respect to the Congressional review of agency rulemaking will not apply with respect to regulations that implement adjustments to the physician fee schedule or the application of market based payment systems. The existing requirement that the Secretary study the effect on AWP of Medicare's policy to pay for covered outpatient drugs at 95% of AWP is repealed.

Extension

Payment for Inhalation Drugs and Certain Other Drugs (Section 305 of the Conference Agreement, Section 602(c) of the House Bill, and Section 432(b)(7) of the Senate Bill**).**

Present Law

Medicare will cover outpatient prescription drugs and biologicals if they are necessary for the effective use of covered durable medical equipment (DME), including those drugs that must be put directly into the equipment such respiratory drugs given through a nebulizer (inhalation drugs).

House Bill

GAO would be required to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program and submit the results of the study in a report to Congress no later than May 1, 2004.

Senate Bill

The Secretary would be able to increase payments for covered DME associated with inhalation drugs and biologicals and make separate payments for such drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. The associated spending attributed to the increased and separate payments for the covered DME and inhalation drugs and biologicals in the year would not exceed the 10% of the difference between the savings in total spending for these drug and biologicals attributed to the prescription drug pricing changes enacted in this legislation. The provision would be effective upon enactment.

Conference Agreement

Inhalation drugs or biologicals furnished through covered durable medical equipment that is not described in subparagraph (A) (iv) will be paid at 85% of AWP in 2004. In 2005, it will be the amount provided under the average sales price methodology.

GAO is be required to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program and submit the results of the study in a report to Congress no later than 1 year from the enactment date of this legislation.

Demonstration Project for Use of Recovery Audit Contractors (Section 305 of the Conference Agreement and Section 304 of the House Bill)**.**

Present Law

No provision.

House Bill

The Secretary would be required to conduct a demonstration project for up to 3 years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors would identify underpayments and overpayments in the Medicare program and would recoup overpayments made to providers. Payment would be made to these contractors on

a contingent basis, a percentage of the amount recovered by the contractors would be able to be retained by the Secretary and available to the program management account of Centers for Medicare & Medicaid Services (CMS), and the Secretary would be required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise. The demonstration project would be required to cover at least 2 states that are among the states with the highest per-capita utilization rates of Medicare services and have at least 3 recovery audit contractors. The Secretary would be able to waive Medicare statutory provisions to pay for the services of the recovery audit contractors. Recovery of an overpayment through this project would not prohibit the Secretary or the Attorney General from investigating and prosecuting appropriate allegations of fraud and abuse. Fiscal intermediaries, carriers, and Medicare Administrative Contractors would not be eligible to participate as a recovery audit contractor. The Secretary would be required to show preference to contracting with entities that have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or state Medicaid programs. Within 6 months of completion, the Secretary would be required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program. The provision would be effective upon enactment.

Senate Bill

No provision

Conference Agreement

The conference agreement requires the Secretary to conduct a demonstration project for up to 3 years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors will identify underpayments and overpayments in the Medicare program and recoup overpayments made to providers. Payment may be made to these contractors on a contingent basis, a percentage of the amount recovered by the contractors is to be retained by the Secretary and available to the program management account of the Centers for Medicare & Medicaid Services (CMS), and the Secretary is required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

The demonstration project is required to cover at least 2 states that are among the states with the highest per-capita utilization rates of Medicare services and that have at least 3 recovery audit contractors. The Secretary is required to waive Medicare statutory provisions as necessary in order to pay for the services of the recovery audit contractors. The Secretary is required to show preference to contracting with entities that have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or state Medicaid programs. Fiscal intermediaries, carriers, and Medicare Administrative Contractors are not eligible to participate as a recovery audit contractor. Recovery of an overpayment through this project does not prohibit the Secretary or the Attorney General from investigating and prosecuting allegations of fraud or abuse arising from the overpayment. Within 6 months of completion, the Secretary is required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program. The provision is effective upon enactment.

Pilot Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities or Providers (Section 306 of the Conference Agreement and Section 620 of the Senate Bill)**.**

Present Law

Nursing homes and home health agencies may request the Federal Bureau of Investigation (FBI) to search its all-state national data bank of arrest and convictions for the criminal histories of applicants who would provide direct patient care, as long as states establish mechanisms for processing these requests. Most states have enacted laws that require or allow nursing homes and home health agencies to conduct these criminal background checks for certain categories of potential employees. The Attorney General may charge nursing homes and home health agencies fees of no greater than $50 per request.

To conduct a criminal background check, nursing homes and home health agencies must provide a copy of an applicants fingerprints, a statement signed by the applicant authorizing the search, and other information to the appropriate state agency. Such information must be provided no later than 7 days after its acquisition by the nursing home or home health agency. Nursing facilities or home health care agencies that deny employment based on reasonable reliance on information from the Attorney General are exempt from liability for any action brought by the applicant. The information received from either the state or Attorney General may be used only for the purpose of determining the suitability of the applicant for employment by the agency in a position involved in direct patient care.

HHS maintains a national health care fraud and abuse data base, the Healthcare Integrity and Protection Data Bank (HIPDB), for the reporting of final adverse actions, including health care related civil judgments and criminal convictions of health care practitioners, providers and suppliers. This information is currently available for self-query by government agencies, health plans, health care providers, suppliers and practitioners. All states also maintain their own registries of persons who have completed nurse aide training and competency evaluation programs and other persons for whom the state determines meet the requirements to work as a nurse aide. Included in these registries are data describing state findings of resident neglect, abuse and/or the misappropriation of resident property.

State agencies that survey providers to ensure they meet Medicare and/or Medicaid requirements for participation are referred to as survey and certification agencies, or state survey agencies. Under current law, state survey agencies are required to investigate allegations of resident neglect, abuse and/or the misappropriation of resident property in nursing homes.

House Bill

No provision.

Senate Bill

Medicare and/or Medicaid certified nursing homes, home health agencies, hospices, long-term care hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), and other entities providing long-term care services would be required to initiate background checks for certain workers. These workers would include those licensed, certified, nonlicensed, or contracted employee of a long term care facility or provider (other than a volunteer) that has access to a

patient or resident, including nurse assistants, nurse aides, home health aides, individuals who provide home care, and personal care workers and attendants.

Providers would be required to: (1) give written notice to workers about background checks, (2) obtain a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse from the worker, (3) receive written permission from workers authorizing a criminal background check, (4) obtain fingerprints or thumb prints of workers, (5) conduct self-queries of the HIPDB, and 6) comply with other information requirements specified by the Secretary. States would then be required to check state arrest and conviction data banks, and if appropriate, request the FBI to check national criminal history records on behalf of providers that are required to conduct these background checks.

The long-term care providers would be prohibited from employing a worker who has any conviction for a relevant crime or a finding of patient or resident abuse. Those found to violate these requirements would be subject to criminal penalty fines and/or imprisonment. Providers that are found to violate these requirements would face civil monetary fines. Providers would be permitted to provisionally employ workers pending completion of the criminal background checks as long as they comply with supervisory requirements. Special consideration would be given to rural facilities and home health providers.

Providers would be reimbursed for their costs associated with the requirements of this provision by the Secretary of HHS. The Attorney General could charge fees to any state requesting a search and exchange of records. States could also charge providers fees. Yet, providers could not charge fees to workers.

The nurse aide registry would be expanded to include all employees of providers, including non-licensed workers, and renamed an employee registry. Survey and certification agencies would be required to investigate abuse and neglect allegations and misappropriation of resident property concerning any individual employed or used by any participating health and long-term care providers. $10.2 million would be authorized to be appropriated for FY 2004, with compliance with these provisions phases in for various groups of providers.

Grants would be available to public or private non-profit entities to develop information on best practices in patient abuse prevention training (including behavior training and interventions) for managers and staff of hospital and health care facilities, and for other purposes.

Long-term care providers could access the HIPDB data bank and HIPDB would be expanded to include findings of abuse, neglect, or misappropriation of resident property. A report would be due to Congress no later than 2 years after enactment on the number of requests for searches and exchanges of records, the disposition of requests, and the cost of responding to such requests.

Conference Agreement

The conference agreement requires the Secretary to establish pilot projects in no more than 10 states for the purpose of expanding background checks for workers to other Medicare and Medicaid long-term care providers. Long-term care facilities or providers include Medicare- and/or Medicaid-certified nursing homes, home health agencies, hospices, long-term care hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), and other entities that provide long-term care services (except for those paid through a self-directed arrangement).

States that agree to participate in this pilot project will be responsible for monitoring provider compliance and must establish procedures for workers to appeal or dispute the findings of the background checks. The Secretary will establish criteria for selecting those states seeking to participate and pay those states for the costs of conducting the pilot program (reserving 2% of the payments for the program's evaluation).

Long-term care providers in participating states are required to: (1) give notice to new workers about background checks, and (2) obtain a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse from the worker, (3) receive written permission from workers authorizing a criminal background check, (4) obtain a rolled set of finger prints of workers, (5) obtain any other information specified by the state; and (6) initiate a check of available registries that document findings of resident or patient neglect, abuse, or misappropriation of property (if no information about a conviction of a relevant crime or finding of abuse are found). Providers must also obtain information on the workers from the state through a 10-fingerprint background check to be conducted using state criminal records and the Integrated Automated Fingerprint Identification system of the Federal Bureau of Investigation. Disqualifying information for employment includes information about a conviction for a relevant crime, a finding of patient or resident abuse, or a felony conviction related to health care fraud or a controlled substance. Under the agreement, at least one state should test if providers could contract with employment agencies, subject to conditions specified by the state, to conduct these background checks.

Pending completion of the national and state criminal history background checks, states may permit providers to provisionally employ workers as long as they comply with supervisory requirements established by the state. These requirements would take into account the cost or other burdens associated with small rural providers as well as the nature of care delivered by home health or hospice providers.

The information obtained from the check may only be used for the purpose of determining the suitability of the applicant for employment. Providers are also protected from liability for denying employment based on reasonable reliance on information from the background checks. For fiscal years 2005 and 2006, $25 million is appropriated from funds not otherwise appropriated.

GAO Study (Section 303(e) of the House Bill)**.**

Present Law

No provision.

House Bill

GAO would be required to conduct a study to assess the impact of amendments made by this section on the delivery of services and their impact on access to drugs by beneficiaries. The report would be due no later than 2007.

Senate Bill

GAO would be required to conduct a study that examines the impact of the drug payment and adjustment provisions on the access of Medicare beneficiaries' to covered drugs and biologicals.

The report, including appropriate recommendations, would be due to Congress no later than January 1, 2006. The Inspector General would be required to conduct one or more studies that examine the market prices for Medicare covered drugs and biologicals, which are widely available to physicians and suppliers. The report would examine report would examine those drugs and biologicals that represent the largest portion of Medicare spending on such items and include a comparison of market prices with Medicare payment amounts.

Conference Agreement

No provision.

Study on Codes for Non-Oncology Codes (Section 303(h) of the House Bill)**.**

Present Law

No provision.

House Bill

The Secretary would be required to submit a study to Congress within one year of enactment that examines the appropriateness of establishing and implementing separate codes for non-oncology infusions that address the level of complexity and resource consumption. If deemed appropriate, the Secretary would be able to implement appropriate changes in the payment methodology. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

No provision.

Payment for Chemotherapy Drugs Purchased But Not Administered by Physicians (Section 432(b)(9) of the Senate Bill)**.**

Present Law

Medicare does not pay for chemotherapy drugs that purchased by physicians, are not dispensed, and must be discarded.

House Bill

No provision.

Senate Bill

The Secretary would be able to compensate a physician for chemotherapy drugs that are purchased with a reasonable intent to administer to a Medicare beneficiary but which cannot be administered despite the physician's reasonable efforts, because the beneficiary is too sick or the

beneficiary's condition changes and the physician must discard the drugs. The Secretary would be able to increase the Medicare payment amount for all covered chemotherapy drugs, but the total amount of the increase could not exceed one percent of the payment for chemotherapy drugs. The beneficiary's cost sharing amounts would not be affected. The provision would be effective upon enactment.

Conference Agreement

No provision.

Extension of Medicare Secondary Payer Rules for Individuals with End-Stage Renal Disease (Section 450F of the Senate Bill)**.**

Present Law

Generally, Medicare is the primary payer, that is, it pays health claims first, with an individual's private or other public plan filling in some or all of the coverage gaps. In certain cases, the beneficiary's other coverage pays first, while Medicare is the secondary payer. This is known as the Medicare secondary payer (MSP program. The MSP provisions apply to group health plans for the working aged, large group health plans for the disabled, and, for 30 months, employer health plans for the end-stage renal disease (ESRD) population.

House Bill

No provision.

Senate Bill

This provision would extend the limited time period that employer health plans are primary payer for beneficiaries with end-stage renal disease from 30 months to 36 months.
The provision would apply for items and services furnished beginning January 1, 2004.

Conference Agreement

No provision.

TITLE IV - RURAL PROVISIONS

Subtitle A- Provisions Relating to Part A Only

Equalizing Urban and Rural Standardized Payment Amounts under the Medicare Inpatient Hospital Prospective Payment System (Section 401 of the Conference Agreement, Section 402 of the House Bill, and Section 401 of the Senate Bill)**.**

Present Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6% more than the standardized amount used to pay hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (PL.108-7) provided for a temporary payment increase for rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, will be paid on the basis of the large urban area amount. This temporary increase was further extended to discharges through March 31, 2004 by P.L. 108-89, which permitted the Secretary to delay implementation of the payment increase until November 1, 2003, if necessary.

Under Medicare's prospective payment system for inpatient services, separate standardized amounts are used to establish payments for discharges from short-term general hospitals in Puerto Rico. The separate amounts are a blended calculation based on an equal proportion of the federal national amount and the local amount, which are computed using data from hospitals in Puerto Rico. Presently, two local amounts are calculated: one for hospitals in large urban areas and one for hospitals in other areas.

House Bill

Beginning for discharges in FY2004, the standardized amount for hospitals located in areas other than large urban areas would be equal to the amount used to pay hospitals located in large urban areas. Technical conforming amendments would also be adopted.

Senate Bill

Medicare would pay hospitals in rural and small urban areas in the fifty states using the standardized amount used to pay hospitals in large urban areas starting for discharges in FY2004. The Secretary would compute one standardized amount for hospitals in Puerto Rico equal to that for urban areas.

Conference Agreement

Medicare will pay hospitals in rural and small urban areas in the fifty states using the standardized amount that would be used to pay hospitals in large urban areas starting for discharges in FY2004. The Secretary will compute one local standardized amount for all hospitals in Puerto Rico equal to that for hospitals in large urban areas in Puerto Rico starting for discharges in FY2004. The existing single standardized amount will continue for hospitals that are not in Puerto Rico are not affected. Hospitals in Puerto Rico will receive the legislated payment increase starting for discharges on April 1, 2004.

Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds (Section 402 of the Conference Agreement, Section 401 of the House Bill, and Section 404 of the Senate Bill)**.**

Present Law

Medicare makes additional payments to certain acute hospitals that serve a large number of low-income Medicare and Medicaid patients as part of its inpatient prospective payment system (IPSS). As specified by BIPA, starting with discharges occurring on or after April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH patient percentage or threshold amount exceeds 15%. Different formulas are used to establish a hospital's DSH payment adjustment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). Although a SCH or RRC can qualify for a higher DSH adjustment, generally, the DSH adjustment that a small urban or rural hospital can receive is limited to 5.25%. Large (100 beds and more) urban hospitals and large rural hospitals (500 beds and more) are eligible for a higher adjustment that can be significantly greater; the amount of the DSH adjustment received by these larger hospitals will depend upon its DSH percentage. Certain urban hospitals (Pickle hospitals) receive DSH payments under an alternative formula that considers the proportion of a hospital's patient care revenues that are received from state and local indigent care funds.

House Bill

Starting for discharges after October 1, 2003, a hospital that is not a large urban hospital that qualifies for a DSH adjustment would receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for any of these hospitals, except for rural referral centers, would be capped at 10%. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Senate Bill

Starting for discharges after October 1, 2004, a hospital that qualifies for a DSH adjustment when its DSH patient percentage exceeds the 15% DSH threshold would receive the DSH payments using the current formula that establishes the DSH adjustment for a large urban hospital. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Conference Agreement

Starting for discharges after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a DSH adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for any of these hospitals, except for rural referral centers, will be capped at 12%. A Pickle hospital receiving a DSH adjustment under the alternative formula will not be affected by this provision.

Adjustment of the Medicare Inpatient Hospital Prospective Payment System Wage Index to Revise the Labor-Related Share of Such Index (Section 403 of the Conference Agreement, Section 416 of the House Bill, and Section 402 of the Senate Bill)**.**

Present Law

Medicare's payments to acute hospitals are adjusted, either increased or decreased as appropriate, by the wage index of the area where the hospital is located or where it has been reassigned. Presently, approximately 71% of the standardized amount for each hospital discharge is adjusted by the area wage index. Decreasing this proportion or labor-related share would increase Medicare payments to hospitals in areas with wage indices below one and decrease Medicare payments to hospitals in areas with wage indices above one.

House Bill

For discharges occurring on or after October 1, 2003, the Secretary would be required to decrease the labor-related share to 62% of the standardized amount only if such change would result in higher total payments to the hospital. This provision would be applied without regard to certain budget-neutrality requirements.

Senate Bill

For cost reporting periods beginning on or after October 1, 2004, the Secretary would be required to decrease the labor-related share to 62% of the standardized amount only if such change would result in higher total payments to the hospital. This provision would be applied without regard to certain budget-neutrality requirements.

Conference Agreement

For discharges on or after October 1, 2004, the Secretary is required to decrease the labor-related share to 62% of the standardized amount when such change will result in higher total payments to the hospital. This provision is applied without regard to certain budget-neutrality requirements. For discharges on or after October 1, 2004, the Secretary is also required to decrease the labor-related share to 62% of the standardized amount for hospitals in Puerto Rico when such change results in higher total payments to the hospital.

More Frequent Update in Weights Used in Hospital Market Basket (Section 404 of the Conference Agreement and Section 404 of the House Bill)**.**

Present Law

Medicare's standardized amounts, which serve as the basis of its payment per discharge from an acute hospital, are increased annually using an update factor that is determined in part by the projected increase in the hospital market basket. The market basket is a fixed-weight hospital input price index, which measures the average change in the price of goods and services that hospitals purchase in order to furnish inpatient care. The Centers for Medicare and Medicaid Services (CMS) revises the cost category weights, reevaluates the price proxies for such categories, and rebases (or changes the base period) for the market basket every 5 years. CMS implemented a revised and rebased market basket using 1997 cost data to set the FY2003 Medicare hospital payment rates.

House Bill

The Secretary would be required to revise the market basket weights to reflect the most currently available data and to establish a schedule for revising the cost category weights more often than once every 5 years. The Secretary would be required to submit a report to Congress by October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

Senate Bill

No provision

Conference Agreement

The Secretary is required to revise the market basket weights to reflect the most currently available data and to establish a schedule for revising the cost category weights more often than once every 5 years. The Secretary is required to publish the reasons for and the options considered in establishing such a schedule in the final rule establishing FY2006 inpatient hospital payments.

Improvements to the Critical Access Hospital (CAH) Program (Section 405 of the Conference Agreement, Section 405 of the House Bill, and Section 405 of the Senate Bill)**.**

Increase in Payment Amounts (Section 405(a) of the Conference Agreement and Section 405(a) of the House Bill)**.**

Present Law

Generally, a critical access hospital (CAH) receives reasonable cost reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient service reimbursement or an all-inclusive rate, which is equal to a reasonable cost reimbursement for facility services plus 115% of the fee schedule payment for professional services. Ambulance services that are owned and operated by CAHs are reimbursed on a reasonable cost basis if these ambulance services are 35 miles from another ambulance system.

House Bill

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH would be reimbursed at 102% of reasonable costs of services furnished to Medicare beneficiaries. This provision would apply to cost reporting periods beginning on or after October 1, 2003.

Senate Bill

No provision

Conference Agreement

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH will be reimbursed at 101% of reasonable costs of services furnished to Medicare beneficiaries. This provision applies to cost reporting periods beginning on or after January 1, 2004.

Coverage of Costs For Certain Emergency Room On-Call Providers (Section 405(b) of the Conference Agreement, Section 405(b) of the House Bill, and Section 405(c) of the Senate Bill)**.**

Present Law

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

House Bill

Reimbursement of on-call emergency room providers would be expanded to include the costs associated with physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services. This provision would apply to costs for services provided on or after January 1, 2004.

Senate Bill

The provision would expand reimbursement of on-call emergency room providers to include physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services provided on or after January 1, 2005.

Conference Agreement

The provision expands reimbursement of on-call emergency room providers to include physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for the costs associated with covered Medicare services provided on or after January 1, 2005.

Authorization of Periodic Interim Payment (PIP) (Section 405(c) of the Conference Agreement, Section 405(d) of the House Bill, and Section 405(d) of the Senate Bill)**.**

Present Law

Eligible hospitals, skilled nursing facilities, and hospices which meet certain requirements receive Medicare periodic interim payments (PIP) every 2 weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

House Bill

An eligible CAH would be able to receive payments made on a PIP basis for its inpatient services. The Secretary would be required to develop alternative methods based on the expenditures of the hospital for these PIP payments. This provision would apply to payments made on or after January 1, 2004.

Senate Bill

Starting with payments made on or after January 1, 2005, an eligible CAH would be able to receive payments made on a PIP basis for inpatient services. The provision would apply to payments for inpatient CAH services furnished on or after January 1, 2005.

Conference Agreement

An eligible CAH will be able to receive payments made on a PIP basis for its inpatient services. The Secretary is required to develop alternative methods for the timing of PIP payments to these CAHs. This provision applies to payments made on or after July 1, 2004.

Condition for Application of Special Professional Service Payment Adjustment (Section 405(d) of the Conference Agreement and Section 405(e) of the House Bill)**.**

Present Law

As specified by BBRA, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115% of the fee schedule for professional services otherwise included within its outpatient critical access hospital services for cost reporting periods starting on or after October 1, 2000.

House Bill

The Secretary would not be able to require that all physicians providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115% of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115% of the fee schedule for any individual physician who did not assign billing rights to the CAH. This provision would be effective as if it had been included as part of BBRA.

Senate Bill

No provision.

Conference Agreement

The Secretary cannot require that all physicians or practitioners providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115% of the fee schedule for the professional services provided by the physicians. However, a CAH will not receive payment based on 115% of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH. This provision applies to cost report periods starting on or after July 1, 2004 except for those CAHs that have already elected payment for physician services on this basis in the past; this provision will apply to those CAHs starting for cost reporting periods on or after July 1, 2003.

Revision in Bed Limitation for Hospitals (Section 405(e) of the Conference Agreement, Section 405(f) of the House Bill, and Section 405(a) of the Senate Bill)**.**

Present Law

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute-care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time of the facility's application for CAH designation are not counted toward these bed limits.

House Bill

The Secretary would be required to specify standards for determining whether a CAH has seasonal variations in patient admissions that would justify a 5-bed increase in the number of beds it can maintain (and still retain its classification as a CAH). CAHs that operate swing beds would be able to use up to 25 beds for acute care services as long as no more than10 beds at any time are used for non-acute services. Those CAHs with swing beds that made this election would not be eligible for the 5-bed seasonal adjustment. A CAH with swing beds that elects to operate 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment. These provisions would only apply to CAH designations made before, on or after January 1, 2004.

Senate Bill

A CAH would be able to operate up to 25 swing beds or acute care beds, subject to the 96 hour average length of stay for acute care patients. The requirement that only 15 of the 25 beds be used for acute care at any time would be dropped. The provision would be effective for designations made on or after October 1, 2004.

Conference Agreement

A CAH will be able to operate up to 25 beds. The requirement that only 15 of the 25 beds be used for acute care at any time will be dropped. The provision will apply to CAH designations made before, on, or after January 1, 2004, but any election made pursuant to the regulations promulgated to implement this provision will only apply prospectively.

Provisions Relating to FLEX Grants (Section 405(f) of the Conference Agreement, Section 405(g) of the House Bill, and Section 405(f) of the Senate Bill)**.**

Present Law

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. For example, the Medicare Hospital Flexibility Program awards grants to states for rural health care planning and implementation activities, rural network development and implementation, to establish or expand rural emergency medical services and for CAH designations.

The Secretary may also award grants to hospitals to assist eligible small rural hospitals in implementing data systems required under BBA 1997. Small rural hospitals are short term general hospitals with less than 50 beds that are located in rural areas.

Funding for the rural hospital flexibility grant program was $25 million from FY1999 through FY2001; $40 million in FY2002; and $25 million in 2003. The authorization to award the grants expired in FY2002.

House Bill

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up $25 million each year. The provision would be effective upon enactment.

Senate Bill

The provision would permit the Secretary to award grants under the Small Rural Hospital Improvement Program to hospitals that have submitted applications to assist eligible small rural hospitals in reducing medical errors, increasing patient safety, protecting patient privacy, and improving hospital quality. These grants would not exceed $50,000 and would be able to be used to purchase computer software and hardware, educate and train hospital staff, and obtain technical assistance. The provision would authorize appropriations of $40 million each year from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund for grants to States for specified purposes. States that are awarded grants would be required consult with the hospital association and rural hospitals in the state on the most appropriate way to use such funds. The provision would also authorize $25 million each year from FY2004 through FY2008 for the Small Rural Hospital Improvement Program. This amount would be appropriated from amounts in the treasury not otherwise appropriated.

The provisions would be effective upon enactment. They would apply to grants awarded on or after the date of enactment and would apply to grants awarded prior to the date of enactment to the extent that the funds have not yet been obligated.

Conference Agreement

The authorization to award rural hospital flexibility grants is established at $35 million each year from FY2005 through FY2008. Starting with funds appropriated for FY2005 and in subsequent years, a state is required consult with the hospital association and rural hospitals in the state on the most appropriate way to use such funds. A state may not spend more than 15% of the grant amount or the States federally negotiated indirect rate for administrative purposes. Beginning with FY2005 up to 5% of the total amount appropriated for grants will be available to the Health Resources and Services Administration for administering these grants.

Exclusion of Certain Beds from Bed Count and Removal of Barriers to Establishment of Distinct Part Units (Section 405(g) of the Conference Agreement and Section 405(g) of the Senate Bill)**.**

Present Law

Beds in distinct part psychiatric or rehabilitation units operated by an entity seeking to become a CAH would not count toward the bed limit.

House Bill

No provision

Senate Bill

The Secretary would not be able to count any beds in a distinct part psychiatric or rehabilitation unit operated by the entity seeking to become a CAH. The total number of beds in these distinct part units would not be able to exceed 25. A CAH would be able to establish a distinct part psychiatric or rehabilitation unit. The provision would apply to designations on or after October 1, 2003.

Conference Agreement

A CAH can establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements for such beds established for a short-term, general hospital, specifically, a subsection (d) hospital as defined in 1886(d)(1)(B). If the distinct part units do not meet these requirements during a cost reporting period, then no Medicare payment will be made to the CAH for services furnished in the unit during the period. Medicare payments will resume only after the CAH demonstrates that the requirements have been met. Medicare payments for services provided in the distinct part units will equal payments that are made on a prospective payment basis to distinct part units of short term general hospitals. The Secretary will not count any beds in the distinct part psychiatric or rehabilitation units toward the CAH bed limit. The total number of beds in these distinct part units cannot exceed 10. The provision will apply to cost reporting periods starting October 1, 2004.

Waiver Authority (Section 405(h) of the Conference Agreement)**.**

Present Law

Currently to qualify as a CAH, the rural, for-profit, non profit or public hospital must be located more than 35 miles from another hospital or 15 miles in areas with mountainous terrain or those where only secondary roads are available. These mileage standards may be waived if the hospital has been designated by the State as a necessary provider of health care.

House Bill

No Provision

Senate Bill

No Provision

Conference Report

Currently to qualify as a CAH, the rural, for-profit, non profit or public hospital must be located more than 35 miles from another hospital or 15 miles in areas with mountainous terrain or those where only secondary roads are available. These mileage standards may be waived if the hospital has been designated by the State as a necessary provider of health care. This authority is eliminated 2 years after enactment.

Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals (Section 406 of the Conference Agreement and Section 403 of the Senate Bill)**.**

Present Law

Medicare pays inpatient acute hospital services on a discharge basis without regard for the number of beneficiaries discharged from any given hospital. Under certain circumstances, however, sole community hospitals (SCHs) and Medicare dependent hospitals with more than a 5% decline in total discharges from one period to the next may apply for an adjustment to their payment rates to partially account for higher costs associated with a drop in patient volume due to circumstances beyond its control.

House Bill

No provision.

Senate Bill

The provision would require the Secretary to provide for a graduated adjustment to Medicare's inpatient payment rates to account for the higher unit costs associated with low-volume hospitals. Certain hospitals with fewer than 2,000 total discharges during the 3 most recent cost reporting periods would be eligible for up to a 25% increase in their Medicare payment amount starting for FY2005 cost reporting periods. Eligible hospitals would be located at least 15 miles from a similar hospital or those determined by the Secretary to be so located due to factors such as weather conditions, travel conditions, or travel time to the nearest alternative source of appropriate inpatient care. Certain budget-neutrality requirements would not apply to this provision.

Conference Agreement

The Secretary is required to provide for a graduated adjustment to Medicare's inpatient payment rates to account for the higher unit costs associated with low-volume hospitals starting for discharges occurring in FY2005. The Secretary shall determine the empirical relationship between the standardized cost per case, the number of discharges, and the additional incremental costs (if any) for low-volume hospitals; the percentage payment increase for these hospitals will be based on this relationship, but in no case will be greater than 25%. A low-volume hospital is a short-term general hospital (as defined by 1886(d)(B) of the Social Security Act or SSA) that is located more than 25 road miles from another such hospital and that has less than 800 discharges during the fiscal year. A discharge means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to Part A benefits. Certain budget-neutrality requirements would not apply to this provision. The determination of the percentage payment increase is not subject to administrative or judicial review.

Treatment of Missing Cost Reporting Periods for Sole Community Hospitals (Section 407 of the Conference Agreement and Section 414 of the House Bill)**.**

Present Law

Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole source of inpatient services reasonably available in a geographic area, or are located more than 35 road miles from another hospital. The primary advantage of an SCH classification is that these hospitals receive Medicare payments based on the current national PPS national standardized amount or on hospital-specific per discharge costs from either FY 1982, FY1987 or FY1996 updated to the current year, whatever amount will provide the highest Medicare reimbursement. The FY1996 base year option became effective for discharges on or after FY2001 on a phased in basis and will be fully implemented for SCH discharges on or after FY2004.

House Bill

A hospital would not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available. The provision would apply to cost reporting periods beginning on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

A hospital will not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available. The provision applies to cost reporting periods beginning on or after January 1, 2004.

Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients (Section 408 of the Conference Agreement, Section 409 of the House Bill, and Section 407 of the Senate Bill)**.**

Present Law

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of the patient's medical care when the patient makes an election to receive hospice care.

House Bill

A beneficiary electing hospice care would be able to identify a nurse practitioner as an attending physician. This nurse practitioner would not be able to certify the beneficiary as terminally ill for the purpose of entering hospice care. The provision would be effective upon enactment.

Senate Bill

A terminally ill beneficiary under hospice care would be able to receive services provided by a physician assistant, nurse practitioner, or clinical nurse specialist who is not an employee of the hospice program and who the beneficiary identifies, when electing hospice care, as the health care provider having the most significant role in the determination of medical care provided to the beneficiary. A physician assistant, nurse practitioner, or clinical nurse specialist so identified by the beneficiary would be able to periodically review the beneficiary's written plan of care. The amendments would apply to hospice care furnished on or after October 1, 2004.

Conference Agreement

The conference agreement expands the definition of attending physician in hospice to include a nurse practitioner. A nurse practitioner is not permitted to certify a beneficiary as terminally ill for the purposes of receiving the hospice benefit. The provision would be effective upon enactment.

Rural Hospice Demonstration Project (Section 409 of the Conference Agreement and Section 418 of the House Bill)**.**

Present Law

Medicare's hospice services are provided primarily in a patient's home to beneficiaries who are terminally ill and who elect such services. Medicare law prescribes that the aggregate number days of inpatient care provided to Medicare beneficiaries who elect hospice care in any 12-month period cannot exceed 20% of the total number of days of hospice coverage provided to these persons.

House Bill

The Secretary would be required to establish a demonstration project of no more than 5 years in 3 hospice programs to deliver hospice care to Medicare beneficiaries in rural areas. Those Medicare beneficiaries who lack an appropriate caregiver and are unable to receive home-based hospice care would be able to receive hospice care in a facility of 20 or fewer beds that offers a full range of hospice services within its walls. The facility would not be required to offer services outside of the home and the limit on the aggregate number of inpatient days provided to Medicare beneficiaries who elect hospice care would be waived. The Secretary would be able to require the program to comply with additional quality assurance standards. Payments for the hospice care would be made at the rates that would be otherwise applicable to Medicare. Upon completion of the demonstration project, the Secretary would be required to submit a report to Congress, including recommendations, regarding the extension of the project to hospice programs serving rural areas.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a demonstration project in 3 hospice programs to deliver hospice care to Medicare beneficiaries in rural areas. A project is not permitted to last longer than 5 years. Those Medicare beneficiaries who lack an appropriate caregiver and are unable to receive home-based hospice care could receive hospice care in a facility of 20 or fewer beds that offers a full range of hospice services within its walls. The facility will not be required to offer services outside of the home. The limit on the aggregate number of inpatient days provided to Medicare beneficiaries who elect hospice care is waived under the demonstration. The Secretary may require the program to comply with additional quality assurance standards. Payments for the hospice care will be made at the rates that would be otherwise applicable to Medicare. Upon completion of the demonstration project, the Secretary is required to submit a report to Congress, including recommendations, regarding the extension of the project to hospice programs serving rural areas.

Establishment of Essential Rural Hospital Classification (Section 403 of the House Bill)**.**

Present Law

Under current law, a critical access hospital (CAH) is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH is exempt from Medicare's inpatient prospective payment system (IPPS) and receives reasonable cost reimbursement for care rendered to Medicare beneficiaries. Certain acute care general hospitals, particularly those facilities identified as isolated or essential hospitals primarily located in rural areas, receive special treatment under IPPS.

House Bill

The definition of CAH hospitals and services would be amended to add an essential rural hospital. An essential rural hospital would apply for such a classification, would have more than 25 licensed acute care beds, and would be located in a rural area as defined by IPPS. The Secretary would have to determine that the closure of this hospital would significantly diminish the ability of beneficiaries to obtain essential health care services based on the certain criteria. Specifically, the Secretary would determine that high proportion of Medicare beneficiaries residing in the service area of the hospital received basic inpatient care from the hospital; a hospital with more than 200 licensed beds would have to provide specialized surgical care to a high percentage of beneficiaries residing in the area who were hospitalized during the most recent year for which data are available. Regardless of the size of the hospital, almost all physicians in the area would have to have admitting privileges and provide their inpatient services primarily at the hospital. Also, the Secretary would have to determine the closure of the hospital would have a significant adverse impact on the availability of health care service in the absence of the hospital. In making such determination, the Secretary may also consider: (1) whether ambulatory care providers in the hospital's area are insufficient to handle the outpatient care of the hospital; (2) whether beneficiaries would have difficulty accessing care; and (3) whether the hospital has a significant commitment to provide graduate medical education in a rural area. The essential rural hospital would have to have a quality of care score above the median score for hospitals in the State. A hospital classified as an essential rural hospital would not be able to change such classification and would not be able to be treated as a sole community

hospital, Medicare dependent hospital or rural referral center under IPPS. A hospital that is classified as an essential rural hospital for a cost reporting period beginning on or after October 1, 2004 would be reimbursed 102% of its reasonable costs for inpatient and outpatient services provided by acute hospitals Beneficiary cost-sharing amounts would not be affected and required billing for such services would not be waived. The provision would apply to cost reporting periods beginning on or after October 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

Modification of the Isolation Test for Cost-Based CAH Ambulance Services (Section 405(c) of the House Bill and Section 405(b) of the Senate Bill).

Present Law

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

House Bill

The 35-mile requirement would not apply to the ambulance services that are furnished after the first cost reporting period beginning after the date of enactment by a provider or supplier of ambulance services who is determined by the Secretary to be a first responder to emergencies. This provision would apply to ambulance services furnished on or after the first cost reporting periods that begins after the date of enactment.

Senate Bill

The provision would drop the requirement that the CAH or the related entity be the only ambulance provider with a 35-mile drive in order to receive reasonable cost reimbursement for the ambulance services. The provision would apply to services furnished on or after January 1, 2005

Conference Agreement

No provision.

Exclusion of New CAHs from PPS Hospital Wage Index Calculation (Section 405(e) of the Senate Bill)**.**

Present Law

Certain qualified small hospitals are converting to CAHs. After conversion, these facilities are paid on a reasonable cost basis and are not paid under the hospital inpatient prospective payment system (IPPS). Medicare's IPPS payments to acute hospitals are adjusted by the wage index of the area where the hospital is located or has been reassigned. Although the hospital wage index is recalculated annually, the wage index for any given fiscal year is based on data submitted as part of a hospital's cost report from 4 years previously. As established by regulation, starting for FY2004 payments, wage data from hospitals that have converted to CAHs will be excluded in the IPPS wage index calculation.

House Bill

No provision.

Senate Bill

The Secretary would be required to exclude wage data from hospitals that have converted to CAHs from the IPPS wage index calculation starting for cost reporting periods on or after January 1, 2004. The provision would be effective upon enactment.

Conference Agreement

No provision.

Rural Community Hospital Demonstration Program (Section 410A of the Conference Report and Section 414 of the Senate Bill)**.**

Present Law

No provision

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year rural community hospital (RCH) demonstration program in 4 areas including Kansas and Nebraska that will pay for acute inpatient services, outpatient services, and certain home health services in qualifying hospitals either on the basis of its reasonable costs (without regard to the amount of customary charges) or using the respective prospective payment systems for those services. In this instance, reasonable cost reimbursement of capital costs would include a return on equity payment of 150% of the average rate of interest on obligations issued for purchase by the Federal Hospital Insurance (HI) Trust Fund.

Eligible rural hospitals would be those (1) located in counties that have not been assigned to metropolitan statistical areas or those urban hospitals that have been designated as rural; (2) with less than 51 acute inpatient beds (psychiatric and rehabilitation beds in distinct part units would not be counted); (3) offering 24-hour emergency care services; and (4) have a provider agreement in effect and is open to the public as of January 1, 2003. Critical access hospitals

would be able to participate in the demonstration. Entities with replacement facilities, obtaining a new provider number because of an ownership change, or with a binding agreement for the construction, reconstruction, lease, rental or financing of building on January 1, 2003 would not be prohibited from participating. A qualified-RCH based home health agency would be a provider based agency that is located in a county in which no main or branch office of another home health agency is located or is at least 35 miles from any main or branch office of another home health agency.

Consolidated billing associated with skilled nursing facilities would be permitted. The cost of Medicare beneficiaries' bad debt would be reimbursed at 100%. Beneficiary copayments for hospital outpatient services would established as under the hospital outpatient prospective payment system. No cost sharing would apply to clinical diagnostic laboratory services. The cost sharing amounts associated with other services would be established according to the payment methodology selected by the provider for the services in question. Funding for the demonstration project would be transferred in appropriate proportions from the HI and the Federal Supplementary Insurance trust funds. The Secretary would be required to ensure that aggregate payments under this demonstration program do not exceed what would have been spent if the program had not been implemented. The Secretary would be permitted to waive administrative, peer review as well as fraud and abuse requirements in Title 11 and other Medicare requirements in Title 18 of the Social Security Act. The Secretary would be required to submit a report including recommendations to Congress no later than 6 months after completion of the demonstration. The Secretary would be required to implement the demonstration no later than January 1, 2005, but not before October 1, 2004.

Conference Agreement

The Secretary is required to establish a demonstration program in rural areas to test. different payment methods for under 50 bed rural hospitals. The hospitals are paid their costs for inpatient and extended care (swing-bed) services for 5 years, subject to a cap. The payment methodology is similar to the Tefra payment system used for Children's hospitals. The hospitals cannot be eligible for the CAH program.

Critical Access Hospital Improvement Demonstration Program (Section 415 of the Senate Bill)**.**

Present Law

No provision

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year critical access hospital (CAH) demonstration program in 4 areas including Kansas and Nebraska to test various methods to improve the CAH program. Participating CAHs would be able maintain distinct part psychiatric and rehabilitation units of up to 10 beds that would not be counted toward the CAH-bed limit. These psychiatric and rehabilitation services would be paid on a reasonable cost basis (without

regard to the amount of customary charges). Home health agencies operated by participating CAHs would be able to opt out of the home health prospective payment system (PPS) and would be reimbursed on the basis of reasonable costs (without regard to the customary charge limit). Distinct part skilled nursing facilities (SNF) operated by a CAH would be exempt from SNF-PPS and would be reimbursed on the basis of reasonable costs (without regard to the customary charge limit). Consolidated billing associated with skilled nursing facilities would be permitted. In this instance reasonable cost reimbursement of capital costs associated with inpatient, outpatient, extended care, post-hospital extended care, home health, and ambulance services would include a return on equity payment of 150% of the average rate of interest on obligations issued for purchase by the Federal Hospital Insurance (HI) Trust Fund.

Eligible CAHs in the 4 demonstration areas would have to apply to participate in the demonstration project. Funding for the demonstration project would be transferred in appropriate proportions from the HI and the Federal Supplementary Insurance trust funds. The Secretary would be required to ensure that aggregate payments under this demonstration program do not exceed what would have been spent if the program had not been implemented. The Secretary would be permitted to waive administrative, peer review as well as fraud and abuse requirements in Title 11 and other Medicare requirements in Title 18 of the Social Security Act. The Secretary would be required to submit a report including recommendations to Congress no later than 6 months after completion of the demonstration. The Secretary would be required to implement the demonstration no later than January 1, 2005, but not before October 1, 2004.

Conference Agreement

No provision.

Increase in Payments for Certain Services Furnished by Small Rural Hospitals Under Medicare Prospective Payment System for Hospital Outpatient Department Services
(Section 424 in the Senate Bill)**.**

Present Law

Under the OPPS, which was implemented in August, 2000, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Beneficiary copayments are established as a percentage of Medicare's fee schedule payment and differ by APC. Certain hospitals, including rural hospitals with no more than 100 beds, are protected from financial losses that result from implementation of the new outpatient PPS under hold harmless provisions.

House Bill

No provision.

Senate Bill

The provision would increase Medicare payments for covered outpatient clinic and emergency room visits that are provided by rural hospitals with up to 100 beds on or after January 1, 2005 and before January 1, 2008. Applicable Medicare outpatient fee schedule amounts would be increased up by 5%. The beneficiary copayment amounts for these services would not be affected. The resulting increase in Medicare payments would not be considered as PPS

payments when calculating whether a rural hospital's PPS payments are less than its pre-BBA payment amounts under the temporary hold harmless provisions. Also, the budget-neutrality provisions for Medicare's outpatient PPS would not be applicable. Finally, these increased payments would not affect Medicare payments for covered outpatient services after January 1, 2007.

Conference Agreement

No provision.

Subtitle B-Provisions Relating to Part B Only

2-Year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services (Section 411 of the Conference Agreement, Section 407 of the House Bill, and Section 423 of the Senate Bill)**.**

Present Law

The prospective payment system (PPS) for services provided by outpatient departments (OPD) was implemented in August, 2000 for most acute care hospitals. Under the OPD PPS, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered OPD services because of hold harmless provisions. The hold harmless provisions apply to services provided before January 1, 2004.

House Bill

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be extended until January 1, 2006. The hold harmless provisions would be extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary would be required to conduct a study to determine if the costs, by APC groups, incurred by rural providers exceed those costs incurred by urban providers. If appropriate, the Secretary would provide a payment adjustment to reflect the higher costs of rural providers by January 1, 2005.

Senate Bill

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be extended until January 1, 2006. These hold harmless provisions would be extended to sole community hospitals located in rural areas for services provided in 2006.

Conference Agreement

The hold harmless provisions governing OPD reimbursement for small rural hospitals are extended until January 1, 2006. The hold harmless provisions are extended to sole community

hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary is required to conduct a study to determine if the costs, by APC groups, incurred by rural providers exceed those costs incurred by urban providers. If appropriate, the Secretary will provide for a payment adjustment to reflect the higher costs of rural providers by January 1, 2006.

Establishment of Floor on Work Geographic Adjustment (Section 412 of the Conference Agreement, Section 605 of the House Bill, and Section 421 of the Senate Bill)**.**

Present Law

Medicare's payment for physicians' services under a fee schedule has three components: the relative value for the service, geographic adjustment factors and a conversion factor into a dollar amount. A service's relative value is made up of a physician work component, a practice expense component, and a malpractice expense component. Each of these is then adjusted by a separate geographic adjustment factor and combined together to calculate an indexed relative value for that service provided in a given location. This locality adjusted relative value unit is multiplied by the conversion factor to calculate Medicare's payment for a service provided by a physician in a given area.

The geographic adjustment factors are indices that reflect the relative cost difference in a given area in comparison to the national average. An area with costs above the national average would have an index greater than 1.00; alternatively, an area with costs below the national average would have an index less than 1.00. The physician work geographic adjustment factor is based on a sample of median hourly earnings in six professional specialty occupational categories. Unlike the other geographic adjustments, the work adjustment factor reflects only one-quarter of the cost differences in an area. The practice expense adjustment factor is based on employee wages, office rents, medical equipments and supplies, and other miscellaneous expenses. The malpractice adjustment factor reflects differences in malpractice insurance costs.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

House Bill

For services furnished after January 1, 2004 and before January 1, 2006, the Secretary would be required to increase the value of any work geographic index that is below 1.00 to 1.00 unless the Secretary determines, based on the subsequent GAO study, that there is no sound economic rationale for such change. The provision would be effective upon enactment.

Senate Bill

For services furnished after January 1, 2004, the Secretary would be required to increase the value of any work geographic index that is below .980 to .980. The values for work index would be raised to 1.0 for services furnished in 2005, 2006, and 2007. The practice expense and malpractice geographic indices in low value localities areas would be raised to 1.00 for services furnished in 2005 through 2008.

Conference Agreement

The Secretary is required to increase the value of any work geographic index that is below 1.0 to 1.0 for services furnished on or after January 1, 2004 and before January 1, 2007.

Medicare Incentive Payment Program Improvements for Physician Scarcity (Section 413 of the Conference Agreement, Section 417 of the House Bill, and Section 422 of the Senate Bill)**.**

Present Law

Physicians providing services in a health professional shortage area (HPSA) are entitled to an incentive payment from the Medicare program. This incentive payment is a 10% increase over the amount which would otherwise be paid under the physician fee schedule. Physicians are responsible for indicating their eligibility for this bonus on their billing forms.

House Bill

This provision would establish a new five percent bonus payment program for physicians providing care to Medicare beneficiaries in physician scarcity areas. The Secretary would calculate two measures of scarcity. A primary care scarcity area would be determined based on the number of primary care physicians per Medicare beneficiary -- the primary care ratio. A specialty care scarcity area would be based on the number of specialty care physicians per Medicare beneficiary -- the specialty care ratio. The number of physicians would be based on physicians who actively practice medicine or osteopathy, and would exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The Secretary would rank each county or area based on its primary care ratio. Primary care scarcity counties or areas would be those counties or areas with the lowest primary care ratios, such that 20 percent of Medicare beneficiaries reside in these counties, when each county or area is weighted by the number of Medicare beneficiaries in the county or area. Specialty care scarcity counties or areas would be identified in the same manner, using the specialty care ratio. There would be no administrative or judicial review of the identification of counties or areas, or of a specialty of any physician.

To the extent feasible, the Secretary would treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

The Secretary would be required to publish a list of all areas which would qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The provision would also include improvement to the Medicare Incentive Payment Program, which provides a 10 percent bonus to physicians in shortage areas. The Secretary would be required to establish procedures under which the Secretary, and not the physician furnishing the service, would be responsible for determining when a bonus payment should be made. As part of the physician proposed and final rule for the physician fee schedule, the Secretary would be

required to include a list of all areas which would qualify as a health professional shortage area for the upcoming year.

Senate Bill

The Secretary would be required to establish procedures to determine when the physician is eligible for a bonus payment. The Secretary would also be required to (1) establish an ongoing program to educate physicians about the incentive program; (2) establish an ongoing study of the incentive program to determine whether beneficiaries' access to physician's services within the HPSA has improved; and (3) submit annual reports including appropriate recommendations for necessary administrative or legislative action concerning improvements to the program. GAO would be required to conduct an ongoing study of the MIP program on beneficiary access to services and submit a report, including appropriate recommendations, no later than 1 year from the date of enactment.

Conference Agreement

Additional Incentive Payment for Certain Physician Scarcity Areas (Section 413(a) of the Conference Agreement)**.**

The Conference Agreement establishes a new 5 percent incentive payment program designed to reward both primary care and specialist care physicians for furnishing services in the areas that have fewest physicians available to serve beneficiaries. The incentive payment will be made in counties accounting for 20 percent of Medicare beneficiaries, which is likely to represent more than 20 percent of counties. As with the current HPSA bonus program, the 5 percent bonus would be added to the amount that Medicare pays after deducting beneficiary cost sharing so that beneficiaries do not pay cost-sharing on the incentive payment.
The Secretary will calculate two measures of scarcity. A primary care scarcity area will be determined based on the number of primary care physicians per Medicare beneficiary -- the primary care ratio. A specialty care scarcity area will be based on the number of specialty care physicians per Medicare beneficiary -- the specialty care ratio. The number of physicians will be based on physicians who actively practice medicine or osteopathy, and will exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The provision requires identification of the county in which the service is furnished in order to apply to the bonus. Currently, it is the understanding of the Conferees that the address where the service is furnished, including the 5-digit zip code, is contained on the Medicare claim form. Since some zip codes cross county boundaries, the provision allows the Secretary to assign zip codes to counties based on the dominant county of the zip code as determined by the US Postal Service or otherwise. However, nothing would preclude, nor require, the Secretary ultimately to use 9-digit zip codes to determine the county in which the service is furnished. The provision requires periodic review and revision of the counties eligible for the bonus, but not less often than once every three years. To the extent feasible, the Secretary will treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

There will be no administrative or judicial review of the designation of the county or area as a scarcity area, the designation of an individual physician's specialty, the assignment of a physician to a county or the assignment of a postal zip code to the county or other area.

The Secretary will be required to publish a list of all areas which will qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The list of eligible counties will be published each year in the proposed and final rule implementing the physician fee schedule. The list of counties will be posted on the Internet website of the Centers for Medicare and Medicaid Services (CMS).

The new five percent bonus for physicians in either primary care scarcity counties or specialty care scarcity counties will increase financial incentives for physicians to provide care to Medicare beneficiaries in these areas with a shortage of physicians. This bonus payment will make it easier to recruit and retain physicians in these scarcity areas.

Improvement to Medicare Incentive Payment Program (Section 413(b) of the Conference Agreement)**.**

The Conference Agreement requires the Secretary to pay the current law 10 percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify that the services were furnished in such area. The implementation of the incentive payment will be the same as for the physician scarcity full county incentive payments, namely use of the 5 digit zip code with the dominant county of the zip code in cases where zip codes cross county boundaries. A physician will not need to report the HPSA modifier on the claim form for services furnished in full county HSPAs.

The Conference agreement does not contain a requirement to automate payment of incentive payments for services furnished in partial county HPSAs. However, the provision does not preclude the Secretary from automating payment in partial county HPSAs if the Secretary determines that it is feasible to do so based on information on the Medicare claim form.

The Conference Agreement requires the Secretary to develop a user friendly web site through which physicians may obtain information on partial county HPSAs to facilitate reporting of the modifier to identify the applicability of the incentive payment in partial county HPSAs. The provision requires that before the beginning of a calendar year the Secretary will identify the HPSAs for which the incentive payments will be made for such calendar year. Since HRSA designates HPSAs, HRSA will transmit to CMS the list of applicable HPSAs with enough lead time for CMS to implement the incentive payments for the following calendar year.

Improvements to the Medicare Incentive Program will shift responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary. A service furnished in a county that is both a full county HPSA and a scarcity county would receive both bonuses -- a total incentive payment of 15 percent.

GAO Study of Geographic Differences in Payments for Physicians' Services (Section 413(c) of the Conference Agreement, Section 413 of the House Bill, and Section 444 of the Senate Bill)**.**

Present Law

No provision.

House Bill

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; and (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, would be due to Congress within 1 year of enactment.

Senate Bill

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weighs for the malpractice component; (4) an evaluation of the economic basis for the floors on the geographic adjustments established previously in this legislation; (5) an evaluation of the effect of the geographic adjustments on physician retention, recruitment costs, physician mobility; (6) an evaluation of the appropriateness of extending such adjustment; (7) an evaluation of the adjustment of the work geographic practice cost index to reflect 1/4 the area cost difference in physician work; (8) an evaluation of the effect of the geographic practice cost index on physician location and retention in higher cost areas; and (9) an evaluation of the 1/4 adjustment of such an index. The study would include recommendations concerning use of more current data and use of cost data rather than price proxies. The study would be due to Congress within 1 year of enactment.

Conference Agreement

GAO will study payment differences under the physician fee schedule for different geographic areas, including: (1) an assessment of the validity of the geographic adjustment factors for each component of the fee schedule; (2) an evaluation of the measures used for such adjustment, including the frequency of revisions; (3) an evaluation of the method used to determine professional liability insurance costs including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weighs for the malpractice component; and (4) an evaluation of the effect of the physician work geographic adjustment as modified by this legislation on physician location and retention taking into account differences in recruitment costs and retention rates for physicians (including specialists) between large urban areas and other areas and the mobility of physicians over the last decade. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, is due to Congress within 1 year of the enactment date.

Payment for Rural and Urban Ambulance Services.

Phase-In Providing Floor Using Blend of Fee Schedule and Regional Fee Schedule (Section 414(a) of the Conference Agreement and Section 622 of the House Bill)**.**

Present Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 1997 provided for the establishment of a national fee schedule which was to implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002 with full implementation by January, 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

House Bill

Payments for ambulance services would be based on the ambulance specific amount blended with the national fee schedule amount or a combined rate of the national fee schedule and a regional fee schedule, whichever resulted in the larger payment. The blended rate during the phase-in period would incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions. Generally, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. For services provided in 2004, the blended rate would be based on 20% of the national fee schedule and 80% of the regional fee schedule; in 2005 blended rate would be based on a 40% national and 60% regional split; in 2006, the blended rate would be based on a 60% national and 40% regional split; in 2007, 2008 and 2009, the blended rate would be based on a 80% national and 20% regional split; and in 2010 and subsequently, the ambulance fee schedule would be based on the national fee schedule.

Senate Bill

No provision.

Conference Agreement

Payments for ambulance services will be based on the ambulance specific amount blended with either the national fee schedule amount or a combined rate of the national fee schedule and a regional fee schedule, whichever resulted in the larger payment. The blended rate during the phase-in period will incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions. Generally, the regional fee schedules will be based on the same methodology and data used to construct the national fee schedule. For 2004, starting for services on July 1, 2004, the blended rate is based on 20% of the national fee schedule and 80% of the regional fee schedule; for 2005, the blended rate is based on a 40% national and 60% regional split; in 2006, the blended rate is based on a 60% national and 40% regional split; in 2007, 2008 and 2009, the blended rate is based on a 80% national and 20% regional split; and in 2010 and subsequently, the ambulance fee schedule is based on the national fee schedule.

Adjustment in Payment for Certain Long Trips (Section 414(b) of the Conference Agreement and Section 622 of the House Bill)**.**

Present Law

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

Medicare's payments for ground ambulance services would be increased by one quarter of the amount otherwise established for trips longer than 50 miles occurring on or after January 1, 2004 and before January 1 2009. The payment increase would apply regardless of where the transportation originated. GAO would be required to submit an initial report to Congress on the access and supply of ambulance services in regions and states where ambulance payments are reduced by December 31, 2005. GAO would be required to submit a final report to Congress no later than December 31, 2007. The provision would apply to ambulance services furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

Medicare's payments for ground ambulance services will be increased by one quarter of the payment per mile rate otherwise established for trips longer than 50 miles occurring on or after July 1, 2004 and before January 1, 2009. The payment increase applies regardless of where the transportation originates.

Improvement in Payments to Retain Emergency Capacity For Ambulance Services in Rural Areas (Section 414(c) of the Conference Agreement and Section 410 of the House Bill)**.**

Present Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 1997 provided for the establishment of a national fee schedule which was to be implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002 with full implementation by January, 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

Starting for services provided January 1, 2004 the Secretary would be required to provide a percentage increase in the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area. The increase would be estimated using the average cost per trip for the base rate in the lowest quartile as compared to the average cost for the base rate in the highest quartile of all rural counties. A qualified rural county is a rural area (a county not assigned to a metropolitan statistical area) with a population density of Medicare beneficiaries in the lowest quartile of all rural counties.

Senate Bill

No provision.

Conference Agreement

The Secretary will provide a percentage increase in the base rate of the fee schedule for ground ambulance services furnished on or after July 1, 2004 and before January 1, 2010 that originate in a qualified rural area. The payment increase is estimated using the average cost per trip for the base rate (not taking into account mileage) in the lowest quartile as compared to the average cost for the base rate (not taking into account mileage) in the highest quartile of all rural counties. The Secretary will determine the population density for each rural area using 2000 Census data and rank each county accordingly. The qualified rural areas are those with the lowest population densities that collectively represent a total of 25% of the population in those areas. To the extent feasible, the Secretary is required to treat certain rural census tracts in metropolitan statistical areas as a rural area. There will be no administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise with respect to the identification of a qualified rural area. In order to promptly implement this provision, the Secretary may use data furnished by GAO.

Temporary Increase for Ground Ambulance Services (Section 414(d) of the Conference Agreement and Section 425 of Senate Bill)**.**

Present Law

The ambulance fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

No provision

Senate Bill

The payments for ground ambulance services originating in a rural area or a rural census tract would be increased by 5% for services furnished on or after January 1, 2005 through December

31, 2007. The fee schedule for ambulances in other areas would be increased by 2%. These increased payments would not affect Medicare payments for covered ambulance services in subsequent periods. The conversion factor for ambulance services would not be adjusted downward because of the Secretary's evaluation of the prior year's conversion factor.

Conference Agreement

The payments for ground ambulance services originating in a rural area or a rural census tract will be increased by 2% (after application of the long trip and low density payment increases) for services furnished on or after July 1, 2004 through December 31, 2007. The fee schedule for ambulances in other areas (after application of the long trip adjustment) will increase by 1%. These increased payments will not affect Medicare payments for covered ambulance services after 2007.

Implementation, GAO Report on Costs and Access, and Technical Amendments (Section 414(e)-(g) of the Conference Agreement)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The Secretary is able to implement the amendments made by Section 414 and revisions to the conversion factor on an interim, final basis or by program instruction. GAO is required to submit an initial report to Congress on cost differences among different types of ambulance providers, and the impact of payment reductions in the ambulance fee schedule on access, supply, and quality of ambulance services in regions and states with such reductions. Other technical amendments will also be adopted.

Providing Appropriate Coverage of Rural Air Ambulance Services (Section 415 of the Conference Agreement and Section 426 in the Senate Bill)**.**

Present Law

Medicare pays for ambulance services under a fee schedule. Seven categories of ground ambulance services, ranging from basic life support to specialty care transport, and two categories of air ambulance services are established. Payment for ambulance services can only be made if other methods of transportation are contraindicated by the patient's medical conditions, but only to the extent provided in regulations.

House Bill

No provision.

Senate Bill

The regulations governing ambulance services would be required to ensure that air ambulance services be reimbursed if: (1) the air ambulance service is medically necessary based on the health condition of the patient being transported at or immediately prior to the time of the transport service; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary. An air ambulance service would be considered medically necessary when requested: (1) by a physician or hospital in accordance with their responsibilities under the Emergency Medical Treatment and Active Labor Act; (2) as a result of a protocol established by a state or regional emergency medical service agency; (3) by a physician, nurse practitioner, physician assistant, registered nurse, or emergency medical responder who reasonably determines or certifies that patient's condition is such that the time involved in land transport significantly increases the patient's medical risks; or (4) by a Federal or State agency to relocate patients following a natural disaster, an act of war, or a terrorist act. Air ambulance services would be defined as a fixed wing or rotary wing air ambulance services. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

The regulations governing the use of ambulance services will provide that to the extent that any ambulance service (whether ground or air) may be covered, a rural air ambulance service will be at the air ambulance rate if: (1) the air ambulance service is reasonable and necessary based on the health condition of the patient being transported at or immediately prior to the time of the transport service; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary. An air ambulance service is considered reasonable and necessary when requested: (1) by a physician or other qualified medical personnel who reasonably determines or certifies that an individual's condition is such that the time needed to transport the individual by land or the instability of land transportation poses a threat to the individual's survival or seriously endangers the individual's health or (2) such services is furnished pursuant to a protocol under which the use of an air ambulance is recommended that is established by a state or regional emergency medical services (EMS) agency and recognized or approved by the Secretary. The EMS agency cannot have an ownership interest in the entity furnishing such service. Also, there cannot be a financial or employment relationship or a common ownership arrangement between the person requesting the rural air ambulance service and the furnishing entity or a financial relationship between an immediate family member of such requester and such an entity. This prohibition does not apply to instances when a hospital and an entity furnishing the rural air ambulance services are under common ownership if remuneration (through employment or other relationship) is for provider based physician services furnished in a hospital which are reimbursed under Part A and is unrelated directly or indirectly to the provision of rural air ambulance services. A rural air ambulance service is defined as a fixed wing or rotary wing air ambulance service where the individual's point of pick up is in a rural area or rural census tract. The provision applies to services furnished on or after January 1, 2005.

Treatment of Certain Clinical Diagnostic Laboratory Tests Furnished To Hospital Outpatients in Certain Rural Areas (Section 416 of the Conference Agreement and Section 427 of the Senate Bill)**.**

Present Law

Generally, hospitals that provide clinical diagnostic laboratory tests under Part B are reimbursed using a fee schedule. Sole community hospitals (SCHs) that provide some clinical diagnostic tests 24 hours a day qualify for a 2% increase in the amounts established in the outpatient laboratory fee schedule; no beneficiary cost-sharing amounts are imposed.

House Bill

No provision.

Senate Bill

SCHs that provide clinical diagnostic laboratory tests covered under Part B in 2005 and 2006 would be reimbursed their reasonable costs of furnishing the tests. No beneficiary cost sharing amounts would apply to these services.

Conference Agreement

Hospitals with under 50 beds in qualified rural areas (low density population rural areas established under Section 414(c) of this legislation) will receive 100% reasonable cost reimbursement for clinical diagnostic laboratory tests covered under Part B that are provided as outpatient hospital services. The Secretary will apply the rules that determine whether clinical diagnostic laboratory tests are furnished as an outpatient critical access hospital service to establish whether these clinical diagnostic laboratory tests are outpatient hospital services. The provision will apply to services furnished during a cost reporting period beginning during the 2-year period starting July 1, 2004.

Extension of the Telemedicine Demonstration Project (Section 417 of the Conference Agreement and Section 415 of the House Bill)**.**

Present Law

BBA 1997 established a single 4-year demonstration project where an eligible health care provider telemedicine network would use high-capacity computer systems and medical infomatics to improve primary care and prevent health complications in Medicare beneficiaries with diabetes mellitus. The Informatics, Telemedicine, and Education Demonstration project uses modified home computers or home telemedicine units linked to clinical information systems to assist beneficiaries residing in medically under-served rural or medically under-served inner-city areas, interaction with a nurse case manager, video conferencing, and access to health information and medical data, in both Spanish and English. The demonstration will expire in February 2004.

House Bill

The demonstration project would be extended for 4 years and total funding would be increased from $30 million to $60 million. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The demonstration project is extended for 4 years and total funding will be increased from $30 million to $60 million. The provision will be effective upon enactment.

Report on Demonstration Project Permitting Skilled Nursing Facilities to Be Originating Telehealth Sites (Section 418 of the Conference Agreement and Section 450H of the Senate Bill)**.**

Present Law

Medicare will pay for use of certain telecommunications systems as a substitute for face-to-face encounters to provide consultations, office or other outpatient visits, individual psychotherapy and pharmacologic management services to eligible beneficiaries. With certain exceptions, Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area or in a county that is not in a metropolitan statistical area. An originating site is the location of the beneficiary at the time the services being furnished by the telecommunications system occurs. Originating sites defined in statute include the office of a physician or practitioner, a hospital, a critical access hospital, a rural health clinic or a federally qualified health center.

House Bill

No provision.

Senate Bill

This provision would add types of providers to the list of originating sites that can bill Medicare for telehealth services. The additional providers are both those defined by the statute and those that would be defined by the Secretary. Providers defined in the statute are: a skilled nursing facility (1918(a)), a community mental health center (1861(ff)(2)(B)), and a facility operated by the Indian Health Service or by an Indian tribe, tribal organization, or an urban Indian organization (as defined in Senate Section 4 of the Indian Health Care Improvement Act). Providers that would be defined by the Secretary are: an assisted-living facility, a board-and-care home, a county of community health clinic, and a long-term care facility (as defined by the Secretary.) In addition, the Secretary would be required to encourage and facilitate the adoption of State provisions allowing for multi-state practitioner licensure across State boundaries. The provision would be effective upon enactment.

Conference Agreement

The Secretary will evaluate a demonstration project under which a skilled nursing facility is treated as an originating site for telehealth services. The Secretary will delegate the evaluation to the Administrator of the Health Resources and Services Administration who will consult with the Administrator for the Centers for Medicare & Medicaid Services. No later than January 1, 2005, the Secretary will submit a report to Congress on the evaluation including recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for

the use of telehealth services or any other services delivered via a telecommunications system does not substitute for in-person required visits furnished by physicians, physician assistants, nurse practitioners or clinical nurse specialists at specified intervals as required by the Secretary. If the Secretary concludes that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services, and the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits, the Secretary may deem a skilled nursing facility to be an originating site beginning on January 1, 2006.

Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities (Section 410 of the Conference Report and 408 of the House Bill and Section 429 of the Senate Bill)**.**

Present Law

Under Medicare's prospective payment system (PPS), skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment will vary depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF-PPS and paid separately under Part B.

House Bill

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004.

Senate Bill

Services provided by a rural health clinic (RHC) and a federally qualified health center (FQHC) after January 1, 2005 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. Outpatient services that are beyond the general scope of SNF comprehensive care plans that are provided by an entity that is 100% owned as a joint venture by two Medicare-participating hospitals or critical access hospitals would be excluded from the SNF-PPS. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004

Improvement in Rural Health Clinic Reimbursement (Section 428 in the Senate Bill)**.**

Present Law

BBA 1997 extended the per visit payment limits that had existed for independent rural health clinics to provider-based rural health clinics (RHC) except for those clinics based in small rural hospitals with fewer than 50 beds. For services rendered from January 1, 2003 through February 28, 2003, the RHC upper payment limit is $66.46, which reflects a 2.6% increase in 2002 payment limit as established by the 2002 Medicare Economic Index (MEI). For services rendered from March 1, 2003 through December 31, 2003, the Medicare RHC upper payment limit is $66.72, which reflects a 3.0% increase in the 2002 payment limit as established by in the 2003 MEI. The 2002 MEI was used as an update for 3 months because the delayed implementation of the 2003 MEI.

House Bill

No provision.

Senate Bill

The RHC upper payment would be increased to $80.00 for calendar year 2005. The MEI applicable to primary care services would be used to increase the payment limit in subsequent years. The provision would be effective upon enactment.

Conference Agreement

No provision.

Frontier Extended Stay Clinic Demonstration Project (Section 434 of the Conference Report and Section 457/Duplicative Provision 460 of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to conduct a demonstration project that would treat frontier extended stay clinics as a Medicare provider. A frontier extended stay clinic is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road. Such clinics are designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or patients who need monitoring and observation for a limited period of time. The provision would be effective upon enactment.

Conference Agreement

The Secretary would be required to conduct a demonstration project that would treat frontier extended stay clinics as a Medicare provider. A frontier extended stay clinic is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road and is designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or patients who need monitoring and observation for a limited period of time. The Secretary is required to develop life safety code standards for these clinics such as sprinkler system because the patients stay overnight. The provision would be effective upon enactment and is budget neutral.

Subtitle C-Provisions Relating To Parts A and B

1-Year Increase for Home Health Services Furnished in a Rural Area (Section 421 of the Conference Agreement, Section 411 of the House Bill, and Section 451 of the Senate Bill)**.**

Present Law

The Medicare home health PPS which was implemented on October 1, 2000 provides a standardized payment for a 60-day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10% for home health services furnished in the home of beneficiaries living in rural areas during the 2-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

House Bill

The provision would extend a 5% additional payment for home health care services furnished in a rural area during FY2004 and FY2005 without regard to certain budget-neutrality requirements. The provision would be effective upon enactment.

Senate Bill

The provision would provide a temporary payment increase of 5% for home health care services furnished in a rural area on or after October 1, 2004 and before October 1, 2006 without regard to certain budget-neutrality requirements. The temporary additional payment would not be considered when determining future home health payment amounts. The provision would be effective upon enactment.

Conference Agreement

The conference agreement provides a 1-year, 5% additional payment for home health care services furnished in a rural area without regard to certain budget-neutrality requirements. The temporary additional payment begins for episodes and visits ending on or after April 1, 2004 and before April 1, 2005 and is not to be used in calculating future home health payment amounts.

Redistribution of Unused Resident Positions (Section 422 of the Conference Agreement and Section 406 of the House Bill)**.**

Present Law

Medicare has different resident limits for counting residents in its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed Prior to BBA 1997, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare DGME payment to a teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period. Residents who are graduates from foreign medical schools do not count unless they pass certain exams.

Generally, the resident counts for both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. It may differ from the IME limit because in 1996 residents training in non-hospital sites were eligible for DGME payments but not for IME payments. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and nonrural hospitals operating training programs in rural areas) can be paid for 130% of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a 3-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years. The rolling average calculation includes podiatry and dental residents.

House Bill

A teaching hospitals total number of Medicare-reimbursed resident positions would be reduced for cost reporting periods starting January 1, 2004 if its resident reference level is less than its applicable resident limit. If so, the reduction would equal 75% of the difference between the hospitals limit and its resident reference level. The resident reference level would be the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. A hospitals reference period would be the 3 most recent consecutive cost reporting periods for which a hospitals cost reports have been settled (or in the absence of such settled cost reports, submitted reports) on or before September 30, 2002. The Secretary would be able to adjust a hospitals resident reference level, upon the timely request for such an adjustment, for the cost reporting period that includes July 1, 2003.

The Secretary would be authorized to increase the applicable resident limits for hospitals by an aggregate number that does not exceed the overall reduction in such limits. No increase would be permitted for any portion of cost reporting period that occurs before July 1, 2004 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital applied for such an increase by December 31, 2005. The Secretary would consider the need for an increase in the physician specialty and the location involved. The Secretary would first distribute the increased resident count to programs in hospitals located in rural areas and hospitals that are not in large urban areas on a first-come-first-served basis. The hospital would have to demonstrate that the resident positions would be filled; not more than 25 positions would be given to any hospital. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospitals resident count established under this section would affect a hospitals IME adjustment. These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs. The Secretary would be required to submit a report to Congress no later than July 1, 2005 on whether to extend the application deadline for increases in resident limits. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

A teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005 if its reference resident level is less than its applicable resident limit. Rural hospitals with less than 250 acute care inpatient beds would be exempt from such reductions. For other such hospitals, the reduction will equal 75% of the difference between the hospital's limit and its reference resident level. The resident reference level is the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. This reference level is the either (1) the resident level of the most recent cost reporting period of the hospital for which a cost report has been settled (or submitted, subject to audit) on or before September 30, 2002 or (2) the resident level for the cost reporting period that includes July 1, 2003, if requested on a timely basis by the hospital subject to audit. Upon this timely request at the discretion of the Secretary, a hospital's reference level will be adjusted to include the number of medical residents for the cost reporting period that includes July 1, 2003. Upon timely request of the hospital, the Secretary will adjust the reference resident level to include the number of medical residents that were approved in an application to the appropriate accrediting organization before January 1, 2002 if the program was not in operation by the cost reporting period in question (either September 30, 2002 or July 1, 2003 depending upon the hospital's circumstances and the Secretary's approval). The reduction will apply to hospitals that are members of the same affiliated group as of July 1, 2003.

The Secretary is authorized to increase the applicable resident limits for hospitals for portions of cost reporting periods occurring on or after July 1, 2005 by an aggregate number that does not exceed the overall reduction in such limits. The Secretary will take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005 when determining which hospitals would receive an increase in their resident levels. The Secretary will establish a priority order to distribute the

increased resident count first to programs in hospitals located in rural areas, then to hospitals that are not in large urban areas and finally to other hospitals in a state where there is no other training program for a particular specialty. The Secretary shall consider giving special consideration to hospitals that train a large share of graduates from historically large medical colleges. Increases to limits with the same priority category will be determined by the Secretary. Not more than 25 additional FTEs will be given to any hospital. These hospitals will be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospital's resident count established under this section will affect a hospital's IME adjustment; the IME adjustment will be calculated as if "c" is equal to 0.66 for these additional positions starting for discharges after July 1, 2005. These provisions will not apply to reductions in residency programs that occurred as part of the voluntary reduction program or will not affect the ability of certain hospitals to establish new medical residency training programs. The Secretary is required to submit a report to Congress no later than July 1, 2005 on whether to extend the application deadline for increases in resident limits. Requirement with respect to Federal information policy established by Chapter 35 of Title 44, United States Code will not apply to applications under this section.

Subtitle D-Other Provisions

Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations (Section 431 of the Conference Agreement and Section 412 of the House Bill)**.**

Present Law

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate directly or indirectly to induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

House Bill

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) resulted in savings of Federal grant funds or increased revenues to the health center; (2) expanded or limited a patient's freedom of choice; and (3) protected a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the *Federal Register* no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) results in savings of Federal grant funds or increased revenues to the health center; (2) expands or limits a patient's freedom of choice; and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish a final regulation establishing these standards no later than 1 year from the date of enactment.

Office of Rural Health Policy Improvement (Section 432 of the Conference Agreement and Section 637 of the Senate Bill)**.**

Present Law

Within the Department of Health and Human Services, the Office of Rural Health Policy advises the Secretary on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in Medicare and Medicaid program on the financial viability of small rural hospitals, the ability of rural areas to attract and retain physicians and other health professionals, and access to and the quality of health care in rural areas. In addition to advising the Secretary, the Office has other responsibilities including coordinating the activities within HHS that relate to rural health care.

House Bill

No provision.

Senate Bill

The list of explicit responsibilities of the Office is expanded to include administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. The provision would be effective upon enactment.

Conference Agreement

The functions of the Office of Rural Health Policy will be expanded; it will be authorized to administer grants, cooperative agreements, and contracts to provide technical assistance and other necessary activities to support activities related to improving rural health care. The provision is effective on enactment.

MedPAC Study on Rural Payment Adjustments (Section 433 of the Conference Agreement)**.**

Present Law

No provision.

House Bill

No provision

Conference Agreement

MedPAC will study the effect on specified rural provisions in this legislation (specifically, Sections 401 through 405, 411, 416, and 504) including total payments, growth in costs, capital spending and other payment factors. An interim report on changes to the critical access hospital program (in Section 405) is due to Congress no later than 18 months from the date of enactment. MedPAC's final report on all topics is due to Congress no later than 3 years from the date of enactment.

TITLE V-PROVISIONS RELATING TO PART A

Subtitle A-Inpatient Hospital Services

Revision of Acute Hospital Payment Updates (Section 501(a) and 501(b) of the Conference Agreement and Section 501 of the House Bill)**.**

Present Law

Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket (MB). Congress establishes the update for Medicare's inpatient prospective payment system (IPSS) for operating costs, often several years in advance. Currently, acute hospitals will receive the MB as an update for FY2004 and subsequently. CMS has asked hospital to report on 10 JCAHO/ CMS measures, developed by the National Quality Foundation. For example, whether a patient with an acute myocardial infarction receives aspirin at arrival. As of October 9, 2003, 420 hospitals (out of the over 5,000 acute care hospitals that bill Medicare) had provided CMS with one of more measures.

House Bill

Acute hospitals would receive an operating update of the MB minus 0.4 percentage points for FY2004 through FY2006. The operating update would be the MB increase in FY2007 and subsequently. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

An acute hospital will receive an operating update of the MB in FY2004. An acute hospital will receive an operating update of the MB from FY2005 through FY2007 if it submits data on the 10 quality indicators established by the Secretary as of November 1, 2003. The Secretary will specify the form, manner, and time of the data submission except that any data collection and editing must be done before the start of the fiscal year. For FY2005, the Secretary will provide for a 30-day grace period for the submission of the required data. A hospital that does not submit data to the Secretary will receive an update of the MB minus 0.4 percentage points for the fiscal year in question. The Secretary will not take into account this reduction when computing the applicable percentage increase in subsequent years.

The Secretary is directed to compile and clarify the procedures and policies for billing for blood and blood costs in the hospital inpatient and outpatient settings as well as the operation of the collection of the blood deductible.

Inpatient rehabilitation facilities (IRF) provide Medicare patients with rehabilitation services. They are distinguished from acute care settings by a number of criteria including that 75 percent of their cases must be in ten categories – stroke, spinal cord injury, congenital deformity,

amputation, major multiple trauma, fracture of femur, brain injury, and polyarthritis, including rheumatoid arthritis, neurological disorders, and burns. This criterion is commonly referred to as the "75 percent rule."

On September 2, 2003, CMS issued proposed changes in classifying IRFs. The Conferees are concerned that the rule, as written, would have severe consequences for access to inpatient rehabilitation hospital services. The Conferees concur with the Medicare Payment Advisory Commission (MedPAC) finding that further analysis should be conducted to identify which conditions are clinically appropriate for inclusion in the calculation of the 75 percent rule used to determine eligibility for reimbursement under the inpatient rehabilitation facility prospective payment system. The Conferees direct the GAO to issue a report, in consultation with experts in the field of physical medicine and rehabilitation to look at whether the current list of conditions represents a clinically appropriate standard for defining IRF services and, if not, which additional conditions should be added to the list. During the study period, the Committee urges the Secretary to delay implementation of the rule and not accept new IRF applications until the report is finished.

GAO Study and Report on Appropriateness of Payments Under the Prospective Payment System for Inpatient Hospital Services (Section 501(c) of the Conference Agreement and Section 413 of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

GAO would be required to use the most current data available to conduct a study to determine (1) the appropriate level and distribution of Medicare payments in relation to costs to short-term general hospitals under the inpatient prospective payment system (IPPS) and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs across geographic areas, kinds of hospitals, and types of cases. The study, including recommendations for necessary legislative and administrative action, would be due to Congress within 18 months of enactment.

Conference Agreement

GAO is required to use the most current data available to conduct a study to determine (1) the appropriate level and distribution of Medicare payments in relation to costs for short-term general hospitals under the inpatient prospective payment system (IPPS) and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs across geographic areas, kinds of hospitals, and types of cases. The study, including recommendations for necessary legislative and administrative action, is due to Congress within 24 months of enactment.

Revision of the Indirect Medical Education (IME) Adjustment Percentage (Section 502 of the Conference Agreement and Section 418 of the Senate Bill)**.**

Present Law

A hospital's IME payment to a hospital is based on a percentage add-on to the PPS rate that is established by a curvilinear formula that currently provides a payment increase of approximately 5.5% for each 10% increase in the hospital's intern and resident-to-bed (IRB) ratio. The following formula is multiplied by a hospital's base payment rate for each Medicare discharge to determine the IME payment: $1.35 \text{ X } [(1+ \text{IRB})^{0.405} - 1]$. The multiplier of 1.35 increases the level of the IME adjustment to the existing target level of 5.5%. Congress has periodically changed the multiplier (or "c") to decrease or increase IME payments to teaching hospitals.

House Bill

No provision.

Senate Bill

The IME multiplier in 2004 and in 2005 would be 1.36; on or after 2005, the multiplier would be 1.355. This would increase payments to teaching hospitals by $300 million over 10 years. The provision would apply to discharges on or after October 1, 2003.

Conference Agreement

From April 1, 2004 until September 30, 2004, the IME multiplier is equal to 1.47; during FY2005, the IME multiplier is 1.42; during FY2006, the IME multiplier is 1.37; during FY2007, the IME multiplier is 1.32; and, starting October 1, 2007, the IME multiplier is equal to 1.35.

Recognition of New Medical Technologies Under Inpatient Hospital Prospective Payment System (Section 503 of the Conference Agreement and Section 502 of the House Bill)**.**

Current Law

BIPA established that Medicare's inpatient hospital payment system should include a mechanism to recognize the costs of new medical services and technologies for discharges beginning on or after October 1, 2001. The additional hospital payments can be made by the means of a new technology groups, an add-on payment, a payment adjustment, or other mechanism, but cannot be a separate fee schedule and must be budget-neutral. A medical service or technology will be considered to be new if it meets criteria established by the Secretary after notice and the opportunity for public comment. The Centers for Medicare and Medicaid (CMS) published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes. (ICD-9-CM codes). The regulation also established that technology that provided a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis related group (DRG) payment was inadequate; this threshold, which was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50% of the costs of the new technology or (b) 50% of the amount by which the costs exceeded the standard DRG payment; however if the new technology payments are estimated to exceed the budgeted target amount of 1% of the total operating inpatient payments, the add-on payments are reduced prospectively.

House Bill

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year but would not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. The Secretary would not be able to deny a service or technology treatment as a new technology because the service (or technology) has been in use prior to the 2-to-3 year period before it was issued a billing code and a sample of specific discharges where the service has been used can be identified. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is the lesser of 75% of the standardized amount (increased to reflect the difference between costs and charges) or 75% of one standard deviation for DRG involved. The Secretary would be required to provide additional clarification in regulation on the criteria used to determine whether a new service represents an advance in technology that substantially improves the existing diagnosis or treatment. The Secretary would be required to deem that a technology provide a substantial improvement on an existing treatment if the technology in question is a drug or biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of Title 21, Code of Federal Regulations, designated for priority review when the marketing application was filed, is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority or expedited review has been provided under section 515(d)(5). For other technologies that may be substantial improvements, the Secretary would be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments recommendations and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions would occur prior to the publication of the proposed regulation. Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary would be directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights would not be affected. The Secretary would be required to increase the percentage associated with add-on payments from 50% to the marginal rate or percentage that Medicare reimburses inpatient outlier cases. The provisions would not affect the Secretary's authority to determine whether services are medically necessary and appropriate. Funding for this new technology would no longer be budget neutral.

The Secretary would be required to implement these provisions to new technology determinations beginning in FY2005. The Secretary would be required to automatically reconsider an application as a new technology that was denied for FY2004 as an application under these new provisions. If such an application is granted, the maximum time period otherwise permitted for such classification as a new technology would be extended by 12 months.

Senate Bill

No provision.

Conference Agreement

The Secretary is required to add new diagnosis and procedure codes in April 1 of each year but is not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is the lesser of 75% of the standardized amount (increased to reflect the difference between costs and charges) or 75% of one standard deviation for the DRG involved. The Secretary should collect at least 2 years of data before incorporating the technology into a permanent group. The Secretary is be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments recommendations and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions will occur prior to the publication of the proposed regulation. Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary is directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary will assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights will not be affected. The Secretary should consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier. Funding for new technology will no longer be budget neutral.

The Secretary is required to implement these provisions to new technology determinations beginning in FY2005. The Secretary is required to automatically reconsider an application as a new technology that was denied for FY2005 as an application under these new provisions. If such an application is granted, the maximum time period otherwise permitted for such classification as a new technology is extended by 12 months.

Increase in Federal Rate for Hospitals in Puerto Rico (Section 504 of the Conference Agreement, Section 503 of the House Bill, and Section 409 of the Senate Bill)**.**

Present Law

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25% of the federal national amount and 75% of the local amount to a blended amount based on a 50/50 split between national and local amounts.

House Bill

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004 though FY2007, an increasing amount of the payment rate would be based on federal national rates as follows: during FY2004,

payment would be 59% national and 41% local; this would change to 67% national and 33% local during FY2005 and 75% national and 25% local during FY2006 and subsequently.

Senate Bill

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between national and local amounts until September 30, 2003. These hospitals would receive Medicare payments based on 100% of the federal rate for discharges on or after October 1, 2004 and before October 1, 2009. The rate for hospitals Puerto Rico would revert to a 50/50 split after October 1, 2009.

Conference Agreement

Hospitals in Puerto Rico will receive Medicare payments based on a 50/50 split between federal and local amounts before April 1, 2004. Starting April 1, 2004 through September 30, 2004, payment will be based on 62.5% national amount and 37.5% local amount; this will change to 75% national and 25% local after October 1, 2004 and in subsequent years.

Wage Index Adjustment Reclassification Reform (Section 505 of the Conference Agreement and Section 504 of the House Bill)**.**

Present Law

Unlike other providers, acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity for purposes of using the other area's wage index. If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services.

Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. This proximity can be established if one of two conditions is met: (1) an urban hospitals must be no more than 15 miles and a rural hospital must be no more than 35 miles from the area where it wants to be reclassified; or (2) at least 50% of the hospital's employees reside in the area. A rural referral center (RRC) or a sole community hospital (SCH) or a hospital that is both a RRC and a SCH does not have to meet the proximity test. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area under established criteria. To use an area's wage index, a rural hospital must demonstrate that its average hourly wage is equal to at least 82% of the average hourly wage of hospitals in the area to which it seeks redesignation; an urban hospital must demonstrate that its average hourly wage is at least 84% of such an area. Also an urban hospital cannot be reclassified unless average hourly wage is at least 108% of the average hourly wage of the area in which it is located; this standard is 106% for rural hospitals seeking reclassification to an area.

For redesignations starting in FY2003, the average hourly wage comparisons used to determine whether a hospital can use another area's wage index are based on 3 years worth of lagged data submitted by hospitals as part of their cost report. For instance, FY2003 wage index reclassifications were based on weighted 3-year averages of average hourly wages using data

from FY1997, FY1998, and FY1999 cost reports. Wage index reclassifications are effective for 3 years unless the hospital notifies the MCGRB and withdraws or terminates its reclassification.

House Bill

The Secretary would be required to establish an application process and payment adjustment to recognize the commuting patterns of hospital employees. A hospital that qualified for such a payment adjustment would have average hourly wages that exceed the average wages of the area in which it is located and have at least 10% of its employees living in 1 or more areas that have higher wage index values. This qualifying hospital would have its wage index value increased by the percentage of its total employees who live in any area with a higher wage index value. The process would be based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment would be effective for 3 years unless a hospital withdraws or elects to terminate its payment. A hospital that receives a commuting wage adjustment would not be eligible for reclassification into another area by the MCGRB. These commuting wage adjustments would not affect the computation of the wage index of the area in which the hospital is located or any other area. It would also be exempt from certain budget neutrality requirements. The provisions would apply to discharges on or after October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The Secretary is required to establish a process and payment adjustment to recognize the out-migration of hospital employees who reside in a county and work in different area with a higher wage index. A hospital that receives such a payment adjustment will be located in a qualifying county that meets criteria established by the Secretary. This criteria will include (1) a threshold percentage of the weighted average of the area wage index or indices for the higher wage index areas; (2) a threshold of not less than 10 percent for minimum out-migration to a higher wage index area or areas and (3) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area where the county is located. A qualifying hospital will have its wage index value increased by the percentage of the hospital employees residing in the qualifying county who are employed in any area with a higher wage value. The adjustment will equal the sum of the products of the difference between the wage index value of any higher wage area and the qualifying county multiplied by the number of hospital employee who reside in the qualifying county but are employed in any higher wage index area. The application process for this adjustment is based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment is effective for 3 years unless a hospital withdraws or elects to terminate its payment. The Secretary may require acute hospitals and other hospitals as well as critical access hospitals to submit data regarding the location of their employee's residence or the Secretary may use data from other sources. A hospital that receives a commuting wage adjustment is not eligible for reclassification into another area by the MCGRB. The commuting wage adjustment does not affect the computation of the wage index of the area in which the hospital is located or any other area. It is also be exempt from certain budget neutrality requirements. The thresholds and other qualifying criteria for the commuting wage adjustment is not subject to judicial review. The provisions apply to discharges on or after October 1, 2004. In initially implementing this

adjustment, the Secretary may modify the deadlines otherwise applicable to data submission and actions on applications for geographic reclassification.

Limitation on Charges for Inpatient Hospital Contract Health Services Provided to Indians by Medicare Participating Hospitals (Section 506 of the Conference Agreement and Section 412 of the Senate Bill)**.**

Present Law

The Indian Health Service (IHS) provides health care both directly, through tribes and tribal consortia, and through urban Indian organizations. The Indian Health Care Improvement Act (P.L. 94-437) authorized IHS to collect directly from Medicare, Medicaid, and other third party insurers for health services covered by those programs. In addition to care provided directly from IHS and tribal providers, contract health services are purchased by IHS and the tribes from more than 2,000 private providers, if the local facility is unable to provide the needed care. These health services are provided principally for members of tribes who live in contract health service delivery areas. Contract support funding across all IHS programs has been insufficient to cover all IHS and tribal costs. When the costs are not reimbursed through appropriations, the tribes and IHS use program funds to make up the difference.

House Bill

No provision.

Senate Bill

The amendment would prohibit hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Services from charging more than the Medicare established rates for these services. This provision would apply to contract health services programs operated by the Indian Health Service, an Indian tribe or tribal organization or an urban Indian organization. The provision would apply to Medicare participation agreements in effect or entered into by a date specified by the Secretary. In no case would this provision be applicable later than 6 months from the date of enactment.

Conference Agreement

Hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Services and operated by the Indian Health Service, an Indian tribe, an Indian tribal organization, or an urban Indian organization will be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payments. This will include the requirement to accept these rates as payment in full. This provision will apply to Medicare participation agreements in effect or entered into by a date specified by the Secretary. In no case will this date be later than 1 year after the date of enactment.

Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals (Section 507 of the Conference Agreement, Section 505 of the House Bill and Section 453 of the Senate Bill)**.**

Present Law

Physicians are generally prohibited from referring Medicare patients to facilities in which they (or their immediate family member) have financial interests. Physicians, however, are not prohibited from referring patients to whole hospitals (and several other entities) in which they have ownership or investment interests.

House Bill

The Medicare Payment Advisory Commission (MedPAC) would be required to conduct a study of specialty hospitals compared with other similar general acute hospitals including the number and extent of patients referred by physicians with an investment interest in the facility, the quality of care furnished, the impact of the specialty hospital on the acute general hospital, and the differences in the scope of services, Medicaid utilization and the amount of uncompensated care that is furnished. The report, including recommendations, would be due to Congress no later than 1 year from enactment.

Senate Bill

The exception for physician investment and self-referral would not extend to specialty hospitals. In this instance, a specialty hospital would be one that is primarily or exclusively engaged in the care and treatment of patients with cardiac or orthopedic conditions, those receiving a surgical procedure, or other specialized categories of patients or cases deemed appropriate. A specialty hospital would not include any hospital that is determined by the Secretary to be in operation, under development as of such date, with the same number of beds and physician investors as of June 12, 2002. The Secretary would consider the following factors in determining whether a hospital is under development: whether the architectural plans have been completed; funding has been received; zoning requirements have been met; necessary approvals from appropriate State agencies have been received and other appropriate evidence.

The rural provider exception would be modified. These rural providers would not include specialty hospitals and the Secretary would determine, with respect to the entity, that such services would not be available in such area but for the ownership or investment interest.

Conference Agreement

For a period of 18 months from the date of enactment, the "whole hospital" exception would be amended to exclude those circumstances in which a physician's ownership interest is in a subsection d hospital devoted primarily or exclusively to cardiac, orthopedic surgical, or other specialties designated by the Secretary. Specialty hospitals in operation or under development as of November 18, 2003 would be exempt from the provision. Within a period of 15 months from the date of enactment MedPAC, in consultation with the General Accounting Office (GAO), and HHS would study the effects of the whole-hospital exception for physician-ownership in specialty hospitals.

In order to qualify for exception from this provision, a specialty hospital must have been in operation or under development (as defined in this bill) as of November 18, 2003. Additionally, in order to maintain the exception, a specialty hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase the total number of beds in

its facilities by more than the greater of 5 beds or 50 percent of the number of beds in the hospital as of November 18, 2003. The Secretary shall determine what constitutes the number of beds in a hospital that is considered under development as of November 18, 2003. The Secretary may evaluate all relevant development plans and documents in order to make this determination.

Long-term acute care hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals are not considered to be specialty hospitals for purposes of this section. When studying the effects of the whole-hospital exception, MedPAC, in consultation with GAO shall undertake a study in accordance with the legislation.

Effective Date

Beginning on the date of enactment, this provision would establish an 18-month moratorium on physician self-referrals to specialty hospitals. Hospitals in existence or under development as of November 18, 2003 would be exempt from the moratorium. A study would be completed within 15 months of date of enactment.

MedPAC Study and Report Regarding Medicare Disproportionate Share Hospital Adjustments (Section 404A of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Medicare Payment Advisory Commission (MedPAC) would be required to conduct a study to determine (1) whether disproportionate share hospital (DSH) payments should be made in the same manner as Medicare's graduate medical education payments; (2) the extent that hospitals receiving Medicaid DSH payments also receive Medicare DSH payments; and (3) whether to add uncompensated care costs to the Medicare DSH formula. The report, including recommendations, would be due to Congress within 1 year from enactment. The provision would be effective upon enactment.

Conference Agreement

No provision.

Treatment of Grandfathered Long-Term Care Hospitals (Section 416/Duplicate Provision 420B of the Senate Bill)**.**

Present Law

A hospital-in-a-hospital is a long-term hospital that is physically located in an acute care hospital and provides inpatient services that are paid at a higher rate than would apply if the long term

hospital were treated by Medicare as an acute care hospital. The Centers for Medicare and Medicaid Services (CMS) has established certain requirements for a hospital-in-a-hospital to be excluded from the inpatient prospective payment system and be paid as a long-term hospital. For instance, a hospital-within-a-hospital has to be able to independently perform certain basic hospital functions. CMS exempted existing hospitals-with-a-hospital (those that were in existence on or before September 30, 1995) when these requirements were established. On May 19, 2003, CMS proposed to revise the conditions of the hospitals' exemption; a hospital-within-a hospital would only be exempt from the existing requirements if it continues to operate within the same terms and conditions that were in effect as of September 30, 1995.

House Bill

No provision.

Senate Bill

The Secretary would not be able to impose any special conditions on the operation, size, and number of beds or location of an existing long-term hospital in order to continue participating in Medicare or Medicaid or to continue being classified as a long-term hospital. The Secretary would not be able to adopt a proposed regulation that would implement such conditions or any revision to such regulation that have a comparable effect. The provisions would apply to cost reporting periods ending on or after December 31, 2002.

Conference Agreement

No provision.

Treatment of Certain Entities For Purposes of Payments Under the Medicare Program (Section 417 of the Senate Bill)**.**

Present Law

Acute care hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity for purposes of using the other area's standardized amount or wage index, or both. (If, as proposed, the standardized amount for all hospitals will equal the amount used to pay hospitals in large urban areas, a hospital's need to reclassify to use of another area's standardized amount will virtually disappear.) If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services. Hospital reclassifications are established on a budget-neutral basis so aggregate inpatient prospective payment system expenditures will not increase as a result.

Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area. Aside from reclassifications through the MGCRB, hospitals have also been reclassified by law.

House Bill

No provision.

Senate Bill

Starting on or after October 1, 2003, Iredell County and Rowan County, North Carolina would be deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, South Carolina Metropolitan Statistical Area for the purpose of Medicare's inpatient and outpatient acute hospital reimbursement. The Secretary would be required to adjust the wage index values of all hospitals in North Carolina to assure that aggregate payments for hospital inpatient operating costs are not greater than they would have been without such a change.

Starting on or after October 1, 2003, Iredell County and Rowan County, North Carolina would be deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, and South Carolina Metropolitan Statistical Area for the purpose of Medicare's skilled nursing facility (SNF) and home health reimbursement. This change will be made in a way to ensure that aggregate payments for SNF and home health services in North Carolina are not greater than they would have been without such a change.

Conference Agreement

No provision.

Calculation of Wage Indices for Hospitals (Conference Report Section 508 and Section 419 of the Senate Bill)**.**

Present Law
Acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area but no later than February 15, 2004. If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services. Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area. The reclassification standards which are established by regulation are different for urban than for rural hospitals. It is easier for a rural hospital to reclassify to a different area. Aside from reclassifications through the MGCRB, hospitals have also been reclassified by law.

House Bill

No provision.

Senate Bill

The Secretary would be able to waive established reclassification criteria in calculating the wage index in a state when making payments for hospital discharges in FY2004. The provision would be effective upon enactment.

Conference Agreement

The Secretary shall establish by instruction not later than January 1, 2004 or otherwise a one-time process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State (or at the discretion of the Secretary to a contiguous state. A qualifying hospital is not eligible for a wage index classification on the basis of distance and/or commuting. It also must meet such other criteria, such as quality, as the Secretary may specify by instruction or otherwise. The reclassification will be effective for three years beginning with April 1, 2004. Hospitals can waive reclassification under this provision during the three year period. The Secretary shall limit the additional expenditures to $900 million.

Subtitle B Other Provisions

Payment for Covered Skilled Nursing Facility Services (Section 511 of the Conference Agreement and Section 511 of the House Bill)**.**

Present Law

Medicare uses a system of daily rates to pay for care in a skilled nursing facility (SNF). There are 44 daily rates categories, known as resource utilization groups (RUGs) and each group reflects a different case mix and intensity of services, such as skilled nursing care and/or various therapy and other services.

House Bill

The per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) would be increased by 128%. This payment increase would not apply on after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS. The provision would be effective for services on or after October 1, 2003.

Senate Bill

No provision.

Conference Agreement

The conference agreement increases the per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) by 128% (the BBRA temporary RUG add-on does not apply in this case). This payment increase would not apply on after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS. The provision is effective for services on or after October 1, 2004.

Coverage of Hospice Consultation Services (Section 512 of the Conference Agreement and Section 512 of the House Bill)**.**

Present Law

Current law authorized coverage of hospice services, in lieu of certain other Medicare benefits, for terminally ill beneficiaries who elect such coverage.

House Bill

Coverage of certain physician's services for certain terminally ill individuals would be authorized. Persons entitled to these services would be individuals who have not elected the hospice benefit and have not previously received these physician's services. Covered services would be those furnished by a physician who is the medical director or employee of a hospice program. Services would include evaluating the individual's need for pain and symptom management, counseling the individual with respect to end-of-life issues and care options, and advising the individual regarding advanced care planning. Payment for such services would equal the amount established for similar services under the physician fee schedule, excluding the practice expense component. The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement provides coverage of certain physician's services for certain terminally ill individuals. Beneficiaries entitled to these services are those who have not elected the hospice benefit and have not previously received these physician's services. Covered services are those furnished by a physician who is the medical director or employee of a hospice program. The covered services are: evaluating the beneficiary's need for pain and symptom management, including the individual's need for hospice care; counseling the beneficiary with respect to end-of-life issues and care options, and advising the beneficiary regarding advanced care planning. Payment for such services equals the amount established for similar services under the physician fee schedule, excluding the practice expense component. The provision would apply to consultation services provided by a hospice program on or after January 1, 2005.
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Increase for Hospitals with Disproportionate Indigent Care Revenues (Section 420A of the Senate Bill)**.**

Present Law

Certain hospitals receive additional Medicare payments because they serve a disproportionate share of poor Medicare and Medicaid patients measured by a formula that incorporates the proportion of the hospital's Medicare inpatient days provided to poor Medicare beneficiaries (those who receive Supplemental Security Income or SSI) added to the proportion of total hospital days provided to Medicaid recipients.. A few urban hospitals receive disproportionate share hospital (DSH) payments under the Pickle Amendment (named after former Representative Pickle from Texas) which establishes an alternative formula that considers the proportion of a hospital's patient care revenues that are received from state and local indigent care funds. If a hospital receives at least 30% of its patient care revenue from these indigent care funds, it qualifies as a "Pickle" hospital and will get a 35% increase in its Medicare operating payments. The Pickle hospitals receive a capital DSH adjustment of 14.16%. The capital adjustment is

calculated with the presumption that other urban hospitals would have had a DSH patient share percentage of 65.4% in order to receive a 35% operating DSH adjustment. If so, 65.4% DSH adjustment entered into the capital formula (a complicated calculation involving "e is the natural antilog of 1") would equal 14.16%.

House Bill

No provision.

Senate Bill

Hospitals that qualify for the DSH adjustment under the Pickle amendment would receive a DSH operating and capital adjustment of 40% for discharges on or after October 1, 2003. The provision would be effective upon enactment.

Conference Agreement

No provision.

Equitable Treatment for Children's Hospitals (Section 450J of the Senate Bill)**.**

Present Law

Outpatient hospital prospective payment contains a permanent "hold harmless" for cancer hospitals and children's hospitals. Under this hold harmless, payments to these hospitals cannot fall below what these hospitals would have received under the payment system in place before PPS.

House Bill

No provision.

Senate Bill

The provision would modify the hold harmless that certain children's hospitals receive. To receive the hold harmless a children's hospital would be required to be located in a state with an inpatient PPS waiver (Maryland is the only state that continues its waiver under 1814(b) (3)) and to have an outpatient PPS payment that is less than either what the hospital would have received under the previous payment system or the hospital's reasonable operating and capital costs. A children's hospital meeting these criteria would receive payment reflecting the greater difference between the outpatient PPS amount and the greater of either the previous payment system amount or the reasonable costs. The provision would be effective for services furnished on or after October 1, 2003.

Conference Agreement

No provision.

TITLE VI - PROVISIONS RELATING TO PART B

Subtitle A-Provisions Relating to Physicians' Services

Revision of Updates for Physicians' Services (Section 601 of the Conference Agreement, Section 601 of the House Bill, and Sections 464/Duplicative Provisions 622 and 629 of the Senate Bill)**.**
Present Law

Medicare pays for services of physicians and certain non-physician practitioners on the basis of a fee schedule. The fee schedule, in place since 1992, is intended to relate payments for a given service to the actual resources used in providing that service. The fee schedule assigns relative values to services. These relative values reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The law provides a specific formula for calculating the annual update to the conversion factor. The intent of the formula is to place a restraint on overall increases in spending for physicians' services. Several factors enter into the calculation of the formula. These include: 1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services; 2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services; and 3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced.

The annual percentage update to the conversion factor equals the MEI, subject to an adjustment (known as the update adjustment factor) to match target spending for physicians services under the SGR system. (During a transition period, 2001-2005, an additional adjustment is made to achieve budget neutrality.) The update adjustment sets the conversion factor at a level so that projected spending for the year will meet allowed spending by the end of the year. Allowed spending for the year is calculated using the SGR. However, in no case can the update adjustment factor be less than minus 7% or more than plus 3%.

The update adjustment factor is the sum of: 1) the prior year adjustment component, and 2) the cumulative adjustment component. The prior year adjustment component is determined by: 1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year; 2) dividing this amount by the actual expenditures for that year; and 3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: 1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period; 2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined; and 3) multiplying that amount by 0.33. Use of both the prior year adjustment component and the cumulative adjustment component allows any deviation between cumulative

actual expenditures and cumulative allowed expenditures to be corrected over several years rather than a single year.

The law also specifies a formula for calculating the SGR. It is based on changes in four factors: 1) estimated changes in fees; 2) estimated change in the average number of Part B enrollees (excluding Medicare+Choice beneficiaries); 3) estimated projected growth in real gross domestic product (GDP) growth per capita; and 4) estimated change in expenditures due to changes in law or regulations. This system is designed to adjust for how well actual expenditures meet SGR target expenditures.

Provisions in the Consolidated Appropriations Resolution of 2003 (P.L. 108-7) permitted redeterminations of SGR for prior years. As a result, the conversion factor for 2003 was increased 1.6% over the 2002 level. Other aspects of the formula for the annual payment rate were not addressed. CMS reports an update factor of -4.5% for 2004.

House Bill

The update to the conversion factor for 2004 and 2005 would be not less than 1.5% and would be exempt from the budget neutrality adjustment. This modification would not be treated as a change in law and regulation in SGR determination.

The formula for calculating the sustainable growth rate would be modified. The GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average). This calculation would replace the current GDP factor which measures the 1-year change from the preceding year. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

Senate Bill

The provision expresses a sense of the Senate that Medicare beneficiary access to quality care may be compromised if Congress does not prevent cuts in 2004 and following years that stem from the sustainable growth rate (SGR) formula.

The provision provides a sense of the Senate that the reductions in Medicare=s physician fee schedule are untenable if not destabilizing, primarily caused by the sustainable growth rate calculation, and that CMS should use its discretion to make certain exclusions and adjustments to the calculation.

Conference Agreement

The update to the conversion factor for 2004 and 2005 will not be not less than 1.5% and will be exempt from the budget neutrality adjustment, instead of -4.5% in 2004 and a smaller reduction in 2005. This modification would not be treated as a change in law and regulation in SGR determination.

The formula for calculating the sustainable growth rate will be modified. The GDP factor will be based on the annual average change over the preceding 10 years (a 10-year rolling average). This calculation will replace the current GDP factor which measures the 1-year change from the

preceding year. The 10-year rolling average calculation of the GDP will apply to computations of the SGR starting in 2003.

Treatment of Physicians' Services furnished in Alaska (Section 602 of the Conference Agreement and Section 450K of the Senate Bill).

Current Law

Physicians who provide services to Medicare beneficiaries are paid based on a physician fee schedule, which has three components: the relative value for the service, a geographic adjustment factor and a conversion factor. The geographic adjustment factor is the sum of three geographic practice cost indices (GPCIs), namely a work GPCI, a practice expense GPCI, and a malpractice GPCI. An area with costs above the national average would have a GPCI greater than 1.00; an area with costs below the national average would have a GPCI less than 1.00.

House Bill

No provision.

Senate Bill

For calendar year 2004, physicians providing Medicare services in Alaska would be paid 90 percent of the Veterans Affairs (VA) fee schedule for physician services that was used for fiscal year 2001. For calendar year 2005, this payment amount would be increased by the update amount for the Medicare physician fee schedule for 2005. If no VA fee schedule amount existed for a physician service, the payment amount would be the sum of the Medicare payment amount plus 90% of the percentage difference between the Medicare fee schedule and the VA fee schedule (on a claims-weighted basis). The provision would be effective for services furnished on or after January 1, 2004 and before January 1, 2006.

Conference Agreement

In calendar years 2004 and 2005, for physician services provided in Alaska, the Secretary is required to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense and malpractice cost indices.

Inclusion of Podiatrists, Dentists, and Optometrists under Private Contracting Authority (Section 603 of the Conference Agreement and Section 604 of the House Bill)**.**

Present Law

Private contracting allows a physician and Medicare beneficiary not to submit a claim for a service which would otherwise be covered and paid for by Medicare. Under private contracting, physicians can bill patients at their discretion without being subject to upper payment limits specified by Medicare. If a physician decides to enter into a private contract with a Medicare beneficiary, that physician must agree to forego any reimbursement by Medicare for all Medicare beneficiaries for 2 years. The patient is not subject to the 2-year limit and is able to receive services from other physicians who do not have such private contracts and have Medicare pay for the services. Both physicians and practitioners may enter private contracts. In this instance, a physician is limited to a doctor of medicine and osteopathy; chiropractors, podiatrists, dentists,

and optometrists are not included. Practitioners are physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, and clinical social workers.

House Bill

Doctors of dental surgery or of dental medicine and doctors of podiatric medicine would be able to enter into private contracts with Medicare beneficiaries. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

Doctors of dental surgery or of dental medicine, doctors of podiatric medicine, and doctors of optometry will be able to enter into private contracts with Medicare beneficiaries. The provision will be effective upon enactment.

GAO Study on Access to Physicians' Services (Section 604 of the Conference Agreement and Sections 602(a) and 602(b) of the House Bill)**.**

GAO Study on Beneficiary Access to Physicians' Services.

Present Law

Periodic analyses by the Physician Payment Review Commission, and subsequently MedPAC, as well as CMS showed that access to physicians' services generally remained good for most beneficiaries through 1999. Detailed data are not available for a subsequent period; however, several surveys have showed a decline in the percentage of physicians accepting new Medicare patients.

House Bill

GAO would be required to conduct a study on access of Medicare beneficiaries to physician's services under Medicare. The study would include an assessment of beneficiaries' use of services through an analysis of claims data. It would also examine changes in use of physicians' services over time. Further, it would examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO would be required to submit a report to Congress on this study within 18 months of enactment. The report would determine whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would determine whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

The Secretary would be required to request the Institute of Medicine to conduct a study on the adequacy of the supply of physicians (including specialists) in the country and the factors that affect supply. The Secretary would be required to submit the results of the study in a report to Congress no later than 2 years of the date of enactment.

Senate Bill

No provision.

Conference Agreement

GAO is required to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study will include an assessment of beneficiaries' use of physician services through an analysis of claims data. It will also examine changes in use of physicians' services over time. Further, it will examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO is required to submit a report to Congress on this study within 18 months of enactment. The report will determine whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report will also determine whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

Collaborative Demonstration-based Review of Physician Practice Expense Geographic Adjustment Data (Section 605 of the Conference Report and Section 421 of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

For services furnished after January 1, 2004, the Secretary would be required to increase the value of any work geographic index that is below .980 to .980. The values for work index would be raised to 1.0 for services furnished in 2005, 2006, and 2007. The practice expense and malpractice geographic indices in low value localities areas would be raised to 1.00 for services furnished in 2005 through 2008.

Conference Agreement

The Secretary is required to review and consider alternative data sources than those currently used to establish the geographic index for the practice expense component under Medicare's physician fee schedule no later than January 1, 2005. The Secretary will collaborate with State and other appropriate organizations representing physicians, and other appropriate persons. The Secretary will select 2 physician payment localities for this evaluation; one of the localities will be a rural area and one will be a statewide locality that includes both urban and rural areas. The Secretary will submit a report to Congress including recommendations on alternative data sources, including their accuracy and validity, the feasibility of using the alternative data, and the estimated impact of using these data for the practice expense adjustment. The report is due no later than January 1, 2006.

MedPAC Report on Payment for Physicians' Services (Section 606 of the Conference Agreement and Section 603 of the House Bill)**.**

Present Law

Medicare pays for physicians' services on the basis of a fee schedule. The fee schedule assigns relative values to services. These relative values reflect physician work, practice expenses and malpractice expenses. Resource-based practice expense relative values were phased-in beginning in 1999. Beginning in 2002, the values were totally resource-based.

Certain services have a professional component and a technical component. The technical component does not include a relative value for physician work. A global value includes both the professional and technical components. The physician must bill for the global value if the physician furnishes both the professional component and the technical component.

House Bill

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component of payments for physicians' services after full implementation of the resource-based payment in 2002. The report is to examine the following by specialty: (1) the effect of refinements on payments for physicians services; (2) interaction of the practice expense component with other components of and adjustments to payment for physicians' services; (3) appropriateness of the amount of compensation by reason of such refinements; (4) effect of such refinements on access to care by Medicare beneficiaries to physicians' services; and (5) effect of such refinements on physician participation under the Medicare program. The report would be due within 1 year of enactment. MedPAC would also be required to study the extent to which increases in the volume of physician services improves beneficiaries' health and well-being. MedPAC would be required to analyze the trends in components included in the sustainable growth rate calculation; the growth in volume of physician services provided to Medicare beneficiaries in comparison to other populations; the extent to which coverage determinations and new technology has affected growth in volume; the effect of demographic changes on volume; the effect of shifts in sites of services; and the extent to which the impact of law and regulations is taken into account.

Senate Bill

No provision.

Conference Agreement

MedPAC is required to report to Congress on the effects of refinements to the practice expense component of payments for physicians' services after full implementation of the resource-based payment in 2002. The report will examine the following by specialty: (1) the effect of refinements on payments for physicians' services; (2) the interaction of the practice expense component with other components of and adjustments to payment for physicians' services; (3) the appropriateness of the amount of compensation by reason of such refinements; (4) the effect of such refinements on access to care by Medicare beneficiaries to physicians' services; and (5) the effect of such refinements on physician participation under the Medicare program. The report is due within 1 year of enactment. MedPAC is also required to study the extent to which increases in the volume of physician services improves beneficiaries' health and well-being. MedPAC is required to analyze the trends in components included in the sustainable growth rate calculation; the growth in volume of physician service provided to Medicare beneficiaries in

comparison to other populations; the extent to which coverage determinations and new technology has affected growth in volume; the effect of demographic changes on volume; the effect of shifts in sites of services; and the extent to which the impact of law and regulations is taken into account. The report is due within 1 year of enactment.

GAO Report Section (Section 605(b) of the House Bill)**.**

Present Law

No provision.

House Bill

As part of the previously mandated study of geographic differences in physician payments, GAO would be required to evaluate (1) whether a sound economic basis for raising the geographic work adjustment exists; (2) the effect of such adjustment of physician location and retention including differences in recruitment cost and physician mobility; and the appropriateness of establishing a floor of 1.00 on the work geographic adjustment. GAO would be required to submit the report to Congress and the Secretary by September 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

GAO Study and Report on the Propagation of Concierge Care (Section 447 of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

GAO would be required to conduct a study on concierge care provided to Medicare beneficiaries and its affect on their access to Medicare covered services and submit a report to Congress, including recommendations, no later than 12 months from enactment. In this instance, concierge care would be an arrangement where a physician or practitioner charges an individual seeking care a membership fee or other fee or requires the purchase of an item or service as a prerequisite for providing the care. The provision would be effective upon enactment.

Conference Agreement

No provision.

Subtitle B Preventive Services

Coverage of An Initial Preventive Physical Examination (Section 611 of the Conference Agreement and Section 611 of the House Bill)**.**

Present Law

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

House Bill

Medicare coverage of an initial preventive physical examination would be authorized. The physical examination would be defined as physicians' services consisting of a physical examination with the goal of health promotion and disease detection. It would include items and services (excluding clinical laboratory tests) consistent with the recommendations of the United States Preventive Services Task Force as determined by the Secretary. A covered initial preventive physical examination would be one performed no later than 6 months after the individual's initial coverage date under Part B. Initial preventive physical exams would be included in the definition of physicians' services for purposes of the physician fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams. The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

Senate Bill

No provision.

Conference Agreement

Medicare coverage of an initial preventive physical examination is authorized, subject to deductible and beneficiary cost sharing. The physical examination is defined as physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram) with the goal of health promotion and disease detection. The examination includes education, counseling, and referral with respect to specific screening services and other preventive services, but does not include clinical laboratory tests. The screening and preventive services are certain vaccines, screening mammography, screening pap smear and screening pelvic exam, prostate cancer screening tests, colorectal cancer screening tests, diabetes outpatient self management, bone mass measurement, screening for glaucoma, medical nutrition therapy, cardiovascular screening blood tests and diabetes screening tests. A covered initial preventive physical examination is performed no later than 6 months after the individual's initial coverage date under Part B. Initial preventive physical exams are included in the definition of physicians services for purposes of the physician fee schedule. The provision applies to services furnished on or after January 1, 2005, but only for those individuals whose coverage begins on or after such date.

The Conference encourages the United States Preventive Services Task Force to examine aortic aneurysm screening using ultrasound. Aortic aneurysms are a leading cause of death in the United States, and many in the medical community believe that most, if not all, of the approximately 15,000 known deaths each year would be prevented with appropriate screening.

Coverage of Cardiovascular Screening Blood Tests (Section 612 of the Conference Agreement, Section 612 of the House Bill, and Section 450D of the Senate Bill)**.**

Present Law

Medicare covers a number of preventive services. However, it does not cover cardiovascular screening tests.

House Bill

Medicare coverage of cholesterol and blood lipid screening would be authorized. The screening would be defined as diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels. The Secretary would be required to establish standards regarding the frequency and type of these screening tests, but not more often than once every 2 years. The provision would apply to services furnished on or after January 1, 2005.

Senate Bill

Medicare coverage of cardiovascular screening tests would be authorized. The screening would be defined as diagnostic testing for the early detection of cardiovascular disease including tests for cholesterol levels, lipid levels of the blood, and other appropriate tests for cardiovascular disease. The Secretary would be required to consult with appropriate organizations and to establish standards regarding the frequency and type of these screening tests, but not more often than once every 2 years. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

Medicare coverage of cardiovascular screening blood tests is authorized. The screening is defined as a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) including tests for cholesterol levels and other lipid or triglyceride levels as well as such other indications associated with the presence of (or an elevated risk for) cardiovascular disease as the Secretary may approve for all individuals or for some individuals determined to be at risk for such disease. These indications may include indications measured by non-invasive testing. The Secretary cannot approve an indication for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force. The Secretary is required to consult with appropriate organizations and to establish standards regarding the frequency and type of these screening tests, but the frequency may not be more often than once every 2 years. The provision applies to services furnished on or after January 1, 2005.

Coverage of Diabetes Screening Tests (Section 613 of the Conference Agreement and Section 630 of the House Bill)**.**

Present Law

On July 1, 1998, Medicare began covering diabetes self-management training services. These educational and training services are provided on an outpatient basis by physicians or other certified providers who have experience in diabetes self-management training services. Blood testing strips and home blood glucose monitors are used by diabetics to measure blood glucose levels to determine if these levels are being maintained adequately. Medicare covers blood testing strips and blood glucose monitors for all individuals with diabetes regardless of whether they are insulin-dependent. The Secretary is also required to consult with appropriate organizations to establish outcome measures to assess improvements in the health status of individuals with diabetes. Based on this information, the Secretary will make recommendations to Congress on changes to Medicare's coverage of services for these beneficiaries. Medicare does not presently cover laboratory diagnostic tests and other services that are used to screen for diabetes.

House Bill

Diabetes screening tests and services would be included as a covered medical service. In this instance, diabetes screening tests would include fasting plasma glucose tests and other appropriate tests provided to an individual at risk for diabetes. Individuals at risk for diabetes would have any or a combination of the following conditions: (1) have a family history of diabetes; (2) are overweight with a body mass index greater than or equal to 25 kg/m2; (3) are habitually physically inactive; (4) are a member of a high-risk ethnic or racial group; (5) have previously been identified with an elevated impaired fasting glucose; (6) have hypertension; (7) have dyslipidemia; (8) have a history of gestational diabetes mellitus or have delivered a baby weighing more than 9 pounds; or (9) have polycystic ovary syndrome. The Secretary would be required to establish standards, in consultation with appropriate organizations regarding the frequency of screening tests except the tests would not be covered more often that twice in the 12-month period following the date of the individual's most recent diabetes screening test. The provision would apply to tests furnished on or after 90 days from enactment.

Senate Bill

No provision.

Conference Agreement

Diabetes screening tests furnished to an individual at risk for diabetes for the purpose of early detection of diabetes are included as a covered medical service. In this instance, diabetes screening tests include fasting plasma glucose tests as well as other tests and modifications to those tests deemed appropriate by the Secretary after consultation with appropriate organizations. Individuals at risk for diabetes have any or a combination of the following conditions: (1) hypertension; (2) dyslipidemia; (3) obesity, with a body mass index greater than or equal to 30 kg/m^2; (4) previous identification of an elevated impaired fasting glucose; (5) previous identification of impaired glucose tolerance or (6) a risk factor of at least 2 of the following characteristics: overweight with a body mass index of greater than 25, but less than 30, kg/m^2; a family history of diabetes; a history of gestational diabetes mellitus or delivery of a baby

weighing more than 9 pounds; or age of 65 years or more. The Secretary is required to establish standards, in consultation with appropriate organizations regarding the frequency of screening tests except the tests will not be covered more often that twice in the 12-month period following the date of the individual's most recent diabetes screening test. The provision applies to tests furnished starting January 1, 2005.

Improved Payment for Certain Mammography Services (Section 614 of the Conference Agreement, Section 614 of the House Bill, and Section 445 of the Senate Bill**).**

Present Law

Screening mammography coverage includes the radiological procedure as well as the physician's interpretation of the results of the procedure. The usual Part B deductible is waived for tests. Payment is made under the physician fee schedule.

Certain services paid under fee schedules or other payment systems including ambulance services, services for patients with end-stage renal disease paid under the ESRD composite rate, professional services of physicians and non-physician practitioners paid under the physician fee schedule, and laboratory services paid under the clinical diagnostic laboratory fee schedule are excluded from Medicare's outpatient prospective payment system (OPPS).

House Bill

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from OPPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2004.

Senate Bill

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from OPPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2005.

Conference Agreement

Screening mammography and diagnostic mammography will be excluded from OPPS. This provision will apply to screening mammography services furnished on or after the date of enactment and will apply to diagnostic mammography services furnished on or after January 1, 2005.

Waiver of Deductible for Colorectal Cancer Screening Tests (Section 613 of the House Bill)**.**

Present Law

Covered colorectal screening tests for prevention purposes include (1) an annual fecal-occult blood test for individuals age 50 and older; (2) flexible sigmoidoscopy every 4 years for

individuals age 50 and older; (3) colonoscopy for high-risk individuals every 2 years and for other individuals every 10 years; and (4) screening barium enemas every 4 years for individuals age 50 and older who are not at high risk of developing colorectal cancer or every 2 years for high risk individuals. Payment is made according to the applicable payment system for the provider performing the test.

Unless otherwise specified, Part B services are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount. Colorectal screening tests are subject to the deductible and coinsurance.

House Bill

The Part B deductibles would be waived for colorectal cancer screening tests. The provision would apply to items and services furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

Subtitle C-Other Provisions

Hospital Outpatient Department (HOPD) Payment Reform (Section 621 of the Conference Report, Section 621(a) of the House Bill, and Section 436 of the Senate Bill)**.**

Payment for Drugs (Section 621(a) of the Conference Agreement, Sections 621(a) and 621(d) of the House Bill, and Section 436 of the Senate Bill)**.**

Present Law

Under hospital outpatient department (HOPD) prospective payment system (OPPS), the unit of payment is the individual service or procedure as assigned to one of about 570 ambulatory payment classifications (APCs) groups. Services are classified into APCs based on their Healthcare Common Procedure Coding System (HCPCS), a standardized coding system used to identify products, supplies, and services for claims processing and payment purposes. To the extent possible, integral services and items including drugs are bundled or packaged within each APC. For instance, an APC for a surgical procedure will include operating and recovery room services, anesthesia and surgical supplies. Medicare's payment for HOPD services is calculated by multiplying the relative weight associated with an APC by a geographically adjusted conversion factor. The conversion factor is updated on a calendar year schedule and the annual updates are based on the hospital market basket (MB). Currently, the CY2004 HOPD update will equal the projected change in the MB.

Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through payment, (2) as a separate APC payment; or (3) as packaged APC payment with other services.

Transitional pass-through payments are supplemental payments to cover the incremental cost associated with new medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for 2 or 3 years and then the costs are incorporated into the APC relative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiophamaceutical drugs and biological products; and new drugs and biological agents.

Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95% of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision. The pass-through amount for new drugs with a substitute drug recognized in a separate drug APC payment is the difference between 95% of new drug's AWP and the payment rate for the comparable dose of the associated drugs APC.

CMS imputes the hospital costs for these drugs to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending in order to calculate the uniform reduction to payments under the budget neutrality constraint. This imputed value is calculated by multiplying the average wholesale price (AWP) for the drug by the applicable cost-to-charge ratio which varies by the class of drug. For CY2003, the average ratio of cost to AWP for sole-source drugs manufactured by one entity is 0.71, for multiple source drugs is 0.68, and for multiple source drugs with generic competitors is 0.43. There is enormous variation within a category from close to zero to above 100% of AWP.

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain of these drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim line for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated. However, the cost to charge ratios are from only one department.

House Bill

Under Section 621(a), starting for services furnished on or after January 1, 2004, certain covered OPD drugs would be paid no more than 95% of AWP or be less than the transition percentage of the AWP from CY2004 through CY2006. In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program under 1847A. The covered OPD drugs affected by this provision are radiopharmceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003 or those drugs for which a temporary HCPCS code has not been assigned. Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95% of the AWP.

The transition percentage to AWP for sole-source drugs manufactured by one entity is 83% in CY2004, 77% in CY2005, and 71% in CY2006. The transition percentage to AWP for innovator multiple source drugs is 81.5% in CY2004, 75% in CY2005, and 68% in CY2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is 46% in CY2004 through CY2006. Generally, a multiple source drug is a covered drug for which there are 2 or more therapeutically equivalent drug products. An innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration (FDA). A sole source drug is not a multiple source drug. The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement

Starting in CY2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher costs drugs from $150 to $50 per administration. These separate drug APC groups would not be eligible for outlier payments. Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95% of AWP.

Under Section 621(d), the Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost $50 per administration and more that are reimbursed under the HOPD-PPS. The study would encompass a representative sample of urban and rural hospitals. The report including recommendations on the usefulness of the cost data and frequency of subsequent data collection efforts would be due to Congress no later than January 1, 2006. The report would also discuss whether the data is appropriate for making adjustments to payments made under the competitive acquisition contract established by section 1847A and whether separate estimates can be made for overhead costs including handling and administering drugs. The provision would be effective upon enactment.

Senate Bill

A new payment mechanism for certain drugs and biologicals provided in hospital outpatient departments (OPD) would be established from January 1, 2005 and before January 1, 2007. The drugs and biologicals would be those for which hospitals received transitional pass-through payments prior to January 1, 2005 and those that would have been paid in such a manner but for the application of this provision or those that are assigned to drug specific APCs on or after the date of enactment. Payments made under this provision would be exempt from the budget neutrality requirement in FY2005 and FY2006.

In 2005, these drugs or biologicals furnished as part of a current OPD service would be paid as follows: a single source or orphan product would be paid at 94% of the AWP existing on May 1, 2003; a multiple source drug would be paid at 91% of the AWP existing on May 1, 2003; and a multiple source drug with generic equivalents would be paid at 71% of AWP on May 1, 2003. Drugs and biologicals that were furnished as part of other OPD services would be paid using the same applicable percentage of the AWP that would have been determined on May 1, 2003 if payment could have been made on that date. For 2006, these payment amounts would be increased by the percentage increase in the consumer price index for all urban consumers for the 12-month period ending in June of the previous year.

The Secretary would be required to contract with an eligible organization (a private nonprofit organization) to conduct a study to determine the hospital acquisition, pharmacy services, and

handling costs for each the drugs paid in this fashion. The study would be required to be accurate with 3% of the true mean hospital acquisition and handling costs for each drug and biological at the 95% confidence level; begin not later than January 1, 2005; and be updated annually. Each year, beginning January 1, 2006, the Secretary would be required to submit a report to Congress, including recommendations, on the drug costs. These drug costs would be used in determining the payment amounts for each drug and biological provided as part of a covered OPD services furnished on or after January 1, 2007.

Conference Agreement

Starting for services furnished on or after January 1, 2004, specified covered OPD drugs would be paid based on a percentage of the reference average wholesale price for the drug. The percentage of the reference price for sole-source drugs manufactured by one entity can be no less than 88% and no greater than 95% in CY2004 and no less than 83% and no greater than 95% in CY2005. The percentage of the reference price for innovator multiple source drugs can be no greater than 68% in CY2004 and CY2005. The percentage of the reference price for noninnovator multiple source drugs can be no greater than 46% in CY2004 and CY2006. The reference average wholesale price is the average wholesale price for the drug as of May 1, 2003.

A *sole source drug* is biological product approved under a biologics license application under section 351 of the Public Health Services Act or a single source drug produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA) which includes a drug product marketed by appropriate cross-licensed producers or distributors as established in Section 1927(k)(7)(A)(iv) of the Social Security Act (the Act); *an innovator multiple source drug* is a multiple source drug that was originally marketed under an original new drug application approved by FDA as established in Section 1927(k)(7)(A)(ii) of the Act; and, a *noninnovator multiple source drug* is a multiple source drug that is not an innovator multiple source drug as established in 1927(k)(7)(A)(iii) of the Act. A biological includes any product that the Centers for Medicare and Medicaid services has determined to be a biological under section 1861(t)(1) of the Act.

It is the intent of the Conference that products eligible for the transitional payment under the hospital outpatient department section include all products paid by Medicare on a pass-through list as a drug or biologic prior to December 31, 2002, or as a radiopharmaceutical product as a pass-through product are in a separate ambulatory payment classification (APC). This section clarifies that radiopharmaceuticals are drugs under the hospital outpatient department section and that the term “specified covered outpatient drug” includes radiopharmaceuticals.

In subsequent years, payment will be equal to the average acquisition cost for the drug for that year (which may vary by hospital group taking into account hospital volume or other hospital characteristics) or if hospital acquisition cost data are not available, the average price for the drug in the year other than radiopharmacuticals established under Sections 1842(o), 1847A or 1847B as calculated and adjusted by the Secretary. The covered OPD drugs affected by this provision are outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003; those drugs for which a temporary HCPCS code has not been assigned; or, during 2004 and 2005, orphan drugs. Drugs for which a temporary HCPCS code has not been assigned will be reimbursed at 95% of the AWP. Orphan drugs during this 2 year time period will be paid at an amount specified by the Secretary.

GAO is required to conduct an acquisition cost survey for each specified covered drug in 2004 and 2005. The surveys (those done by GAO and then subsequently by the Secretary) will be based on a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. No later than April 1, 2005, GAO will furnish this survey data to the Secretary to use in setting payment rates for 2006. GAO will evaluate the 2006 payment rates and submit a report to Congress on their appropriateness no later than 30 days after the date the Secretary promulgates the proposed rule setting forth these rates.

Upon completion of their surveys, GAO will submit recommendations regarding the survey methodology and survey frequency to the Secretary for subsequent surveys. The Secretary will conduct periodic surveys to determine the hospital acquisition costs for each specified covered outpatient drug to set subsequent payment rates. GAO will report to Congress on the justification for the size of the sample used in order to assure the validity of the estimates; the extent of variation in hospital acquisition costs among hospitals based on the volume of covered OPD services or other relevant characteristics.

MedPAC will submit a report to the Secretary on the payment adjustment to ambulatory payment classifications for specified covered outpatient drugs that takes into account overhead and related expenses (such as pharmacy services and handling costs). The report will include (1) a description and analysis of the available data; (2) a recommendation as to whether the payment adjustment should be made; and (3) if such an adjustment should be made, a recommendation regarding the appropriate methodology. The Secretary is authorized to adjust the weights for ambulatory payment classification based on such a recommendation.

The additional expenditures that result from the previous changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account in subsequent years.

For drugs and biologicals furnished in 2004 and 2005, the Secretary is required to lower the threshold for establishing a separate APC group for higher costs drugs from $150 to $50 per administration. These separate drug APC groups are not be eligible for outlier payments. Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average price for the drug or biological for all competitive acquisition areas calculated and adjusted by the Secretary for that year.

Special Payment for Brachytherapy (Section 421(b) of the Conference Report, Section 621(b) of the House Bill and Section 450A of the Senate Bill)**.**

Present Law

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. The Center for Medicare and Medicaid Services (CMS) established separate APC payments for certain of these drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim line for a drug to qualify for a separate APC payment as a higher-cost drug. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

House Bill

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to cost. The Secretary would be required to create separate APCs to pay for these devices that reflect to the number, isotope, and radioactive intensity of such devices. This would include separate groups for palladium-103 and iodine-125 devices. GAO would be required to study the appropriateness of payments for brachytherapy devices and submit a report including recommendations to Congress no later than January 1, 2005. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to conduct a 3-year demonstration project that would exclude brachytherapy devices from the OPPS and paid on the basis of the hospital's charges for each device, adjusted to cost. The Secretary would be required to create separate, additional groups of covered HOPD services for brachytherapy devices to reflect the number, isotope, and radioactive intensity of such devices. The Secretary would be required to assure that aggregate payments under this project would not exceed what otherwise would have been spent. The project would begin 90 days after the date of enactment. The Secretary would be required to submit a report on the evaluation of patient outcomes and cost effectiveness of the project to Congress no later than January 1, 2007.

Conference Agreement

The provision would require the Secretary to make payment for each brachytherapy devise furnished under the hospital outpatient prospective payment system equal to the hospital's charges for the brachytherapy device adjusted to cost for all brachytherapy devices furnished on or after January 1, 2004 and before January 1, 2007. Charges for such devices will not be included in determining any outlier payment.

The provision also would require the Secretary to create and use ambulatory payment classification (APC) groups that classify brachytherapy devices separately from all the other services and items paid for under the hospital outpatient prospective payment system. The Secretary must reflect the number, the radioactive isotope and the radioactive intensity of the brachytherapy devices furnished to each patient, including the use of separate APCs for brachytherapy devices made from palladium-103 and iodine-125.

Limitation of Application of Functional Equivalence Test (Section 622 of the Conference Agreement, Section 621(c) of the House Bill, and Section 437 of the Senate Bill)**.**

Present Law

In the November, 1 2002 *Federal Register*, CMS established a new concept of functional equivalence for drugs to an existing treatment. The transitional pass-through rate for a drug was reduced to zero starting for services in 2003.

House Bill

The Secretary would be prohibited from applying a functional equivalence standard or any similar standard in order to deem a particular drug or biological to be similar or functionally equivalent to another drug unless the Commissioner of the Food and Drug Administration establishes such a standard and certifies that the two products are functionally equivalent. The Secretary would be able to implement this standard after applicable rulemaking requirements.

This provision would apply to the application of a functional equivalent on or after the date of enactment. The provision prohibits the application of this standard to a drug or biological prior to June 13, 2003.

Senate Bill

The Secretary would be prohibited from publishing regulations that apply a functional equivalence standard to a drug or biological for transitional pass-through payments under OPPS. This prohibition would apply to the application of the functional equivalence standard on or after the date of enactment, unless such application was made prior to enactment and the Secretary applies such standard to the drug only for the purposes of transitional pass-through payments. This provision would not affect the Secretary authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of the Food and Drug Administration.

Conference Agreement

The Secretary is prohibited from publishing regulations, program memorandum local medical review policies or any other guidance (including the HOPD-PPS payment rate rules) that apply a functional equivalence or similar standard to a drug or biological for transitional pass-through payments under OPPS. This prohibition applies to the application of the functional equivalence standard on or after the date of enactment, unless such application was made prior to enactment and the Secretary applies such standard to the drug only for the purposes of transitional pass-through payments. This provision does not affect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of the Food and Drug Administration.

Payment for Renal Dialysis Services (Section 623 of the Conference Agreement, Section 623 of the House Bill, Section 432(b)(5) of the Senate Bill)**.**

Present Law

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment, regardless of whether services are provided at the facility or in the patient's home. The composite rate includes the dialysis costs but excludes separately billable drugs and biologicals and laboratory services. Providers receive 95% of the AWP for separately billable injectable medications other than erythropoietin (EPO) administered during treatments at the facility.

Medicare pays separately for EPO which is used to treat anemia for persons with chronic renal failure who are on dialysis. Congress has set Medicare's payment for (EPO) at $10 per 1,000 units whether it is administered intravenously or subcutaneously in dialysis facilities or in patients' homes.

BBRA increased the composite rates by 1.2% for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the 2001 update to 2.4%. The composite rate has not been increased since then.

Prior to BIPA, an increase in the composite rate would trigger an opportunity for facilities to request an exception to the composite rate in order to receive higher payments. BIPA prohibited the Secretary from granting new exceptions to the composite rate (after applications received after July 1, 2001).

In 2003, Secretary announced a demonstration project establishing a disease-management program that will allow organizations experienced with treating end-stage renal disease (ESRD) patients to develop financing and delivery approaches to better meet the needs of beneficiaries with ESRD. CMS is soliciting a variety of types of organizations to coordinate care to patients with ESRD, encourage the provision of disease-management services for these patients, collect clinical performance data and provide incentives for more effective care.

House Bill

The provision would increase the ESRD composite payment rate by 1.6% for 2004.

The prohibition on exceptions contained in BIPA section 422(a)(2) would not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric facilities would be defined as a renal facility with 50% of its patients under 18 years old. The provision would be effective upon enactment.

The provision would require the Secretary to establish an advisory board for the ESRD disease management demonstration. The advisory board would be comprised of representatives of patient organizations, clinicians, the Medicare Payment Advisory Commission (MedPAC), the National Kidney Foundation, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, ESRD networks, Medicare contractors to monitor quality of care, providers of services and renal dialysis facilities furnishing ESRD services, economists, and researchers. The provision would be effective upon enactment.

Senate Bill

The composite rate for dialysis services furnished during 2004 would be increased by an amount to ensure that the sum of the total amount of the composite rate payments plus the payments that are billed separately for drugs and biologicals (but not EPO) would equal the composite rate payments plus payments made for separately billed drugs and biologicals (not including EPO) as if this drug pricing provisions of this legislation were not enacted. During 2005, the ESRD composite rate would be increased by 0.05% and further increased by 1.6%. During 2006, the ESRD composite rate of the previous year would be increased by 0.05% and then further increased by 1.6%. During 2007 and subsequently, the composite ESRD rate of the previous year would be increased by 0.05%. In any year after 2004, the Secretary would be required to provide for additional increases in the composite rate to account for any payment reductions for separately administered drugs and biologicals (but not EPO) in the same manner as in 2004.

These payment amounts, methods or adjustments would not be subject to administrative or judicial review under the statutory appeals processes in established by Senate section 1869 of the SSA, by the Provider Reimbursement Review Board established by Senate section 1878 of the SSA, or otherwise. The provision would be effective upon enactment.

Conference Agreement

The conference agreement increases the composite rate for renal dialysis by 1.6% for 2005.

The prohibition on exceptions contained in BIPA section 422(a)(2) does not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric ESRD facilities are defined as renal facilities with 50% of their patients under 18 years old. The provision is effective upon enactment.

The Inspector General of HHS is required to conduct 2 studies regarding drugs and biologicals (including erythropoietin) furnished to ESRD patients and billed separately to Medicare by ESRD facilities. The first study will address existing drugs and biologicals B those for which a billing code exists prior to January 1, 2004 B and is required to be submitted to the Secretary by April 1, 2004. The second study is of new drugs and biologicals B those for which a billing code does not exist prior to January 1, 2004 B and is due to the Secretary by April 1, 2006. Each study is required to determine the difference, or spread, between the Medicare payment amount to ESRD facilities for drugs and biologicals, and the facilities' acquisition costs for the drugs and biologicals which are separately billed by the facilities. The studies are also to estimate the rates of growth of expenditures for these drugs and biologicals.

The conference agreement requires the Secretary to establish a *basic* case-mix adjusted prospective payment system for dialysis services. The basic case-mix adjusted system is required to begin for services furnished on January 1, 2005. The system is required to adjust for a limited number of patient characteristics (the case-mix).

The basic case-mix adjusted system is composed of two components: (1) those services which currently comprise the composite rate (including the 1.6% increase in 2005), and (2) the spread on separately billed drugs and biologicals (including erythropoietin and as determined by the Inspector General reports).

Drugs and biologicals (including erythropoietin) currently billed separately, will continue to be billed separately under the basic case-mix adjusted system at acquisition costs . They cannot be bundled into the new system.

In addition, the Secretary is also required to adjust the basic case-mix adjusted system payment rates by a geographic index. If the geographic index is different from the one used with the composite rate, then the Secretary is required to phase-in the application over a multi-year period.

Overall, spending for ESRD services included under the basic case-mix adjusted system is required to result in the same aggregate amount of expenditures as would occur if the current system continued in 2005

The system would be updated in 2006 for growth in drug spending for the portion of the basic case-mix adjusted payment amount that is represented by what is current spread on separately billed drugs and biologicals. However, the provision does not provide for an update to the

composite rate portion of the base rate in 2006 and forward. The increase for drug growth for the spread component would be adjusted downward by its proportionate share (of the spread and composite rate components) and the resulting increase applied to the sum.
. An adjustment would be made in 2007 for the spread calculated for new drugs and biologicals (those for which a billing code does not exist prior to January 1, 2004) using the 2006 Inspector General study.

Payments for separately billed drugs and biologicals will be 95% of the AWP for 2004 and acquisition costs in 2005, and, beginning in 2006 the Secretary has the authority to apply a payment methodology he determines appropriate which may include the average sales price payment methodology (under the new section 1847A found in section 303(c) of the conference agreement) or acquisition costs.

No administrative or judicial review is permitted of the case-mix system, the relative weights, payment amounts, the geographic adjustment factor, or the update of the basic case-mix adjusted system portion related to drug spending growth applied to spread, or in the determination of the difference between Medicare payment amounts and acquisition costs for separately billed drugs and biologicals.

By October 1, 2005, the Secretary is required to report to Congress on the elements and features for the design and implementation of a fully case-mix adjusted, bundled prospective payment system for services furnished by ESRD facilities, including to the extent feasible, drugs, clinical laboratory tests, and other items that are separately billed by ESRD facilities. The report is required to include a description of the methodology to be used for the establishment of payment rates including the bundle of items and services, case-mix, wage index, rural area payment adjustments, other adjustments, and update framework.

The Secretary is required to establish a 3-year demonstration project of the fully case-mix adjusted payment system for ESRD services, beginning January 1, 2006. The fully case-mix adjusted system is to include a case-mix system for patient characteristics identified in the report and to bundle separately billed drugs and biologicals and related clinical laboratory tests into the payment rates. The Secretary is required to ensure that sufficient numbers of providers of dialysis services and ESRD facilities participate in the demonstration, but not to exceed 500. The Secretary is required to ensure that urban, rural, not-for-profit, for-profit, independent, and specialty providers and facilities are included in the demonstration. During the demonstration, the Secretary is required to increase payment rates that would otherwise apply by 1.6% for dialysis services furnished by demonstration participants. In carrying out the demonstration, the Secretary is required to establish an advisory board comprised of representatives of: patient organizations; individuals with expertise in ESRD services, such as clinicians, economists, and researchers; the Medicare Payment Advisory Commission, the National Institutes of Health, network organizations; Medicare contractors to monitor quality of care; and providers of services and renal dialysis facilities. The advisory panel is required to terminate December 31, 2008. Appropriations are authorized from the Medicare trust funds in the amount of $5 million in FY 2006 to conduct this demonstration.

1-Year Moratorium on Therapy Caps; Provisions Relating to Report (Section 624 of the Conference Agreement and Section 624 of the House Bill)**.**

Present Law

Medicare provides that therapy patients must be under the care of a physician; a plan of treatment must be developed by the physician or therapist; and the plan must be periodically reviewed by the physician.

BBA 97 established annual payment limits per beneficiary for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. There are 2 beneficiary limits. The first is a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a $1,500 per beneficiary annual cap for all outpatient occupational therapy services. Beginning in 2002, the amount would increase by the Medicare Economic Index (MEI), rounded to the nearest multiple of $10. The limits did not apply to outpatient services provided by hospitals. BBRA 99 suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. The therapy caps became effective in September 2003.

BBA 97 required the Secretary to report to Congress by January 1, 2001, on recommendations on a revised coverage policy of outpatient physical therapy and occupational therapy services based on a classification of individuals by diagnostic category and prior use of services, in both inpatient and outpatient settings, in place of uniform dollar limitations. BIPA required the Secretary to conduct a study on the implications of eliminating the "in the room" supervision requirement for Medicare payment for physical therapy assistants who are supervised by physical therapists and the implications of this requirement on the physical therapy cap. A report on the study was due within 18 months of enactment.

House Bill

Application of the therapy caps would be suspended in 2004. The Secretary would be required to submit the reports required by BBA 97 and BIPA by December 31, 2002. The Secretary would be required to request the Institute of Medicine to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. The Secretary would be required to submit to Congress a preliminary report on the conditions and diseases identified by July 1, 2004. A final report, including recommendations, would be due by October 1, 2004.

Senate Bill

No provision.

Conference Agreement

Application of the therapy caps is suspended as of the date of enactment through calendar year 2005. The implementation of this provision shall not be deemed to have any retroactive impact upon beneficiaries who exceeded their caps prior to the date of enactment. The Secretary is required to submit the reports required by BBA 97 and BIPA by March 31, 2004 relating to the alternatives to a single annual dollar cap on outpatient therapy and the utilization patterns for outpatient therapy. The GAO is required to identify conditions or diseases that may justify waiving the application of the therapy caps and report to Congress by October 1, 2004. The report is required to include a recommendation of criteria, with respect to the conditions and diseases, under which a waiver of the therapy caps would apply.

Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period (Section 625 of the Conference Agreement, Section 627 of the House Bill, and Section 439 of the Senate Bill)**.**

Present Law

A late enrollment penalty is required to be imposed on beneficiaries who do not enroll in Medicare part B upon becoming eligible for Medicare.

House Bill

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. There is a late enrollment penalty for military retirees who do not enroll in Medicare Part B upon becoming eligible for Medicare. This provision would waive the late enrollment penalty for military retirees, 65 and older, who enroll(ed) in the TRICARE for Life program from 2001–2004.

The Secretary would also be required to provide a special Part B enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. The provision would apply to premiums for months beginning January 2004. The Secretary would be required to rebate premium penalties paid for months on or after January 2004 for which a penalty does not apply as a result of this provision, but for which a penalty was collected.

Senate Bill

Beginning January 2005, the provision would waive the late enrollment penalty for certain military retirees who enrolled in Part B during 2002, 2003, 2004 or 2005. A special enrollment period, beginning 1 year after enactment and ending December 31, 2005 would be provided.

Conference Agreement

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. The provision waives the late enrollment penalty for military retirees who did not enroll in Medicare Part B upon becoming eligible for Medicare. The waiver applies to the late enrollment penalty for military retirees, 65 and over, who enroll(ed) in the TRICARE for Life program from 2001 to 2004.

The Secretary is required to provide a special Part B enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. The provision applies to premiums for months beginning January 2004. The Secretary is required to rebate premium penalties paid for months on or after January 2004 for which a penalty does not apply as a result of this provision, but for which a penalty was collected.

Payments for Services Furnished in Ambulatory Surgical Centers (Section 626 of the Conference Agreement and Section 625 of the House Bill)**.**

Present Law

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ambulatory surgery center (ASC). The associated physician services (surgery and anesthesia) are reimbursed under the physician fee schedule. CMS maintains the list of approved ASC procedures which is required to be updated every 2 years. The Secretary is required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years beginning no later than January 1, 1995. Between revisions, the rates are to be updated annually on a calendar year schedule using the CPI-U. From FY1998 through FY2002, the update was established as the CPI-U minus 2.0 percentage points, but not less than zero.

In June 1998, CMS issued a proposed notice which would have implemented a prospective payment system (PPS) for ASCs. The Balanced Budget Refinement Act of 1999 required that full implementation of the proposed ASC rates be phased in over a 3-year period. The Benefits Improvement and Protection Act of 2000 (BIPA) delayed implementation of the PPS before January 1, 2002. BIPA also required that CMS use 1999 or later cost survey data in the PPS. A final rule implementing the new payment system for ASCs has not yet been issued.

House Bill

The reduction in the update would be extended. ASCs would get an increase calculated as the CPI-U minus 2.0 percentage points (but not less than zero) in each of the fiscal years from 2004 through 2008.

Senate Bill

No provision.

Conference Agreement

In FY2004, starting April 1, 2004, the ASC update will be the CPI-U (estimated as of March 31, 2003 minus 3.0 percentage points. In FY2005, the last quarter of calendar year 2005, and each of the calendar years 2006 through 2009 the update will be 0%. Upon implementation of the new ASC payment system, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years. Subject to GAO's recommendations (discussed subsequently), the Secretary will implement a revised payment system for surgical services furnished in an ASC. This payment system will be designed to be budget neutral in the year it is implemented; the amount of aggregate expenditures for such services under the new system will be the same as would have occurred under the old system. The new system will be implemented so that it is first effective on or after January 1, 2006 and not later than January 1, 2008. There will be no administrative or judicial review of the ASC classification system, relative weights, payment amounts and any geographic adjustment factor. GAO will conduct a comparative study of the relative costs of procedures furnished in ASCs to those furnished in hospital outpatient departments under OPPS. The study will examine the accuracy of the ambulatory payment categories with respect to the procedures furnished in the ASCs. GAO will submit recommendations and consider ASC data with respect to (1) the appropriateness of using groups and relative weights established for the outpatient hospital PPS as the basis of the new ASC payment system; (2) if such weights are appropriate,

whether the ASC payments should be based on a uniform percentage of such weights, whether the percentages should vary, or whether the weights should be revised for certain procedures or types of services; and (3) the appropriateness of a geographic adjustment in the ASC payment system and if appropriate, the labor and non-labor shares of such payment.

Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics (Section 627 of the Conference Agreement, and Section 626 of the House Bill)**.**

Present Law

Subject to specified limits and under certain circumstances, Medicare will pay for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease. Coverage is limited to one of the following within a calendar year: (1) one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or (2) one pair of extra-depth shoes (not including inserts provided with such shoes) and three pairs of inserts. An individual may substitute modifications of custom-molded or extra-depth shoes instead of obtaining one pair of inserts, other than the initial pair of inserts. Footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist, or prosthetist. The certifying physician may not furnish the therapeutic shoe unless the physician is the only qualified individual in the area.

Payment is made on a reasonable charge basis, subject to upper limits established by the Secretary. These limits are based on 1988 amounts that were set forth in Section 1833(o) of the Act and then adjusted by the same percentage increases allowed for DME fees except that if the updated limit is not a multiple of $1, it is rounded to the nearest multiple of $1. The Secretary or a carrier may establish lower payment limits than established by statute if shoes and inserts of an appropriate quality are readily available at lower amounts.

Although updates in payment for diabetic shoes are related to that used to increase the DME fee schedule, the shoes are not subject to DME coverage rules or the DME fee schedule. In addition, diabetic shoes are neither considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

House Bill

Payment for diabetic shoes would be limited by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary would be able to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary would be required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures. The provision would apply to items furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

Payment for diabetic shoes is limited under the conference agreement by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary may establish lower payment limits than these amount if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary is required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures. The provision applies to items furnished on or after January 1, 2005.

Payment for Clinical Diagnostic Laboratory Tests (Section 628 of the Conference Agreement, Section 431 of Senate Bill).

Present Law

Medicare payment for clinical diagnostic laboratory test is made using a fee schedule. The fee schedule is updated on a calendar year basis using the CPI-U. BBA 97 froze the fee schedule from 1998 through 2002. The update for 2003 was equal to the full CPI-U increase. No beneficiary cost-sharing is imposed.

House Bill

No provision.

Senate Bill

Medicare would pay all clinical laboratories 80% of the applicable fee schedule amount. Hospital-based and physician office and independent laboratories would be able to charge beneficiaries a 20% coinsurance amount. The Medicare Part B deductible would apply to clinical diagnostic laboratory tests furnished across all settings; except for those tests provided by sole community hospitals (see Senate Section 427). The provision would apply to tests furnished on or after January 1, 2004.

Conference Agreement

The conference agreement does not provide for any updates to the clinical diagnostic laboratory test fee schedule for 2004 through 2008.

Indexing Part B Deductible to Inflation (Section 629 of the Conference Agreement, Section 628 of the House Bill, Section 433 of the Senate Bill)**.**

Present Law

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has been set at $100 since 1991.

House Bill

Starting for January 1, 2004, the Medicare Part B deductible would be increased by the same percentage as the Part B premium increase. Specifically, the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance

Trust Fund would be used as the update. The amount would be rounded to the nearest dollar. The provision would be effective upon enactment.

Senate Bill

The Medicare Part B deductible would be set at $100 through 2005 and then increased to $125 in 2006. Effective January 1 of subsequent years, the deductible would be increased annually by the percentage change in the CPI-U for the previous year ending in June. The amount would be rounded to the nearest dollar. The provision would be effective upon enactment.

Conference Agreement

The Medicare Part B deductible will remain $100 through 2004. The deductible will be $110 for 2005, and in subsequent years the deductible will be increased by the same percentage as the Part B premium increase. Specifically, the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance Trust Fund will be used as the update. The deductible amount will be rounded to the nearest dollar. The provision is effective upon enactment.

In 1966, Medicare's $50 Part B deductible equaled about 45 percent of Part B charges. Today's $100 deductible equals about three percent of such charges. Indexing the Part B deductible to grow at the same rate as total Part B spending per beneficiary would maintain the deductible at 3 percent of such charges over time.

An unchanged Part B deductible is a benefit increase over time, as costs of medical care rise. Beneficiaries pay about 25 percent of this benefit increase, through increased Part B premiums; taxpayers finance the remaining 75 percent. The Part B deductible has increased only three times since the beginning of Medicare, when it was $50. The deductible has since been increased to $60 in 1973, $75 in 1982, and $100 in 1991. About one-half of beneficiaries are insulated from Part B deductibles through Medigap, Medicaid, or employer-sponsored supplemental insurance that covers the Part B deductible. The Part B deductible has increased only three times since Medicare began in 1965, when it was $50. It was raised to $60 in 1973, $75 in 1982, and $100 in 1991.

5-year Authorization of Reimbursement for All Medicare Part B Services Furnished by Certain Indian Hospitals and Clinics (Section 630 of the Conference Agreement and Section 450C of the Senate Bill)**.**

Present Law

Medicare covers specified Part B services provided by a hospital or ambulatory care clinic (whether provider-based or freestanding) that is operated by the Indian Health Service, by an Indian tribe, or by a tribal organization. These services include physicians' services, health practitioners (physician assistant, nurse practitioner, or clinical nurse specialist; certified registered nurse anesthetist; certified nurse-midwife; clinical social worker; clinical psychologist; and a registered dietitian or nutrition professional) and outpatient physical therapy services provided by a physical or occupational therapists.

House Bill

No provision.

Senate Bill

The provision would expand covered Medicare Part B items and services provided in hospitals or ambulatory care clinics (whether provider-based or freestanding) that are operated by the Indian Health Service or by an Indian tribe or tribal organization. All covered Part B items and services would be paid when provided in a hospital or ambulatory care clinic operated by the Indian Health Service or by an Indian tribe or tribal organization. The provision would apply to items and services furnished on or after October 1, 2004.

Conference Agreement

The conference agreement provides a 5-year expansion of the items and services covered under Medicare Part B when furnished in Indian hospitals and ambulatory care clinics. The conference agreement applies to items and services furnished on or after January 1, 2005.

Conforming Changes Regarding Federally Qualified Health Centers (Section 420 of the Senate Bill).

Present Law

Medicare pays federally qualified health centers (FQHCs) for their services on a reasonable cost basis.

House Bill

No provision.

Senate Bill

Medicare would exclude the costs incurred by a FQHC for providing services and receiving payments through a contract with an eligible entity operating a Medicare prescription drug plan. The provision would be effective upon enactment.

Conference Agreement

No provision.

Reimbursement for Total Body Orthotic Management for Certain Nursing Home Patients (Section 450B of the Senate Bill)**.**

Present Law

Orthotics are rigid devices, often called braces, which are applied to the outside of the body as a means of support for a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. They are categorized into one of three groups of devices: custom fitted, which require alterations to a prefabricated product; custom fabricated, which are made for a specific patient from his/her individual measurements; and molded to

patient model, which are created from a cast of the patient's body part. Examples of orthotics include spinal body jackets, hip abductors, and knee braces. Add-ons, such as straps and linings, are billed separately. Suppliers of orthotics include certified orthotists, medical equipment companies, and physicians' offices.

Orthotics (e.g., leg, arm, back, and neck braces) are covered Part B benefits when furnished in an institutional setting, such as in a hospital or skilled nurses facility, while durable medical equipment (DME) is not covered in those settings. Medicare considers a brace as an orthotic device when it can be used independently of DME. On the other hand, if a brace must be used in conjunction with, or is an accessory of, a DME item, then the brace is considered an item of DME. Orthotic devices include braces that are part of a bracing system even if the system depends on attachment to an external structure or frame.

At one point, the Centers for Medicare and Medicaid (CMS) in HCFA Ruling, No. 96-1, declared that bracing systems should be characterized as DME rather than orthotics. That ruling was deemed invalid because it made a substantive change in Medicare coverage rules and was not properly promulgated. Although the braces in a bracing system are attached to an external frame, they perform the functions of braces and the external frame is assistive in nature rather than determinative of the system's classification. Since the patients who need bracing systems typically are cared for in the nursing home environment, the classification of the bracing systems is crucial because orthotics are covered when furnished to nursing home patient, while DME is not. However, under the Benefits Improvement and Protection Act of 2000 (BIPA) (PubLNo 106-554), no payment may be made for prosthetics and certain custom-fabricated orthotics unless they are furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at an approved facility. Affected custom-fabricated orthotics are items requiring education, training, and experience to custom-fabricate and that are on a list to be published by the Secretary.

House Bill

No provision.

Senate Bill

The Secretary would be required to issue product codes that qualified practitioners and suppliers may used to receive Medicare reimbursement for qualified total body orthotic management devices no later than 60 days from enactment. These medically prescribed devices would consist of custom fitted individual braces with adjustable points at the hip, knee, ankle, elbow and wrists when the braces are attached to a frame that is integral to the device and the frame serves no purpose without the braces. The device would be designed to improve function, retard the progression of musculoskeletal deformity or restrict, eliminate, or assist in the functioning of the upper or lower extremities for a beneficiary who is in the full time care of a skilled nursing facility who requires such care for medical reasons. The provision would be effective upon enactment.

Conference Agreement

No provision.

Medicare Coverage of Self Injected Biologicals (Section 450E of the Senate Bill)**.**

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs and biologicals is specifically authorized by statute. For example, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Generally, Medicare will cover an outpatient drug as usually self-administered if it is delivered by intramuscular injection, but not if it is injected subcutaneously.

House Bill

No provision.

Senate Bill

From January 1, 2004 and before January 1, 2006, Medicare would cover self-injected biologicals that are approved by the Food and Drug Administration and that are prescribed as complete replacements for drugs or biologicals that are currently covered in physicians' offices or as hospital services provided to outpatients that are usually self-administered and provided incident to a physician's services. Medicare would cover self-injected drugs that are used to treat multiple sclerosis. The provision would apply to drugs and biologicals furnished on or after January 1, 2004 and before January 1, 2006.

Conference Agreement

No provision.

Requiring the Internal Revenue Service to Deposit Installment Agreement and Other Fees in the Treasury as Miscellaneous Receipts (Section 450G of the Senate Bill)**.**

Present Law

The Secretary of the Treasury was granted the authority by Senate Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103-286, the Treasury, Postal Service and General Government Appropriations Act of 1995 to establish new fees (if the fee is authorized by another law) or raise fees for services provided by the Internal Revenue Service to supplement appropriations made available to the Internal Revenue Service. The fees must be based on the costs of providing the specific services (to the persons paying the fees), and the Secretary must report quarterly to the Congress on the collection of such fees and how they are spent.

House Bill

No provision.

Senate Bill

The Secretary of the Treasury must deposit any fees collected under the authority provided by Senate Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103-286, the Treasury, Postal Service and General Government Appropriations Act of 1995 into the Treasury as miscellaneous receipts. The fees collected are only available to the Internal

Revenue Service if authority is provided in advance in an appropriations Act. The provision would be effective upon enactment.

Conference Agreement

No provision.

Medicare Coverage of Kidney Disease Education Services (Section 456 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

Kidney disease education services would be covered under Medicare. The services covered would be those: furnished to an individual with kidney disease who will require dialysis or a kidney transplant; furnished upon the referral of the physician managing the individual's kidney condition; and designed to provide comprehensive information regarding the management of comorbidities, the prevention of uremic complications, and each option for renal replacement therapy (including peritoneal diaylsis, hemodialysis and transplantation) and to ensure that the individual has the opportunity to actively participate in the choice of therapy. Kidney disease education services would be paid using the physician fee schedule on an assignment-related basis (thus prohibiting balance billing) outside the ESRD composite rate.

The Secretary would be required to ensure (and to monitor implementation to ensure) that each beneficiary who is entitled to kidney disease education services under Medicare receives such services in a timely manner that ensures that the beneficiary receives the maximum benefit of the services.

The Secretary would be required to report to Congress annually on the number of Medicare beneficiaries who are entitled to these education services and who received these services. In addition, the report would include any recommendations for legislative and administrative action as the Secretary determines appropriate. The first report would be due April 1, 2004. The provision would apply to services furnished on or after January 1, 2004.

Conference Agreement

No provision.

Subtitle D-Additional Demonstrations, Studies and Other Provisions

Demonstration Project for Coverage of Certain Prescription Drugs and Biologics (Section 641 of the Conference Agreement and Section 631 of the House Bill)**.**

Present Law

No provision.

House Bill

The Secretary would be required to conduct a 2-year demonstration project in 3 states covering more than 10,000 patients under Part B of the Medicare program that would pay for drugs and biologicals that are prescribed as replacements for existing covered drugs that are furnished incident to a physician's professional service which are not usually self-administered including oral anticancer chemotherapeutic agents. The project would not extend beyond December 31, 2005 and would not cost more than $100 million. The Secretary would be required to submit an evaluation to Congress concerning patient access and outcomes as well as the project's cost effectiveness. The Secretary would also be required to examine any cost savings attributed to reduced physicians' services and hospital outpatient department services for the administration of the biological. The demonstration project would begin 90 days from enactment and would end no later than December 31, 2005.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to conduct a 2-year demonstration project in 6 states covering more than 50,000 patients under Medicare Part B that pays for drugs and biologics that are prescribed as replacements for existing covered drugs that are furnished incident to a physician's professional service which are not usually self-administered, including oral anticancer chemotherapeutic agents. The project is required to provide for cost-sharing applicable with respect to the drugs or biologics in the same manner as the cost-sharing applicable under part D for standard prescription drug coverage. The project is not permitted to cost more than $500 million. No less than 40 percent of the funding shall be for oral cancer. The Secretary is required to submit an evaluation to Congress concerning patient access and outcomes as well as the project's cost effectiveness. The Secretary is also required to examine any cost savings attributed to reduced physicians' services and hospital outpatient department services for the administration of the biological. The demonstration project is required to begin 90 days following enactment and end no later than December 31, 2005.

The managers intend that this provision of the demonstration will provide immediate Part B coverage for all immunomodulating drugs and biologicals used when treating multiple sclerosis. Coverage will be extended without regard to whether there is medical or other supervision with respect to the administration of such drug or biological, and include the biological administered via intramuscular injection currently covered under Section 1861(s)(2)(A) or (B) of the Social Security Act.

Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home (Section 642 of the Conference Agreement and Section 629 of the House Bill).

Present Law

Intravenous immune globulin (IVIG) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents. Effective October 1, 2002, IVIG is covered for the treatment of certain conditions including pemphigus vulgaris, pemphigus foliaceus, and epidermolysis bullosa acquisita for the following specific patient subpopulations: (1) patients who have failed conventional therapy; (2) patients in whom conventional therapy is otherwise contraindicated; and (3) patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. IVIG for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short term therapy and not as a maintenance therapy. Contractors have discretion to define what constitutes a failure of conventional therapy and what constitutes short-term therapy.

House Bill

Intravenous immune globulin for the treatment of primary immune deficiency diseases in the home would be included as a covered medical service. Intravenous immune globulin would be defined as an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, if a physician determines administration of the derivative in the patient's home is medically appropriate. This would not include items or services related to the administration of the derivative. Intravenous immune globulin would be paid at 80 percent of the lesser of actual charge or the payment amount. This provision would apply to items furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare. Intravenous immune globulin is defined as an approved pooled plasma derivative for the treatment, in the patient's home, of a patient with a diagnosed primary immune deficiency disease, if a physician determines administration of the derivative in the patient's home is medically appropriate. Items or services related to the administration of the derivative are not included in the definition. Intravenous immune globulin is to be paid at 80 percent of the lesser of actual charge or the payment amount. This provision applies to items furnished on or after January 1, 2004.

MedPAC Study of Coverage of Surgical First Assisting Services of Certified Registered Nurse First Assistants (Section 643 of the Conference Agreement and Section 450I of the Senate Bill)**.**

Present Law

Surgical first assisting services are not separately covered services of Medicare and certified registered nurse first assistants are not able to bill the Medicare program directly for their

services. Their services are paid by surgeons who are paid under the Medicare physician fee schedule.

House Bill

No provision.

Senate Bill

The Secretary would be required to conduct a 3-year demonstration in 5 states that would pay for "surgical first assisting services" to Medicare beneficiaries furnished by a certified registered nurse first assistant. These services would consist of assisting a physician with surgery and related preoperative, intraoperative, and postoperative care furnished by a certified registered nurse first assistant. Payment would be 80% of the lesser of: the actual charge for the services or 85% of the physician fee schedule amount. Aggregate payments for the demonstration would be required not to exceed the amount that would have been paid if this demonstration project had not been implemented. The Secretary would be required to report to Congress on the evaluation of patient outcomes and on the cost-effectiveness of the demonstration by January 1, 2007. The demonstration is required to begin 90 days after enactment.

Conference Agreement

The conference agreement requires that MedPAC study the feasibility and advisability of Medicare Part B payment for surgical first assisting services furnished to Medicare beneficiaries by a certified registered nurse first assistant. MedPAC is required to submit the report by January 1, 2005 and to include recommendations for legislation or administrative action.

MedPAC Study of Payment for Cardio-Thoracic Surgeons (Section 644 of the Conference Agreement).

Present Law

Cardio-thoracic surgeons are paid under the Medicare physician fee schedule for their services.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the MedPAC to study the practice expense relative values in the Medicare physician fee schedule for the specialty of thoracic surgery to determine whether such values adequately take into account the attendant costs of nurse assistants at surgery. The study is required to be submitted to Congress by January 1, 2005 and to include recommendations for legislative or administrative action.

Study on Coverage of Outpatient Vision Services Furnished by Vision Rehabilitation Professionals Under Part B (Section 645 of the Conference Agreement and Section 446 of the Senate Bill)**.**

Present Law

Medicare does not cover routine eye care or related services and will not pay for eyeglasses; most contact lenses; eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses; and most procedures performed to determine the refractive state of the eyes.

Medicare pays for prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue) when furnished incident to physicians' services or on a physician's order. The law specifically provides coverage for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

The Rehabilitation Act of 1973 as amended prohibits discrimination in programs conducted by federal agencies, in programs receiving federal financial assistance, in federal employment and employment practices of federal contractors. The act provides much of the basis for the Americans with Disabilities Act including its standards for determining employment discrimination.

House Bill

No provision.

Senate Bill

Medicare Part B would cover vision rehabilitation services furnished to a beneficiary who is diagnosed with certain vision impairments. These vision impairments would be vision loss that constitutes a significant limitation of visual capability that cannot be corrected by conventional means and that is manifested by one or more of the following conditions: (1) best corrected visual acuity of less than 20/60 or significant central field defect; (2) significant peripheral field defect including homonymous or heteronymous bilateral visual field defect or generalized contraction or constriction of field; (3) reduced peak contrast sensitivity; and (4) other appropriate diagnoses or indications. Covered services would be established by a plan of care developed by a qualified physician or qualified occupational therapist whose plan of care is periodically reviewed by a qualified physician. These services would be provided in an appropriate setting by a qualified physician, qualified occupational therapist, or vision rehabilitation professional under the general supervision of a qualified physician using a plan of care established and reviewed by the qualified physician. A qualified physician would be an ophthalmologist or a doctor of optometry. A vision rehabilitation professional would include an orientation and mobility specialist, a rehabilitation teacher, or a low vision therapist who is appropriately licensed and certified under prevailing state laws with appropriate education and training.

Medicare would pay for the services under the physician fee schedule. These services would not be paid under the hospital outpatient department prospective payment system. Payment would be made to the qualified physician or the facility (such as a rehabilitation agency,

a clinic, or other facility) through which services are furnished under the plan care if there is a contractual arrangement between the vision rehabilitation specialist and the facility where the facility submits the bill for the services. Medicare's coverage of vision rehabilitation services would not be taken into account for any purpose under the Rehabilitation Act of 1973.

The Secretary would be required to publish a interim final rule in the Federal Register no later than 180 days from the date of enactment; the regulation, although effective immediately, would be subject to at least a 60-day public comment period. The Secretary would be required to consult with qualified professional and consumer groups including the National Vision Rehabilitation Cooperative, the Association for Education and Rehabilitation of the Blind and Visually Impaired, the Academy for Certification of Vision Rehabilitation and Education Professionals, the American Academy of Ophthalmology, the American Occupational Therapy Association, and the American Optometric Association.

Conference Agreement

The conference agreement requires the Secretary to study the feasibility and advisability of: 1) providing for payment for vision rehabilitation services furnished by vision rehabilitation professionals, and 2) implementing a demonstration project for vision care PPO networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with the insertion of intra ocular lens. The Secretary is urged to examine any licensure or certification difficulties faced by vision rehabilitation professionals. The report is due to Congress by January 1, 2005 and is to include recommendations for legislation or administrative action. In reviewing reimbursement for vision rehabilitation professionals, the report shall examine payments through qualified physicians to vision rehabilitation professionals for either directly supervised services or services delivered under generalized supervision.

Medicare Health Care Quality Demonstration Programs (Section 646 of the Conference Agreement and Section 441 of the Senate Bill)**.**

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) incentives to improve the safety of care provided to beneficiaries; (2) appropriate use of best practice guidelines; (3) reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve safety, quality, and efficiency; (6) appropriate use of culturally and ethnically sensitive care; and (7) related financial effects associated with these changes. The participants would include appropriate health care groups including physician groups, integrated health care delivery systems, or regional coalitions. These health care groups may implement alternative payment systems that encourage the

delivery of high quality care and streamline documentation and reporting requirements. They may also offer benefit packages distinct from those that are currently available under Medicare Parts A and B and under the Part C Medicare Advantage plan. To qualify for this demonstration, health care groups must meet Secretary-established quality standards; implement quality improvement mechanisms that integrate community-based support, primary care, and referral care; encourage patient participation in decisions; among other requirements.

The Secretary may waive Medicare and Peer Review and Administrative Simplification (Title XI) requirements as necessary and may direct agencies within Health and Human Services (HHS) to evaluate, analyze, support, and assist in the demonstration project. The demonstration program would be subject to budget-neutrality requirements. The Secretary would not be permitted to implement the program before October 1, 2004.

Conference Agreement

The conference agreement requires the Secretary to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) incentives to improve the safety of care provided to beneficiaries; (2) appropriate use of best practice guidelines; (3) reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve safety, quality, and efficiency; (6) appropriate use of culturally and ethnically sensitive care; and (7) related financial effects associated with these changes. Health care groups that may participate are physician groups, integrated health care delivery systems, and regional coalitions. These health care groups may implement alternative payment systems that encourage the delivery of high quality care and streamline documentation and reporting requirements. They may also offer benefit packages distinct from those that are currently available under Medicare Parts A and B and under the Part C Medicare Advantage plan.

To qualify for this demonstration, health care groups must meet Secretary-established quality standards; implement quality improvement mechanisms that integrate community-based support, primary care, and referral care; encourage patient participation in decisions; among other requirements. The Secretary may waive Medicare and Peer Review and Administrative Simplification (Title XI) requirements as necessary and may direct agencies within Health and Human Services (HHS) to evaluate, analyze, support, and assist in the demonstration project. The demonstration program is subject to budget-neutrality requirements.

GAO Study on Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services Under Part B of the Medicare Program (Section 647 of the Conference Agreement and Section 448 of the Senate Bill)**.**

Present Law

Medicare's Part B payment for outpatient mental health services is limited to 62.5% of covered expenses incurred in any calendar year in connection with the treatment of a mental, psychoneurotic, or personality disorder of an individual who is not an inpatient of a hospital at the time such expenses are incurred. The term "treatment" does not include brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by the physician. This 62.5% payment limitation applies to outpatient mental health treatments furnished by physicians,

comprehensive outpatient rehabilitation facilities (CORFs), physician assistants, clinical psychologists, and clinical social workers. Items and supplies furnished by physicians or other mental health practitioners in connection with treatment are also subject to the limitation. The limitation is applied only to therapeutic services (e.g., psychotherapy) and to follow-up diagnostic services performed to evaluate the progress of a course of treatment. Charges for initial diagnostic services (i.e., psychiatric testing and evaluation used to diagnose the patient's illness) are not subject to this limitation. The 62.5% limitation is subject to Part B deductible and coinsurance requirements.

Medicare covers outpatient hospital partial hospitalization services connected with the treatment of mental illness. Partial hospitalization services are covered only if the individual would otherwise require inpatient psychiatric care. The 62.5% payment limitation does not apply to partial hospitalization services, except for services that are directly provided by a physician. Under this benefit, Medicare covers: (A) individual and group therapy with physicians or psychologists (or other authorized mental health professionals); (B) occupational therapy; (C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; (D) drugs and biologicals furnished for therapeutic purposes that cannot be self-administered; (E) individualized activity therapies that are not primarily recreational or diversionary; (F) family counseling (for treatment of the patient's condition); (G) patient training and education; and (H) diagnostic services. Partial hospitalization services are also covered in community mental health centers. Family counseling services with members of the household are covered only where the primary purpose of such counseling is the treatment of the patient's condition.

House Bill

No provision.

Senate Bill

Medicare would cover marriage and family therapist services and mental health counselor services for the diagnosis and treatment of mental illness. The therapists would be legally authorized to provide such services under State law and would provide services that would be otherwise covered if furnished by a physician or furnished incident to a physician’s professional service. No facility or other provider would charge or be paid for these services. The amount of payment would be 80% of the lesser of the actual charge or 75% of the amount paid to a psychologist. These services would be subject to assignment. These services would be excluded from the skilled nursing facility prospective payment system. Rural health clinics, federally qualified health centers, hospice programs would be authorized to provide such services. Marriage and family therapists would be authorized to develop post hospital discharge plans for patients. The provisions would apply to services furnished on or after January 1, 2004.

Conference Agreement

The conference agreement requires the GAO to study the feasibility and advisability of providing Medicare Part B coverage of marriage and family therapist services and mental health counselors and of the appropriate settings and payment methodologies of such services. Recommendations for legislation or administrative actions are also required to be included in the study. The report is required to be submitted to Congress no later than January 1, 2005.

MedPAC Study on Direct Access to Physical Therapy Services (Section 648 of the Conference Agreement, Section 624 of the House bill and Section 449 of the Senate bill)**.**

Present Law

No provision.

House Bill

GAO would be required to conduct a study on access to physical therapist services in states authorizing access to such services without a physician referral compared to states that require such a physician referral. The study would: 1) examine the use of and referral patterns for physical therapist services for patients age 50 and older in states that authorize such services without a physician referral and in states that require such a referral; 2) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries; 3) examine the physical therapist services within the facilities of the Department of Defense; and 4) analyze the potential impact on beneficiaries and on Medicare expenditures of eliminating the need for a physician referral for physical therapist services under the Medicare program. GAO would be required to submit a report to Congress on the study within one year of enactment.

Senate Bill

The Secretary would be required to establish a 3-year demonstration project in at least 5 states to examine the costs and patient satisfaction associated with allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and comprehensive outpatient rehabilitation facility (CORF) services. In this instance, the beneficiary would not be required to be under the care of or referred by a physician to receive physical therapy services. Also, a physician or qualified physical therapist would be permitted to certify, recertify, establish and periodically review the beneficiary's plan of care. To the extent possible, the demonstration project would be conducted on a statewide basis. The project would be required to be established not later than 1 year after the date of enactment. The Secretary would be allowed to terminate the operation of a project at a site if, based on actual data, Medicare expenditures are greater than they otherwise would be without implementation of the demonstration project. The Secretary would be able waive Medicare requirements as necessary and appropriate. The Secretary wold be required to conduct interim and final evaluations of the project which would submitted to the Congressional committees of jurisdiction no later than the end of the second year of operation and no later than 180 days after the end of the project. This provision would be effective upon enactment.

Conference Agreement

The conference agreement requires MedPAC to study the feasibility and advisability of allowing Medicare beneficiaries in fee-for-service direct access to outpatient physical therapy services and those physical therapy services that are furnished as comprehensive rehabilitation facility services. For the purposes of the study, direct access is defined as access to physical therapy services without the requirement that beneficiaries be under the care of, or referred by, a physician. Further, the services provided are not required to be under the supervision of a physician. Finally, either a physician or a qualified physical therapist could satisfy any requirement for certification, recertification and establishment and review of a plan of care. This

study, together with recommendations for legislation or administrative actions, must be submitted to Congress no later than January 1, 2005.

Demonstration Project for Consumer Directed Chronic Outpatient Services (Section 648 of the Conference Report and Section 736 of the House bill)

Present Law

No provision. Medicare coverage requires that a beneficiary need medically necessary care. In general, Medicare pays the provider that delivers skilled health care services.

House Bill

The Secretary would be required to establish no fewer than 3 demonstration projects that evaluate methods to improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made on their behalf by Medicare. The methods would be required to include permitting beneficiaries to direct their own health care needs and services. In designing the demonstrations, the Secretary would be required to evaluate practices used by group health plans and practices under State Medicaid programs that permit patients to self-direct the provision of personal care services and to determine the appropriate scope of personal care services that would apply under the demonstration projects.

The Secretary would be required to establish the demonstrations within 2 years of enactment. Demonstrations would be required to be located in an urban area, a rural area, and an area that has a Medicare population with a diabetes rate that significantly exceeds the national average rate. The Secretary would be required to evaluate the clinical and cost effectiveness of the demonstrations. Reports to Congress would be required biannually beginning 2 years after the demonstrations begin.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish no fewer than 3 demonstration projects that evaluate methods to improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made on their behalf by Medicare. The methods are required to include permitting beneficiaries to direct their own health care needs and services. In designing the demonstrations, the Secretary is required to evaluate practices used by group health plans and practices under State Medicaid programs that permit patients to self-direct the provision of personal care services and to determine the appropriate scope of personal care services that apply under the demonstration projects.

The Secretary is required to establish the demonstrations within 2 years of enactment. Demonstrations are required to be located in an urban area, a rural area, and an area that has a Medicare population with a diabetes rate that significantly exceeds the national average rate. The Secretary is required to evaluate the clinical and cost effectiveness of the demonstrations. Reports to Congress are required biannually beginning 2 years after the demonstrations begin.

Medicare Care Management Performance Demonstration (Section 649 of the Conference Report and Section 736 of the House Bill).

Current Law

No provision

House Bill

No provision

Senate Bill

The Secretary would be required to establish a 3-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes before October 1, 2004. Six sites would be designated for the demonstration, 3 in urban areas and at least 1 in a rural area. One site would be required to be located in Arkansas. Any Medicare beneficiary enrolled in part B who has at least 4 complex medical conditions and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.

Each principal care physician who agrees to manage the complex clinical care of a beneficiary eligible to participate would be required to agree to: (1) serve as the primary contact of the beneficiary in accessing items and services under Medicare; (2) maintain medical information related to care and services furnished by other health care providers including clinical reports, medication and treatments prescribed by other physicians, hospital and hospital outpatient services, skilled nursing home care, home health care, and medical equipment services; (3) monitor and advocate for the continuity of care of the beneficiary and the use of evidence-based guidelines; (4) promote self-care and family care giver involvement where appropriate; (5) have appropriate staffing arrangements to conduct patient self-management and other care coordination activities as specified by the Secretary; refer the beneficiary to community service organizations and coordinate the services of such organizations with the care provided by health care providers; and (7) meet such other complex care management requirements as the Secretary may specify.

The Secretary would pay each principal care physician a monthly complex care management fee developed by the Secretary. The fee would be the full payment for all the functions performed by the principal care physician including any functions performed by other qualified practitioners acting on behalf of the physician, appropriate staff under the supervision of the physician, and any other person under a contract with the physician, including any person who conducts patient self-management and caregiver education. Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented. The Secretary would be required to report to Congress on the demonstration program 6 months after its completion.

Conference Agreement

The Secretary would be required to establish a 3-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. Four sites would be designated for the demonstration: with at least two in urban areas and one in a rural area. One of the demonstration sites would be in a state with a medical school with a geriatrics department that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia. Any Medicare beneficiary enrolled in part A and B who has one or more chronic medical conditions specified by the Secretary (one of which may be a cognitive impairment) and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.

The conferees encourage CMS to work with Agency for Healthcare Research and Quality (AHRQ) to provide grants to assist physicians in carrying out the health information technology aspect of the demonstration. In particular, the grants should focus on issues involving clinical decision support tools, clinical reminders, and improved communication between patients, providers and payors. AHRQ is currently working to provide grant programs in this area.

Demonstration of Coverage of Chiropractic Services under Medicare (Section 440 of the Senate Bill)**.**
Present Law

No specific provision with respect to a demonstration project. Medicare covers limited chiropractic services, specifically manual manipulation for correction of a dislocated or misaligned vertebra or subluxation.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 3-year demonstration program at 6 sites to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. These projects may not be implemented before October 1, 2004. The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform. An eligible beneficiary participating in the demonstration project, including those enrolled in Medicare +Choice or Medicare Advantage plans, would not be required to receive approval by physician or other practitioner in order to receive chiropractic services under the demonstration project.

The Secretary would be required to consult with chiropractors, organizations representing chiropractors, beneficiaries and organizations representing beneficiaries in establishing the demonstration projects. Participation by eligible beneficiaries would be on a voluntary basis. The 6 sites would be equally split between rural and urban areas; at least one of the sites would be in a health professional shortage area. The Secretary would be required to evaluate the demonstration projects to determine (1) whether the participating beneficiaries used fewer Medicare covered services than those who did not participate; (2) the cost of providing such

chiropractic services under Medicare; (3) the quality of care and satisfaction of participating beneficiaries; and (4) other appropriate matters.

The Secretary would be required to submit a report, including recommendations, to Congress on the evaluation no later than 1 year after the demonstration projects conclude. The Secretary would waive Medicare requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. Appropriations from the Federal Supplementary Insurance Trust Fund are authorized as necessary to conduct this demonstration. The provision would be effective upon enactment.

Conference Agreement

The Secretary would be required to establish a 2-year demonstration program at 4 sites to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. These projects may not be implemented before October 1, 2004. The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction where treatment occurs. An eligible beneficiary participating in the demonstration project, including those enrolled in Medicare +Choice or Medicare Advantage plans, would not be required to receive approval by physician or other practitioner in order to receive chiropractic services under the demonstration project.

The Secretary would be required to consult with chiropractors, organizations representing chiropractors, beneficiaries and organizations representing beneficiaries in establishing the demonstration projects. Participation by eligible beneficiaries would be on a voluntary basis. The 4 sites would be equally split between rural and urban areas; at least one of the sites would be in a health professional shortage area. The Secretary would be required to evaluate the demonstration projects to determine (1) whether the participating beneficiaries used fewer Medicare covered services than those who did not participate; (2) the cost of providing such chiropractic services under Medicare; (3) the quality of care and satisfaction of participating beneficiaries; and (4) other appropriate matters.

The Secretary would be required to submit a report, including recommendations, to Congress on the evaluation no later than 1 year after the demonstration projects conclude. The Secretary would waive Medicare requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. Appropriations from the Federal Supplementary Insurance Trust Fund are authorized as necessary to conduct this demonstration.

Demonstration Project to Examine What Weight Loss Weight Management Services Can Cost-Effectively Reach the Same Result as the NIH Diabetes Primary Prevention Trial Study: A 50 Percent Reduction in the Risk for Type 2 Diabetes for Individuals Who Have Impaired Glucose Tolerance and Are Obese (Section 450I of the Senate Bill)**.**

Present Law

No provision regarding the demonstration. Medicare covers medical nutrition therapy services for beneficiaries with diabetes or a renal disease who (1) have not received diabetes outpatient self-management training services within a time period to be determined by the Secretary, (2) are not receiving maintenance dialysis, and (3) meet other criteria to be established by the Secretary.

Nutrition therapy services are nutritional diagnostic, therapy, and counseling services for the purpose of disease management. The services must be provided by a registered dietitian or nutritional professional pursuant to a referral by a physician. Payment is based on the lower of actual charges or 85% of the physician fee schedule on an assignment-related basis.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a demonstration project that would examine the cost effectiveness and health benefits of providing group weight loss management services for Medicare beneficiaries who are obese and have impaired glucose tolerance. Group weight loss management services are those furnished to beneficiaries who have been diagnosed and referred by a physician for assessment and treatment based on individual needs or a specific program or method that has demonstrated efficacy to produce and maintain weight loss through results published in peer-reviewed scientific journals. The program would be required to provide assessment of current body weight and recording of weight status at each meeting session; provision of a healthy eating plan; provision of an activity plan; provision of a behavior modification plan; and a weekly group support meeting.

Expenditures would be constrained by 2 limitations: the costs of group weight loss management services could not exceed the annual cost per recipient of the medical nutritional therapy benefit and the total amount of payments made under the demonstration could not exceed $2.5 million for each fiscal year of the project. Medical nutrition therapy services that would be furnished under the demonstration project would be covered under part B of Medicare and payment would be 80% of the lesser of the actual charge for the services or 85% of the applicable physician fee schedule amount. Group weight loss management professionals would be paid by Medicare on an assignment-related basis and balance billing would not be permitted.

The demonstration project would be conducted for 2 years at sites designated by the Secretary. The Secretary would be required to give preference to sites located in rural areas or areas that have a high concentration of Native Americans with type 2 diabetes. The Secretary would be required to submit interim reports on this demonstration project to the Committee on Ways and Means and the Committee on Finance. A final report to both Committees would be due 6 months after the date the demonstration project concludes. The provision would be effective upon enactment.

Conference Agreement

No provision.

TITLE VII-PROVISIONS RELATING TO PARTS A AND B

Subtitle A-Home Health Services

Update in Home Health Services (Section 701 of the Conference Agreement and Section 701 of the House Bill)**.**

Present Law

Home health service payments are increased on a federal fiscal year basis that begins in October. The FY 2004 statutory update will be the full increase in the market basket index. The prospective payment system provides for outlier payment B payments for extraordinarily costly cases B with the total amount of outlier payment (the outlier pool) not exceeding 5 percent of estimated total home health prospective payments.

House Bill

This provision would increase home health agency payments by the home health market basket percentage increase minus 0.4 percentage points for 2004 through 2006. The update for subsequent years would be the full market basket percentage increase. The provision would also change the time frame for the update from the federal fiscal year to a calendar year basis. The home health prospective payment rates would not increase for the October 1 through December 31, 2003 period.

Senate Bill

No provision.

Conference Agreement

The conference agreement changes the time frame for the home health update from the federal fiscal year to a calendar year basis beginning with 2004. Home health agency payments are increased by the full market basket percentage for the last quarter of 2003 (October, November, and December) and for the first quarter of 2004 (January, February, and March). The update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points. The size of the outlier pool for home health prospective payment may not exceed 3 percent of the total payment projected under they payment system beginning January 1, 2004, total payments are not increased to account for the difference.

Demonstration Project to Clarify the Definition of Homebound (Section 702 of the Conference Agreement, Section 704 of the House Bill, and Section 450 of the Senate Bill)**.**

Present Law

Home health services are covered only if the Medicare beneficiary is confined to the home, needs skilled nursing care on an intermittent basis or needs physical or occupational therapy or speech-language pathology services, has had a plan of care established that is periodically reviewed by a physician, and is under a physician's care. Any absence of a beneficiary from the home for purposes of receiving health care treatment, including regular absences for participating in therapeutic, psychosocial, or medical treatment in an adult daycare program does not disqualify an individual from being considered confined to the home (or homebound). Further, any other absence of a beneficiary from the home cannot disqualify an individual from being considered homebound if the absence is of infrequent or of relatively short duration. Absence from the home to attend a religious service is considered an absence of infrequent or short duration.

House Bill

The Secretary would be required to conduct a 2-year demonstration project where beneficiaries with chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary would have to have been certified by a physician to have a permanent and severe condition that will not improve; to permanently need assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); to permanently require skilled nursing services (not including medication management); to need either an attendant during the day to monitor and treat the beneficiary's medical condition or daily skilled nursing; and to require technological assistance or the assistance of another person to leave the home.

The Secretary would be required to select 3 states in which to conduct the demonstration in the northeast, midwest and western regions of the United States. Up to 15,000 beneficiaries would be permitted to participate. Data would be required to be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration would be required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary would be required to report to Congress on whether the subject of the demonstration adversely effected the provision of home health services under Medicare or directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to Medicare. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to conduct a 2-year demonstration project where beneficiaries with chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary would have to have been certified by a physician to have a permanent and severe condition that will not improve; to permanently need assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); to permanently require skilled nursing services (not including medication management); to need either an attendant during the day to monitor and treat the beneficiary's medical condition or daily skilled nursing; and to require technological assistance or the assistance of another person to leave the home.

The Secretary would be required to select 3 states in which to conduct the demonstration in the northeast, midwest and western regions of the United States. Up to 15,000 beneficiaries would be permitted to participate. Data would be required to be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration would be required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary would be required to report to Congress on whether the subject of the demonstration adversely effected the provision of home health services under Medicare or directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to Medicare. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to conduct a 2-year demonstration project where beneficiaries enrolled in Medicare Part B with specified chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary is eligible to be deemed to be homebound if the beneficiary: (1) has been certified by a physician to have a permanent and severe condition that is not expected to improve; (2) permanently needs assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); (3) permanently requires skilled nursing services (not including medication management); (4) needs either an attendant during each day to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living; (5) requires technological assistance or the assistance of another person to leave the home; and (6) does not regularly work in a paid position full-time or part-time outside the home.

The Secretary is required to select 3 states in the northeast, midwest and western regions of the United States in which to conduct the demonstration. Up to 15,000 beneficiaries can participate. Data must be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration is required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary is required to report to Congress on: whether the subject of the demonstration adversely effected the provision of home health services under Medicare or has directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to Medicare. Payment for the costs of carrying out the demonstration project will be made from the Part B Trust Fund. The provision is effective upon enactment.

Demonstration Project for Medical Adult Day Care Services (Section 703 of the Conference Agreement, Section 732 of the House Bill, Section 454 of the Senate Bill)**.**

Present Law

No provision

House Bill

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95% of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The 3-year demonstration project would be conducted in not more than 5 sites (which can include multiple facilities) in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2-year period. A medical adult day care facility would (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous 2-year period; (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions and (2) recommendations concerning the extension, expansion, or termination of the project. The provision would be effective upon enactment.

Senate Bill

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95% of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The 3-year demonstration project would be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2-year period. A medical adult day

care facility would (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous 2-year period; (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions and (2) recommendations concerning the extension, expansion, or termination of the project. The provision would be effective upon enactment.

Conference Agreement

Subject to earlier provisions in the conference agreement, the conference agreement requires the Secretary to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provides medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode will equal 95% of the amount that would otherwise apply subject to budget neutrality provisions. The agency or facility is prohibited from charging the beneficiary separately for the medical adult day care services. The Secretary is required to reduce payments made to medical adult day care facilities under the demonstration to offset excess spending. The 3-year demonstration project is to be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries is on a voluntary basis.

When selecting participants, the Secretary is required to give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2-year period. A medical adult day care facility is one that: (1) has been licensed or certified by a State to furnish medical adult day care services for a continuous 2-year period; (2) has been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary is able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary is required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 6 months after completion of the demonstration. The report is required to include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions, and (2) recommendations concerning the extension, expansion, or termination of the project. The provision is effective upon enactment.

Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Patients (Section 704 of the Conference Agreement, Section 954 in the House Bill, Section 630 in the Senate Bill).

Present Law

Medicare is required to monitor the quality of home health care and services for all patients as part of the survey process with a standardized, reproducible assessment instrument. The purpose of the monitoring is to determine whether the agency is helping all patients achieve and maintain the highest functional capacity that is possible as is reflected in the care plan the home health agency has developed for the patient. Medicare has implemented this requirement using the Outcomes and Assessment Information Set (OASIS). The OASIS data are used for Medicare payment (under home health prospective payment) and for quality improvement purposes for all patients.

House Bill

The requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) patients would be suspended until after the Secretary (1) reported to Congress on the benefits of these data, the value of the data compared to the administrative burden of data collection in small agencies, and the use of the OASIS information by both large and small agencies and then (2) published final regulations regarding the collection and use of non-Medicare/non-Medicaid OASIS data. The provision would not prohibit home health agencies from collecting OASIS data on private pay patients for the agencies' own use.

Senate Bill

Same provision.

Conference Agreement

The conference agreement suspends the requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) until the Secretary (1) reports to Congress on the benefits of these data, the value of the data compared to the administrative burden of data collection in small agencies, and the use of the OASIS information by both large and small agencies, and then (2) publishes final regulations regarding the collection and use of OASIS. The provision does not prohibit home health agencies from collecting OASIS data on private pay patients for the agencies' own use.

MedPAC Study of Medicare Margins of Home Health Agencies (Section 705 of the Conference Agreement and Section 703 of the House Bill)**.**

Present Law

No provision.

House Bill

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare home health prospective payment system. The study would examine whether systematic differences in payment margins were related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report to Congress on the study within 2 years of enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires MedPAC to study payment margins of home health agencies paid under the Medicare home health prospective payment system, using cost reports filed by agencies. The study is required to examine whether systematic differences in payment margins are related to differences in case mix, as measured by home health resource groups (HHRGs), among agencies. MedPAC is required to submit a report to Congress on the study within 2 years of enactment.

Coverage of Religious Nonmedical Health Care Institution Services Furnished In the Home. (Section 706 of the Conference Report)**.**

Present Law

No provision

House Bill

No provision

Conference Report

A religious nonmedical health care institution can provide home health services to individuals that meet the criteria laid out in 1821.

Increase in Medicare Payment for Certain Home Health Services (Section 451/Duplicative Provisions 459 and 463 of the Senate Bill)**.**

Present Law

Home health PPS provides payment for a 60-day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10% for home health services furnished in the home of beneficiaries living in rural areas during the 2-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment was not included in the base for determination of payment updates.

Home health PPS is required to make payments for extraordinarily costly cases. The total amount of the outlier payment may not exceed 5% of the total payment estimated to be made for the fiscal year.

House Bill

No provision.

Senate Bill

A 10% additional payment for home health care services furnished in a rural area during FY 2005 and FY 2006 would be provided without regard to certain budget-neutrality requirements. The total amount of outlier payments would be reduced to no more than 3% of total payments in FY 2004 and 4% for FYs 2005 and 2006. The provision would be effective for services furnished on or after October 1, 2003.

Conference Agreement
No provision.

Limitation on Reduction in Area Wage Adjustment Factors under the Prospective Payment System for Home Health Services (Section 452 of the Senate Bill)**.**

Present Law

Home health agencies are paid under Medicare using the prospective payment system. In calculating payment, the portion of the base payment amount that is attributable to wages and wage related costs is required to be adjusted for those costs. The Secretary is required to calculate an area wage adjustment factor that is actually used to adjust the base payment amount. The factors change annually as new wage data are reported and areas change in relative costliness.

House Bill

No provision.

Senate Bill

The provision would limit any reduction in the home health area wage adjustment factor for fiscal years 2005 and 2006. Any reduction could be no more than 3% less than the area wage adjustment factor applicable to home health services for the area in the previous year. The provision would be effective upon enactment.

Conference Agreement

No provision.

Subtitle B: Graduate Medical Education

Extension of Update Limitation on High Cost Programs (Section 711 of the Conference Agreement and Section 711 of the House Bill)**.**

Present Law

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospital's number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70% of a geographically adjusted national average amount. BIPA increased this floor to 85% of the locality adjusted, updated, and weighted national PRA starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140% of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003-FY2005 would receive an update equal to the Consumer Price Index (CPI) increase minus 2 percentage points. Currently, hospitals with per resident amounts between 85% and 140% of the geographically adjusted national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

House Bill

The hospitals with per resident amounts above140% of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

Senate Bill

No provision.

Conference Agreement

Hospitals with per resident amounts about 140% of the geographically adjusted national average amount would not get an update from FY2004 through FY20013.

Exception to the Initial Residency Period for Geriatric Residency or Fellowship Programs (Section 712 of the Conference Agreement and Section 410 of the Senate Bill)**.**

Present Law

Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period.

Geriatrics is a subspecialty of family practice, internal medicine and psychiatry. A 1-year fellowship is required for certification in geriatrics, following an initial residency in one of those three areas. The certifying boards agreed to reduce the minimum fellowship requirement from 2 years to 1 year, beginning with the 1998 exam. Those physicians interested in an academic career in geriatrics are encouraged to pursue 2-year and 3-year fellowships.

House Bill

No provision.

Senate Bill

The Secretary would be required to promulgate interim final regulations after notice and comment that establish a 2-year exception to the initial residency program for certain geriatric training programs. The regulations would be effective for cost reporting periods on or after October 1, 2003. The provision would be effective upon enactment.

Conference Agreement

The conference agreement clarifies that Congress intended to provide an exception to the initial residency period for geriatric fellowship programs to accommodate programs that require 2 years of training to initially become board eligible in the geriatric specialty. The Secretary is required to promulgate interim final regulations after notice and comment consistent with this intent after notice and subject to public comment. The regulations will be effective for cost reporting periods on or after October 1, 2003. The conferees also clarify that under section 1886(h) (5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

The Conference Committee is pleased that the Secretary has published a proposed rule, on January 12 2001, to provide Medicare payment for clinical psychology internship training programs. The Committee notes that Congress has consistently urged the Secretary to initiate payment for the training of clinical psychologists since 1997 and still awaits a final rule.

The Committee is concerned that delay in the rules will mean that hospitals and institutions will continue to reduce or eliminate psychology training programs as has been occurring in recent years to the detriment of Medicare beneficiaries. The Committee directs implementation of the rule within six months of the date of enactment of the law to which this report is attached. The Committee notes that clinical psychologists provide valuable and unique services to Medicare beneficiaries during their training. Regarding their training, clinical psychologists are distinguishable from other health care professionals in that they are the only doctoral level mental health professionals fully participating in Medicare whose clinical training is not currently reimbursed. In addition, their clinical internship training is entirely controlled, administered, supervised, evaluated, and certified by the hospital or institution, separately accredited, and distinct from any university training they receive. Clinical psychologists are hospital-based in the final stages of their training function in a parallel status to medical interns and residents, not medical nursing or health professional students. Where a clinical psychologist has clearly finished his or her educational curriculum and is training solely in the hospital setting, it is the intention of Congress that the hospital be reimbursed if that training is hospital-based.

Authority to Include Costs of Training of Psychologists in Payments to Hospitals Under Medicare (Section 408 of the Senate)**.**

Present Law

Medicare pays hospitals for its share of direct costs associated with approved hospital-based training programs for nurses and certain other allied health professionals including inhalation therapists, nurse anesthetists, occupational and physical therapists. Medicare will not pay for such costs associated with psychologists' training.

House Bill

No provision.

Senate Bill

Medicare would reimburse its share of the reasonable costs of approved education activities of psychologists under the allied health professional training provisions. The provision would apply for cost reporting periods beginning on or after October 1, 2004.

Conference Agreement

No provision.

Clarification of Congressional Intent Regarding the Counting of Residents in a Nonprovider Setting and a Technical Amendment Regarding the 3-year Rolling Ratio and the IME Ratio (Section 411 of the Senate Bill)**.**

Present Law

Medicare has different resident limits for counting residents its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed (the IRB ratio). Prior to BBA 1997, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances, a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare's DGME payment to teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period. Residents who are graduates from foreign medical schools do not count unless they pass certain exams.

Generally, the resident counts for both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. It may differ from the IME limit because in 1996 residents training in non-hospital sites were eligible for DGME payments but not for IME payments. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130% of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit.

Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a 3-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years. The rolling average

calculation includes podiatry and dental residents. If a hospital is above its limit, the count for the purposes of the rolling average is the FTE cap. In addition to the resident limit, BBA 1997 also places a limit on the IRB ratio itself. A hospital's IRB ratio used to calculate its IME adjustment for the current payment year cannot exceed its IRB ratio from the immediately preceding cost reporting period.

CMS has published regulations that limit Medicare's graduate medical payments when existing residents are transferred from a non-hospital entity to a teaching hospital, particularly when the non-hospital entity has historically paid for the training costs without hospital funding. CMS seeks to limit reimbursement to those residents that rotate from a hospital setting to non-hospital sites in order to (1) encourage hospitals to broaden physician training in ways that will encompass different primary care settings; and (2) prevent cost shifting from existing support within the community to Medicare.

House Bill

No provision.

Senate Bill

The Secretary would be required to reimburse teaching hospitals for residents in non-hospital locations, when hospitals incur all, or substantially all, the costs of the training in that site starting from the effective date of a written agreement between the hospital and the entity owning or operation the non-hospital site. The effective date of the written agreement would be determined according to generally accepted accounting principles. The Secretary would not be able to take into account the fact that the hospital costs incurred are lower than actual Medicare reimbursement. Starting for FY2004, dental and podiatric residents would be removed from the 3-year rolling average calculation for IME and DGME reimbursements. The provision would be effective upon enactment.

Conference Agreement

For 12 months as of January 1, teaching hospitals can count residents in non-hospital locations regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital clinic site participating in a family practice program. Provisions regarding the payment of IME and DME for training in non-hospital sites that were included in the Balanced Budget Act of 1997 Congress were intended to encourage placement of residents in rural and other underserved areas and in ambulatory sites that are more in alignment with the types of practice they would have upon practice. The purpose was two-fold: to increase access to care by increasing the numbers of residents training in those settings, and to increase the likelihood of physicians placing themselves in practice in rural and underserved areas.

For programs established after January 1, 2002, The Secretary shall clarify in future regulation its definition of reasonableness of payment for supervisory physicians.

The Secretary shall initiate a study on the training of residents in non-hospital settings, and the use of volunteer faculty in those settings. The study is due within six months of enactment. The study shall include the following:

examination of the effect of the change in the BBA that allowed payment by Medicare for graduate medical education in non-hospital settings, to include whether access and numbers of physicians placing in rural and underserved areas has increased.
Examination of programs on a national level regarding evidence of possible misuse of federal money with respect to volunteering supervisory physicians.
A determination whether supervisory physicians are freely volunteering their time
A description of what incentives are available in each state that are offered to physicians who volunteer their time as supervisory physicians (eg. CME credit hours, hospital privileges, etc.)

Subtitle C - Chronic Care Improvement

Voluntary Chronic Care Improvement Under Traditional Fee-For-Service (Section 721 of the Conference Agreement, Section 721 of the House Bill, and Section 442 of the Senate Bill).

Present Law

No provision.

A hearing was held by the Ways and Means Committee, Health Subcommittee on February 25, 2003 on the importance of providing chronic care management in fee-for-service Medicare. Statistics from the Robert Wood Johnson Foundation state 84% of Medicare beneficiaries have one or more chronic conditions and account for 95% of Medicare spending. With Americans living longer due to advances in medical procedures and increased availability to medications, Medicare costs will continue to escalate. Thus, chronic care programs should be implemented in both traditional fee-for-service and private plans to target these individuals, improve health outcomes and save money.

The Centers for Medicare & Medicaid Services (CMS) has run demonstration programs in the Medicare program targeting high cost seniors. Currently, CMS is managing more than a dozen disease management demonstration projects. The BBA allowed for the continuation of demonstration projects that were cost-effective, improved quality of care and patient/beneficiary satisfaction. These demonstration sites enrolled more than 7,600 Medicare beneficiaries. CMS has also started on disease management demonstrations authorized by BIPA of 2000, to provide disease management services to Medicare beneficiaries with congestive heart failure, diabetes, or coronary heart disease. CMS estimates that enrollment will include around 30,000 Medicare beneficiaries. BIPA also required a physician group demonstration to encourage coordination and reward physicians for improving beneficiary health outcomes. CMS has demonstrated significant progress in integrating chronic care management programs into fee-for-service Medicare and HMOs. The following provision would increase the number of chronic care management programs (also known as disease management programs) in fee-for-service Medicare, with the intention of expanding these programs nationwide if health outcomes improve and Medicare costs decrease.

Additionally, a 1999 survey showed 56% of employers offer disease management services to their employees, along with 67% of HMOs and 64% of POS plans. Private plans continue to offer disease management programs to reduce costs, improve health outcomes, and increase patient and provider satisfaction. Because many of these health plans offer chronic care

management programs already, it is important to require Medicare Advantage to offer these programs, as well.

House Bill

The Secretary would be required to establish a process for providing chronic care improvement programs for Medicare beneficiaries in fee-for-service Medicare (Parts A and B) who have certain chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke or other diseases identified by the Secretary for inclusion in the program. The Secretary would establish administrative regions (called CCMA regions) within the United States for the chronic care improvement programs. Within each region, the Secretary would select at least two contractors under a competitive bidding process on the basis of the ability of each bidder to achieve improved health outcomes of beneficiaries and improved financial outcomes of the Medicare program. A contractor could be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate. Contractors would be required to meet certain clinical, quality improvement, financial, and other requirements specified by the Secretary. Subcontractors could be used by the contractors. The Secretary would be able to phase-in implementation of the program beginning one-year after enactment.

Each program would be required to have a method for identifying targeted Medicare beneficiaries who would be offered participation in the program. The Secretary would be required to assist the program in identifying beneficiaries. Each beneficiary would be assigned to only one contractor that would be responsible for guiding beneficiaries in managing their health, including all co-morbidities. Initial contact with a Medicare beneficiary would be from the Secretary who would provide information about the program, a description of advantages in participating, notification that the contractor could contact the beneficiary directly concerning participation, the voluntary nature of program participation, and a means to decline participation or decline being contacted by the program. Each program would be required to develop an individualized, goal-oriented chronic care improvement plan with the beneficiary. The chronic care improvement plan would be required to contain: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines to track and monitor each beneficiary across care settings and evaluate outcomes using a clinical information database. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Contractor payments for each chronic care improvement program would be required to result in Medicare program outlays that would otherwise have been incurred in the absence of the program for the three-year contract period. The Secretary would be required to assure that there would be no net aggregate increase in Medicare payments, in entering into a contract for the program over the 3-year period, including program outlays, administrative expenses (that would not have been paid under Medicare without this demonstration), and contractor fees. Contracts for chronic care improvement programs would be treated as a risk-sharing

arrangement. In addition, payment to contractors would be subject to the contractor meeting clinical and financial performance standards established by the Secretary.

Program contractors would be required to report to the Secretary on the quality of care and efficacy of the program in terms of process measures (such as reductions in errors of treatment and rehospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary would be required to submit to Congress annual reports on the program including information on progress made toward national coverage, common delivery models, and information on improvements in health outcomes as well as financial efficiencies resulting from the program. The Secretary would also be required to conduct a randomized clinical trial to assess the potential for cost reductions under Medicare by comparing costs of beneficiaries enrolled in chronic care improvement programs and beneficiaries who are eligible to participate but are not enrolled.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds, but in no case would the funding be permitted to exceed $100 million over 3 years.

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than 1 year after enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish and implement chronic care improvement programs. If the programs are established, they are required to improve clinical quality and beneficiary satisfaction and achieve spending targets for Medicare for beneficiaries with certain chronic health conditions.

The chronic care improvement (CCI) program is required to (1) have a process to screen each targeted beneficiary for conditions other than the specified chronic conditions, such as impaired cognitive ability and co-morbidities, in order to develop an individualized, goal-oriented care management plan; (2) provide each targeted beneficiary participating in the program with the care management plan; and (3) carry out the plan and other chronic care improvement activities. The care management plan is required to be developed with the beneficiary and, to the extent appropriate, include: (1) a designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers; (2) self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members; (3) education for physicians and other providers and collaboration to enhance communication of relevant clinical information; (4) the use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment; and (5) the provision of information about hospice care, pain and palliative care, and end-of-life care. To the extent that a care management plan includes medical nutrition therapy, such services should be delivered by a registered dietician or nutrition professional as defined in Section 1861 of the Social Security Act (42 U.S.C. 1395x.)

The Secretary is required to develop a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program and to communicate with the targeted beneficiary regarding the opportunity to participate. Targeted beneficiaries who are eligible to participate cannot be enrolled in a plan under Medicare Part C and must have one or more of the threshold conditions including: congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions specified by the Secretary. Beneficiary participation is voluntary.

In carrying out the care management plan, the chronic care improvement organization is required to: (1) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant; (2) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and (3) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

The establishment of the chronic care improvement program is conducted in 2 parts. In phase I, the developmental phase, the Secretary is required to enter into contracts with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first contract is required 12 months after enactment for a 3-year period. The Secretary is required to enter into contracts to ensure that chronic care improvement programs cover geographic areas in which at least 10 percent of Medicare beneficiaries reside. The Secretary is further required to ensure that each chronic care improvement program includes at least 10,000 targeted beneficiaries along with a sufficient number of Medicare beneficiaries to serve as a control group. The Secretary is required to contract for an independent evaluation of each chronic care improvement program. The evaluation is required to include quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates; beneficiary and provider satisfaction; health outcomes; and financial outcomes, including any cost savings to Medicare.

If the Secretary finds that the chronic care improvement programs have improved the clinical quality of care, improved beneficiary satisfaction, and achieved specified spending targets, then the Secretary is required to expand the program to additional geographic areas not covered during phase I. Phase II may include national expansion of the program and is required to begin no later than 6 months after the completion of phase I (nor earlier than 2 years after phase I began). The Secretary is also required to evaluate phase II programs using the same criteria used in the phase I evaluation.

Chronic care improvement organizations are required to monitor and report to the Secretary on health care quality, cost, and outcomes, in a time and manner specified by the Secretary. The organizations are also required to comply with any additional requirements the Secretary may specify. The Secretary may deem chronic care improvement organizations which are accredited by qualified organizations to have met requirements that the Secretary may specify.

The Secretary is not permitted to contract with an organization to operate a chronic care improvement program unless the organization meets the requirements for a chronic care improvement program and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the target beneficiaries to be served; and the organization demonstrates (to the satisfaction of the Secretary) that it is able to assume financial risk for performance under the contract. Each contract is required to specify performance

standards for each of the specified evaluation factors including clinical quality and Medicare spending targets, against which the performance of the chronic care improvement organization under the contract is measured. Contractual adjustments are required if the contractor fails to meet specified performance standards. Further, the contract is required to provide for full recovery by the government of any amount by which the fees paid to the contractor exceed the estimated savings to Medicare that are attributable to the implementation of the contract. The Secretary is required to ensure that aggregate Medicare benefit expenditures for targeted beneficiaries participating in the chronic care improvement program do not exceed estimated Medicare expenditures for a comparable population in the absence of such a program.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds, but in no case would the funding be permitted to exceed $100 million over 3 years, beginning October 1, 2003.

The Secretary is required to submit an interim report to Congress on the scope of implementation of the program, the design of the programs, and the preliminary cost and quality findings based on the evaluation criteria no later than 2 years after implementation. No later than 3-1/2 years after implementation, the Secretary is required to submit an update to the interim report to Congress. The Secretary is further required to submit to Congress 2 additional biennial reports on the chronic care improvement programs. The first is due no later than 2 years after the update report.

Medicare Advantage Quality Improvement Programs (Section 722 of the House Bill and Sections 202 and 442 of the Senate Bill)

Present Law

Under the Medicare+Choice program, organizations are required to have quality assurance programs that include measuring outcomes, monitoring and evaluating high volume and high risk services and the care of acute and chronic conditions, and evaluating the effectiveness of the efforts.

House Bill

Each Medicare Advantage plan offered would be required to have a chronic care improvement program for enrollees with multiple or sufficiently severe chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, prostate and colon cancer, hypertension, or other disease identified by the Secretary. The program would be required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions and to develop with an enrollee's consent an individualized, goal-oriented chronic care improvement plan.

The chronic care improvement plan would be required to include: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines track

and monitor each beneficiary across care settings and evaluate outcomes using a clinical information database. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Each Medicare Advantage organization would be required to report to the Secretary on the quality of care and efficacy of the chronic care improvement program in terms of process measures (such as reductions in errors of treatment and rehospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The provision would apply for contract years beginning on or after one year after enactment.

Senate Bill

The quality assurance program for Medicare Advantage plans would be required to provide access to disease management and chronic care services and to provide access to preventive benefits and information for enrollees on the benefits in addition to current quality assurance requirements.

The Secretary would be required to establish a demonstration program that uses qualified care management organizations to provide health risk assessment and care management services to Medicare beneficiaries that are at high-risk (as defined by the Secretary but including beneficiaries with multiple sclerosis or other disabling chronic conditions, nursing home residents or beneficiaries at risk for nursing home placement, or beneficiaries that are also eligible for Medicaid). The Secretary would select 6 sites, giving preference to sites located in rural areas. The demonstration program would last 5 years but would not be implemented before October 1, 2004.

Any high-risk beneficiary residing in a designated area who is not a member of a Medicare+Choice plan may participate if the beneficiary identifies a care management organization that agrees to furnish care management services to the beneficiary under the demonstration program. The Secretary would be required to contract with care management organizations to provide care management services to beneficiaries eligible to participate in the demonstration. The Secretary may contract with more than one care management organization in a geographic area.

The Secretary would pay the care management organization a fee that is based on bids submitted by care management organizations. The fee would be required to place the care management organization partially at risk. Payment of the full fee would depend upon the care management organization meeting benchmarks for quality and cost. The Secretary may cancel a contract with a care management organization if the organization does not meet negotiated savings or quality outcome targets for the year. Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented. The Secretary would be required to report to Congress six months after the completion of the demonstration on the program. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires each Medicare Advantage organization to have an on-going quality improvement program for improving the quality of care provided to enrollees (except for private fee-for-service plans or MSA plans) effective for contract years beginning January 1,

2006. As part of the quality improvement program, each MA organization is required to have a chronic care improvement program. Each chronic care improvement program is required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

Each MA organization is required to provide for the collection, analysis and reporting of data that permit measurement of health outcomes and other indicators of quality. The Secretary will establish through regulation appropriate reporting requirements for regional PPOs. The Secretary is permitted to change the types of data that are required of plans only after submitting to Congress a report on the reasons for the changes that was prepared in consultation with MA plans and private accrediting bodies. The Secretary is not permitted to collect data on quality, outcomes, and beneficiary satisfaction for the purposes of consumer choice and program administration if the data were not already being collected as of November 1, 2003. However, these provision regarding data are not to be construed as restricting the ability of the Secretary to carry out the comparative information dissemination provisions regarding plan quality and performance that are contained in section 1851(d)(4)(D).

The conference agreement also provides that MA organizations are deemed to meet the quality improvement program requirements as the Secretary determines to be appropriate if the MA organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined ensures that the accrediting organization applies and enforces standards that meet or exceed the standards established by the Secretary.

Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy (Section 723 of the Conference Agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries within 6 months after enactment. The plan is required to use existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. The plan is required to: (1) integrate existing datasets including the Medicare Current Beneficiary Survey, the Minimum Data Set, the Outcome and Assessment Information Set, data from the Quality Improvement Organizations, and claims data; (2) identify any new data needs and a methodology to address new data needs; (3) plan for the collection of such data in a data warehouse; and (4) develop a research agenda using the data. In developing the plan, the Secretary is required to consult with experts in the fields of care for the

chronically ill (including clinicians) and is required to enter into contracts with appropriate entities for the development of the plan. The Secretary is required to implement the plan no later than 2 years after enactment. Appropriations are authorized from amounts in the Treasury not otherwise appropriated, such sums as may be necessary in fiscal years 2004 and 2005 to carry out this provision.

Subtitle D-Other Provisions

Improvements in the National and Local Coverage Determination Process to Respond to Changes in Technology (Section 731 of the Conference Agreement, Section 733 of the House Bill, and Sections 458 and 554 of the Senate Bill)**.**

Present Law

Coverage Determinations. Under administrative authorities, CMS announced in March 2003 the establishment of a technology council charged with improving Medicare coverage, coding and payment for emerging technologies. Council membership includes senior CMS staff.

Clinical Trials. No explicit statutory authorization regarding category A clinical trials. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis or treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service, items and services not used in the direct clinical management of the patient, and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.

Coding. The Secretary issues temporary national Health care Common Procedure Coding System (HCPCS) codes under Medicare Part B that are used until permanent codes are established.

House Bill

Coverage. The Secretary would be required to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary would be required to develop guidance documents similar to those required by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)). The provision would establish a time frame for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested.

Following the 6- or 9-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change. In instances where a request for a national coverage determination is not reviewed by the Medicare

Coverage Advisory Committee, the Secretary would be required to consult with appropriate outside clinical experts.

The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort. The provision would be effective for determinations as of January 1, 2004.

Clinical Trials. Medicare would cover the routine costs of care for beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act. The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

Coding. The Secretary would be required to implement revised procedures for the issuance of temporary national HCPCS codes by January 1, 2004. The provision would further require the Secretary to use data reflecting prices and costs of products in the United States in setting payment rates. The provision would be effective upon enactment.

Senate Bill

Coverage. The provision would establish a time frame for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested. Following the 6- or 9-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coverage decision at the end of the 60-day period. The provision would apply to national coverage determinations as of January 1, 2004.

The Secretary would be required to establish a Council for Technology and Innovation composed of senior CMS staff and clinicians to coordinate coverage, coding, and payment processes under Title XVIII and the exchange of information on new technologies between CMS and other entities that make similar decisions. The provision would be effective upon enactment.

Clinical Trials. The routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under Senate Section 530(g) of the Federal Food, Drug, and Cosmetic Act would be covered. This provision would not require the Secretary to modify the existing regulations and cover the cost of a medical device that is the subject of an investigational device exemption by the Food and Drug Administration. The Secretary would be required to ensure that total Medicare expenditures associated with this provision do not exceed: $32 million in 2005; $34 million in 2006; $36 million in 2007; $38 million in 2008; $40 million in 2009; $42 million in 2010; $44 million in 2011; $48 million in 2012; and $50 million in 2013. The Secretary would

be required to take appropriate steps to stay within these funding limitations, including limiting the number of clinical trials covered and paying for only a portion of the associated routine costs. The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after January 1, 2005.

Coding. No provision.

Conference Agreement

Coverage. The conference agreement requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary is required to develop guidance documents similar to those required by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)). The provision establishes a timeframe for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested.

Following the 6- or 9-month period, the Secretary is required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change. In instances where a request for a national coverage determination is not reviewed by the Medicare Coverage Advisory Committee, the Secretary is required to consult with appropriate outside clinical experts.

The Secretary is also required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort. The provision is effective for national determinations as of January 1, 2004 and for local coverage determinations made on or after July 1, 2004.

Clinical Trials. The conference agreement prohibits the Secretary from excluding from Medicare coverage the routine costs of care incurred by a Medicare beneficiary participating in a category A clinical trial, beginning with routine costs incurred on and after January 1, 2005. The conference agreement makes clear that this provision does not apply to, or affect, Medicare coverage or payment for a non-experimental/investigational (category B) device.

Coding. The conference agreement requires the Secretary to implement revised procedures for issuing temporary national HCPCS codes under Medicare Part B no later than July 1, 2004.

Extension of Treatment for Certain Physician Pathology Services Under Medicare (Section 732 of the Conference Agreement, Section 734 of the House Bill, and Section 435 of the Senate Bill)**.**

Present Law

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute care hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a 2-year period starting on January 1, 2001 and ending December 31, 2002.

House Bill

Medicare would make direct payments for the technical component of pathology services furnished to beneficiaries who are inpatients or outpatients of acute care hospitals on or after January 1, 2004 until December 31, 2008. A change in hospital ownership would not affect these direct billing arrangements. The provision would be effective as if it had been included in BIPA.

Senate Bill

Direct payments for the technical component for these pathology services would be made for services furnished during 2005. The provision would be effective upon enactment.

Conference Agreement

Direct payments for the technical component for these pathology services will be made for services furnished during 2005 and 2006.

Payment for Pancreatic Islet Cell Investigational Transplants for Medicare Beneficiaries in Clinical Trials (Section 733 of the Conference Agreement, Section 735 of the House Bill, and Section 462 of the Senate Bill).

Present Law

No explicit statutory authorization. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis or treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service, items and services not used in the direct clinical management of the patient, and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.

House Bill

Medicare would be required to pay for the routine costs for items and services that beneficiaries receive as part of a clinical investigation of pancreatic islet cell transplants conducted by the National Institute of Health. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to establish a 5-year demonstration project to pay for pancreatic islet cell transplantation and related items and services for Medicare beneficiaries who have type 1 diabetes and end-stage renal disease. The Secretary would be required to establish an appropriate methodology to pay for the items and services furnished under the demonstration. A report to Congress would be required on the project 4 months after the demonstration ends. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Beginning no earlier than October 1, 2004, the Secretary is required to pay for the routine costs as well as transplantation and appropriate related items and services for Medicare beneficiaries who are participating in such a trial.

In implementing the clinical investigation of pancreatic islet cell transplantations, CMS, in working with NIH, should ensure that a sufficient number of Medicare beneficiaries participate so that the results are applicable to the broader Medicare population with Type 1 diabetes and Medicare is able to make an informed decision regarding coverage of pancreatic islet transplantation.

Restoration of Trust Funds (Section 734 of the Conference Agreement and Section 623 of the Senate Bill).

Present Law

The Federal Hospital Insurance (HI) Trust Fund was established on July 30, 1965 as a separate account in the U.S. Treasury. All of the HI financial operations are handled through this fund. The trust fund's primary source of income consists of amounts appropriated to it, under permanent authority, on the basis of taxes paid by workers, their employers, and individuals with self-employment income. Up to 85% of an individual or a couples Old Age and Survivors, Disability Insurance (OASDI) benefits may be subject to federal income taxation if their income exceeds certain thresholds. The income tax revenue attributable to the first 50% of the OASDI benefits is allocated to the OAS and DI trust funds. The revenue associated with the amount between 50% and 85% is allocated to the HI trust funds. An incorrect amount of income from the taxation of OASDI benefits was transferred into the HI Trust Fund in April 2001, because of clerical error. An additional amount was transferred into the HI Trust Fund in December, 2001 to correct for the principal component of the error. Correction of the interest component associated with the clerical error requires legislation.

House Bill

No provision.

Senate Bill

After consultation with the Secretary of HHS, the Secretary of the Treasury would be required to transfer into the HI Trust fund an amount that would have been held by that fund if the clerical error had not occurred within 120 days of enactment.

Conference Agreement

The conference agreement requires the Secretary of the Treasury to transfer into the HI Trust Fund an amount that would have been held by that fund if the clerical error had not occurred. Such money is appropriated to the HI Trust Fund. The appropriation is made and transfer is required within 120 days of enactment of this Act. In the case of a clerical error that occurs after April 15, 2001, the Secretary of the Treasury is required to notify the appropriate committees of Congress about the error and the actions to be taken, before such action is taken.

Modifications to Medicare Payment Advisory Commission (MedPAC) (Section 735 of the Conference Agreement and Section 731 of the House Bill)**.**

Present Law

The Medicare Payment Advisory Commission is a 17-member body that reports and makes recommendations to Congress regarding Medicare payment policies. The Comptroller General is required to establish a public disclosure system for Commissioners to disclose financial and other potential conflicts of interest.

House Bill

MedPAC would be required to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service. MedPAC would be required to submit 2 additional reports no later than June 1, 2004. The first report would study the need for current data, and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. MedPAC would be required to examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens. The second report would address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. The provision would also require that members of the Commission be treated as employees of Congress for purposes of financial disclosure requirements.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires that MedPAC is to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service. MedPAC is required to submit 2 additional reports no later than June 1, 2004. The first report is to study the need for current data and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. The second report is to address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals.

The conference agreement requires that the Comptroller General appoint experts in the area of pharmaco-economics or prescription drug benefit programs to MedPAC. In addition, members of the Commission are required to be treated as employees of Congress for purposes of financial disclosure requirements and the Comptroller General is required to ensure compliance with this requirement.

Technical Amendments (Section 736 of the Conference Agreement).

Present Law

The Medicare, Medicaid, and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA) contains certain grammatical omissions.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement corrects the grammatical omissions.

Institute of Medicine Report (Section 723 of the House Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

No provision.

MedPAC Report (Section 724 of the House Report)**.**

Present Law

No provision.

House Bill

MedPAC would be required to evaluate the chronic care improvement program. The evaluation would be required to include a description of the status of the implementation of the programs, the quality of health care services provided to individuals participating in the program, and the cost savings attributed to the implementation of the program. The report of the evaluation would be required to be submitted to Congress not later than two years after the implementation of the programs. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement
No provision.

MedPAC Study on Medicare Payments and Efficiencies in the Health Care System (Section 455 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

MedPAC would be required to make recommendations to Congress regarding ways to recognize and reward efficiencies and lower utilization of services created by the practice of medicine in historically efficient and low-cost areas. The recommendations would be required to be made within established Medicare payment methodologies for hospitals and physicians. The measures of efficiency would include: shorter than average hospital stays; fewer than average physician visits; fewer than average laboratory tests; greater than average utilization of hospice services; and the efficacy of disease management and preventive health services. The recommendations would be due 18 months after enactment.

Conference Agreement

No provision.

VIII – Cost Containment

Subtitle A: Cost Containment

Inclusion in Annual Report of Medicare Trustees of Information on Status of Medicare Trust Funds (Section 801 of the Conference Agreement, Section 131 of House Bill; Sections 131 and 132 of Senate Bill)**.**

Current Law

The Medicare Board of Trustees was established under the Social Security Act to oversee the financial operations of the Medicare Hospital Insurance (HI) trust fund and the Medicare Supplementary Medical Insurance (SMI) trust fund. The Trustees are required to submit annual reports to the Congress.

The HI trust fund revenues come primarily from payroll taxes. Employers and employees each pay 1.45% of their earnings, while self-employed workers pay 2.9% of their net income. Other HI revenue sources include interest on the investments of the trust fund, federal income taxes on Social Security benefits, premiums from voluntary enrollees into Part A, railroad retirement account transfers and reimbursement for certain uninsured persons. Medicare Part A pays for beneficiaries medical expenses incurred in hospitals, skilled nursing facilities, hospices, and a portion of home health care services.

The SMI trust fund revenues are composed of beneficiary premiums to purchase Part B and general revenues. The Part B premium is set at an amount so that aggregate premiums are estimated to equal 25% of program costs and the monthly premium for 2003 is $58.70. General revenues comprise the remaining 75% of Part B program costs. Medicare Part B pays for the following: physician and other health care practitioner services; other medical and health services, including laboratory and diagnostic tests; outpatient hospital services and clinic services; and therapy and ambulance services; durable medical equipment, and home health services not covered under Part A.

House Bill

The provision would require the trustees to submit a combined report on the status of the two trust funds and the Prescription Drug Trust Fund. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury for payment of benefits and the percentage such amount bore to all other general revenue obligations of the Treasury in that year. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 75-year projections would also be required. The report would also provide a comparison to the rate of growth in the gross domestic product. Each report would be published by the Committees on Ways and Means and Energy and Commerce and be made available on the Internet.

Senate Bill

Section 131 would require the trustees to submit a combined report on the status of the two trust funds including the Prescription Drug Account. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the

Treasury and the percentage such amount bore to all other obligations of the Treasury in that year. This calculation would be made separately for Medicare benefits and for administrative and other expenses. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 50-year projections would also be required. The report would also provide a comparison of the rates of growth for both benefits and administrative costs to the rates of growth in the gross domestic product, health insurance costs in the private sector, employment-based health insurance costs in the public and private sectors, and other areas as determined appropriate by the Board of Trustees.

The section would express the sense of the Congress that the committees of jurisdiction would hold hearings on these reports.

Section 132 would require the 2004 reports to include an analysis of the total amount of unfunded obligation of Medicare. The analysis would compare long-term obligations, including the combined obligations of the HI and SMI trust funds, to the dedicated funding sources for the program (not including transfers of general revenue)

Conference Agreement

Beginning with their report in 2005, the Trustees' annual report is required to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for the fiscal year and each of the succeeding 6 fiscal years, 10, 50, and 75 years after the fiscal year, and previous fiscal years; (2) comparisons with the growth trends for the gross domestic product, private health costs, national health expenditures**,** and other appropriate measures; (3) expenditures and trends in expenditures under Part D; and (4) a financial analysis of the combined Medicare trust funds if general revenue funding for Medicare is limited to 45 percent of total Medicare outlays. The trust fund reports are also required to include a determination as to whether there is projected to be "excess general revenue Medicare funding" (as defined in the paragraph below) for any of the succeeding 6 fiscal years in its annual reports of Medicare's trust funds.

"Excess general revenue Medicare funding" is defined as general revenue Medicare funding expressed as a percentage of total Medicare outlays in excess of 45 percent. This measure is calculated by dividing total Medicare outlays minus dedicated Medicare financing sources by total Medicare outlays.

An affirmative determination of excess general revenue funding of Medicare for 2 consecutive annual reports will be treated as funding warning for Medicare in the second year for the purposes of requiring Presidential submission of legislation to Congress. Whenever any Trustees report includes a determination that within the 7-fiscal-year period there will be excess general revenue Medicare funding, Congress and the President are advised to address the matter under existing rules and procedures.

Dedicated Medicare financing sources include amounts appropriated to the HI trust fund for payroll taxes, transfers from the Railroad Retirement accounts, reimbursements for uninsured persons, and reimbursement for transitional insured coverage; taxation of certain OASDI benefits and tier II railroad retirement taxes, state transfers for Medicare coverage of eligible individuals who receive public assistance; premiums for Parts A, B, and D paid by non-Federal sources including amounts from voluntary enrollees (Part A), adjustments (Part B) and the MA monthly prescription drug beneficiary premiums paid under Part C that are attributable to basic

prescription drug coverage (Part D); and gifts received by the Medicare trust funds. The premium amounts are determined without regard to any reduction in the Part B premiums attributable to the beneficiary rebate under the MA program and Part D premium amounts are deemed to include any penalties for late enrollment.

Medicare outlays means total outlays from the Medicare trust funds and include payments made to plans under part C that are attributable to any rebates under the Medicare Advantage program and Medicare administrative expenditures. These outlays are required to be offset by the amount of fraud and abuse collection when applied to or deposited into a Medicare trust fund.

The Medicare trust funds are defined as the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund which includes the Medicare Prescription Drug Account.

Presidential Submission of Legislation (Section 802 of the Conference Agreement)**.**

House Bill

No provision

Senate Bill

No provision

Conference Agreement

In the event that a Medicare funding warning is made, the President is required to submit to Congress proposed legislation to respond to the warning. This must be completed within the 15-day period beginning on the date of the budget submission to Congress for the succeeding year it is made. If during the year in which the warning is made, legislation is enacted which eliminates excess general revenue Medicare funding for the 7-fiscal year period, then the President is not required to make a legislative proposal. The conference agreement expresses a sense of Congress that legislation submitted in this regard should be designed to eliminate excess general revenue Medicare funding for the 7-fiscal year period that begins in such year, as certified by the Board of Trustees not later than 30 days after the date of enactment.

Procedures in the House of Representatives (Section 803 of the Conference Agreement)**.**

House Bill

No provision

Senate Bill

No provision

Conference Agreement

The conference agreement sets out the procedures for House consideration of the President's legislative proposal. Within 3 days of receiving the President's legislative proposal, the Majority Leader and Minority Leader of the House, or their designees, are required to introduce the proposal. Any legislation introduced is required to be referred to the appropriate committees which are required to report Medicare funding legislation no later than June 30. The chairman of the Committee on the Budget is required to certify whether or not Medicare funding legislation eliminates excess general revenue Medicare funding for any year within the 7-fiscal year period and whether the legislation would eliminate excess general revenue Medicare funding within the 7-fiscal year period.

If the House fails to vote on final passage of the legislation by July 30, fallback procedures are provided for under the conference agreement. After 30 calendar days (and concurrently 5 legislative days) after the introduction of the legislation, a move to discharge any committee to which the legislation has been referred is in order, under specified circumstances, and debate on the motion to discharge is limited to one hour.

The conference agreement provides for floor consideration in the House of the discharged legislation by the Committee of the Whole no later than 3 legislative days after discharge.

House Bill

No provision

Senate Bill

No provision

Conference Agreement

Section 804 provides for some limited special procedures in the Senate for consideration of legislation arising from the Medicare Trustees determination that there will be "excess general revenue Medicare funding" under section 801.

If the Medicare Trustees report, pursuant to section 801, includes a "medicare funding warning" and if the President submits the legislation described in section 802 in response to such warning, that legislation (along with any other qualifying legislation otherwise introduced in the Senate or received from the House) will be entitled to the special procedures set out in section 804.

Section 804(a) requires the Majority Leader and the Minority Leader (or their designees) to introduce the President's legislation. Such legislation must be entitled "A bill to respond to a medicare funding warning." This bill, regardless of the subject matter and notwithstanding any jurisdictional precedents of the Senate, shall be referred to the Committee on Finance. Any other legislation introduced by any member of the Senate, bearing this same title, shall also be referred to the Committee on Finance. Such referrals shall not be considered to create any jurisdictional precedents for the Senate.

Section 804(c) provides that this "medicare funding legislation" will be entitled to the special rules set out in subsections (d) and (e) only if: (1) it was passed by the House or (2) it is

limited to matters within the jurisdiction of the Committee on Finance. This subsection ensures that a measure is subject to the special rules (whether it be the President's bill or one introduced by a member of the Senate) only if its contents are limited to matters solely within the jurisdiction of Finance. Thus the President or any member of the Senate may propose any type of legislation in the name of eradicating the "excess general revenue Medicare funding", but only those measures which conform with the jurisdictional constraints of the Committee on Finance, shall be entitled to the special procedures set out in this section.

Clearly however, the Senate can not dictate the content of the House-passed measure. Thus subsection (c) explicitly states that a bill coming over from the House would still be entitled to these special procedures. The conferees intend that these procedures apply to the House-passed bill regardless of any jurisdictional issues, but limit the application of the procedures to a Senate-originated matter that is within the jurisdiction of Finance. If a measure does not qualify for these special procedures, then it shall be considered under the regular order in the Senate.

Section 804(d) provides a unique mechanism in the Senate: a motion to discharge a specific piece of legislation. Subsection (d) states that if the Committee on Finance has not reported any "medicare funding legislation" by June 30 then it is in order for any Senator to move to discharge the committee from any one of the pieces of "medicare funding legislation" that has been referred to that committee. Only one motion may be made in any session of Congress and such motion may only refer to a single piece of legislation. This motion is not amendable and debate of the motion and any related appeals is limited to 2 hours. The 2 hours is to be equally divided and controlled between the maker of the motion and the Majority Leader (or their designees). If the Majority Leader supports the motion, then the time in opposition will be controlled by the Minority Leader (or the Minority Leader's designee).

Unlike other instances of limited debate, in this case, a point of order may be made at any time during the 2 hours – a Senator need not await the expiration or yielding back of time to do so. Any appeal made within the 2 hours, may be debated for whatever time remains if any Senator desires to debate the appeal. Any motion or appeal made after the 2 hours shall be decided without debate. It is not in order to move to proceed to the consideration of any other measure or matter while the motion to discharge (or the motion to reconsider the vote with respect to the motion to discharge) is pending. The only motions in order during the 2 hours (or at the conclusion of the 2 hours) of debate are as follows: to postpone to a day certain, to postpone indefinitely, to lay on the table, to take a recess, to adjourn to a day certain, to adjourn. These motions shall have the same precedence as described in Rule XXII of the Standing Rules of the Senate. Note that pursuant to subsection (d)(2), the motion to proceed to executive business (which is listed in Rule XXII) as well as the motion to proceed to any other legislative matter is explicitly precluded.

Pursuant to subsection (d)(4), this special motion to discharge is no longer available if the Chairman of the Committee on the Budget certifies that "medicare funding legislation" which eliminates the "excess general revenue medicare funding" described in section 801(c) has been enacted in that session.

Subsection (e) reiterates the fact that under existing Senate procedures once "medicare funding legislation" has been placed on the Calendar (having been either reported or discharged from the committee) it is in order for any member of the Senate to make a motion to proceed to the consideration of that measure. Such motion and all subsequent actions in the Senate shall be considered under the Standing Rules of the Senate and the precedents thereto or pursuant to any unanimous consent agreements reached, as the case may be. This section should not be interpreted as creating a "privileged" measure in the Senate. Consequently, it is the intent of the Conferees that there will be no further special procedures (such as a waiver or alteration of the procedures with respect to reports set out in Rule XVII or any other rule of the Standing Rules of the Senate) available to such measures as a result of this Act.

Subtitle B: Income-Related Reduction in Part B Premium Subsidy

Present Law

The Medicare Part B premium is currently set each year to cover 25 percent of Medicare's benefits under Part B. When Medicare was created in 1965, the Part B premium was set to cover 50 percent of the costs of the Part B benefits. The share of Part B spending covered by the premium declined between 1975 and 1983 to less than 25 percent of spending, because during that time premium increases were limited by the cost-of-living adjustment for Social Security benefits. During the late1980s and early 1990s, Congress routinely voted to set the Part B premium at 25 percent of Part B costs, and that percentage was codified in the Balanced Budget Act of 1997 (BBA 97).

All seniors over age 65 who elect Part B during their initial enrollment period pay the same Part B premium, regardless of income.

House Bill

No provision.

Senate Amendment

No provision.

Conference Agreement

In order to begin to address the fiscal challenges facing the Medicare program, beginning in 2007, Medicare beneficiaries with incomes over $80,000 for an individual or $160,000 for a married couple will be asked to contribute more to the cost of their Medicare benefits through payment of a higher premium. Approximately 4 percent of Medicare beneficiaries have incomes above these levels. All beneficiaries will continue to receive some level of premium assistance, and all beneficiaries will continue to be eligible for the full range of Medicare benefits. This proposal will target taxpayer dollars at those who need it the most by reducing the government subsidy for those who have the resources to cover more of their own costs.

Beneficiaries with incomes under $80,000 for an individual and $160,000 for a married couple will continue to receive a government subsidy at 75 percent and pay premiums at the 25 percent rate. Those with incomes between $80,000 and $100,000 ($160,000 and $200,000 for a

married couple) will receive a 65 percent subsidy and pay 35 percent as a premium. Those with incomes between $100,000 and $150,000 ($200,000 and $300,000 for a couple) will receive a 50 percent subsidy and pay a premium at 50 percent. Those with incomes between $150,000 and $200,000 ($300,000 and $400,000 for a married couple) will receive a 35 percent subsidy and pay a premium at a 65 percent rate. Those with incomes above $200,000 ($400,000 for a married couple) will receive a 20 percent subsidy and pay a premium at an 80 percent rate.

Beneficiaries who are affected will be notified of their premium levels at the start of the year. They may appeal their premium level based on major changes in life circumstances, such as divorce, marriage, or death of a spouse. Although this policy affects only a small number of beneficiaries, it will have a significant impact in controlling the growth of Medicare spending in the future.

To facilitate the income-related reduction in Part B premium subsidy, the conference agreement authorizes the disclosure of certain return information to employees and contractors of the Social Security Administration. Upon written request from the Commissioner of Social Security, the IRS may disclose certain items of return information with respect to a taxpayer whose premium may be subject to adjustment. With respect to such taxpayers, the IRS may disclose (1) taxpayer identity information; (2) filing status; (3) adjusted gross income; (4) the amounts excluded from such taxpayer's gross income under sections 135 and 911 of the Internal Revenue Code (relating to income from United States Savings bonds used to pay higher education tuition and fees, and foreign earned income); (5) tax-exempt interest received or accrued during the taxable year to the extent such information is available; (6) amounts excluded from such taxpayer's gross income by sections 931 and 933 of the Internal Revenue Code (relating to income from sources within Guam, American Samoa, the Northern Mariana Islands, or Puerto Rico); (7) for nonfilers only, such other information relating to the liability of the taxpayer as the Secretary may prescribe by regulation, as might indicate that the amount of the premium of the taxpayer may be subject to adjustment (including estimated tax payments and income information derived from Form W-2, Form 1099, or similar information returns); and (8) the taxable year with respect to which the preceding information relates. Return information disclosed under this authority may be used by employees and contractors of the Social Security Administration only for purposes of, and to the extent necessary in, establishing the appropriate amount of any Part B premium adjustment. Employees and contractors of the Social Security Administration are subject to the penalties for unauthorized disclosure and inspection, as well as the applicable safeguard requirements.

Title IX – Regulatory Reduction and Contracting Reform

Administrative Improvements within the Centers for Medicare & Medicaid Services (CMS) (Section 900 of the Conference Agreement, Sections 801 and 802 of the House Bill, Sections 301 and 302 of the Senate Bill).

Present Law

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires that the Administrator of the Centers for Medicare & Medicaid Services (CMS formerly known as the Health Care Financing Administration) be appointed by the President with the advice and consent of the Senate. Title 5 of the U. S. Code sets the Administrator's salary at level IV of the Executive Schedule. The Medicare statute requires that the HCFA administrator appoint a Chief Actuary who reports directly to such administrator and is paid at the highest rate of basic pay for the Senior Executive Service.

House Bill

The section would amend title XVIII to add new section 1809 which, under subsection (a), would establish a new Medicare Benefits Administration (MBA) within the Department of Health and Human Services.

Subsection (b) would provide for an Administrator and Deputy Administrator of the MBA. Both would be appointed by the President with the advice and consent of the Senate for 4-year terms. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 4-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of the MBA and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of MBA, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the MBA except for any unit, component, or provision specifically provided for by section 1809. The Administrator may assign duties, delegate, or authorize redelegations of authority to MBA officers and employees as needed. The Secretary of Health and Human Services shall ensure appropriate coordination between the Administrator of MBA and the Administrator of the Centers for Medicare & Medicaid Services (CMS) in administering the Medicare program. The provision also would establish a position of Chief Actuary within the MBA who would be appointed by the Administrator and paid at the highest rate of basic pay for the Senior Executive Service. The Chief Actuary would exercise such duties as are appropriate for the office of Chief Actuary and in accordance with professional standards of actuarial independence.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the MBA. In administering parts C, D, and E of Medicare, the

Administrator would be required to negotiate, enter into and enforce contracts with Medicare Advantage plans and enhanced fee-for-service plans and with prescription drug plan sponsors for Medicare prescription drug plans. The Administrator would be required to carry out any duty provided for under part C, D, or E of Medicare including implementing the prescription drug discount card endorsement program and demonstration programs (that are carried out in whole or in part under part C, D, or E). The provision specifically prohibits the Administrator from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs, from interfering in any way with negotiations between prescription drug plan sponsors and Medicare Advantage organizations and enhanced fee-for-service organizations and drug manufacturers, wholesalers, or other suppliers of covered drugs; and otherwise interfering with the competitive nature of providing prescription drug coverage through such entities and organizations. These negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.

The Administrator would be required to submit a report to Congress and the President on the administration of parts C, D, and E during the previous year by not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be permitted to hire staff to administer the activities of MBA without regard to chapter 31 of title 5 of the U.S. Code, except for 12 sections. The Administrator would be required to employ staff with appropriate and necessary experience in negotiating contracts in the private sector. The staff of MBA would be paid without regard to chapter 51 (other than section 5101 requiring classification of positions according to certain principles) and chapter 53 (other than section 5301 relating to the principles of pay systems) of title 5 of the U.S. Code. The rate of compensation for staff of MBA would not be able to exceed level IV of the Executive Schedule. The Administrator would be limited in the number of full-time-equivalent (FTEs) employees for the MBA to the number of FTEs within CMS performing the functions being transferred at the time of enactment. The Secretary, the Administrator of MBA and the Administrator of CMS would be required to establish an appropriate transition of responsibility to redelegate the administration of Medicare part C from CMS to MBA. The provision would require the Secretary to ensure that the Administrator of CMS transfers such information and data as the Administrator of MBA requires to carry out the duties of MBA.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within MBA to coordinate Medicare beneficiary outreach and education activities, and provide Medicare benefit and appeals information to Medicare beneficiaries under parts C, D, and E.

Subsection (e) would establish the Medicare Policy Advisory Board (the Board) within the MBA to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C, D, and E. The Board would be required to report to Congress and to the Administrator of MBA such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C, D, and E including: increasing competition under part C, D, or E for services furnished to beneficiaries; improving efforts to provide beneficiaries information and education about Medicare, parts C, D, and E, and Medicare enrollment; evaluating implementation of risk adjustment under parts C and E; and

improving competition and access to plans under parts C, D, and E. The reports would be required to be published in the *Federal Register*. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the *Federal Register*.

The Board would be made up of 7 members serving three-year terms, with 3 members appointed by the President, 2 appointed by the Speaker of the House of Representatives, and 2 appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for 3 years. The Board is required to meet at least three times a year and at the call of the Chair.

The Board would be required to have a director who, with the approval of the Board, may appoint staff without regard to chapter 31 of title 5 of the United States Code (which addresses authority for employment). In addition, the director and staff could be paid without regard to the provisions of chapter 51 and 53 of title 5 which are related to classification and pay rates and pay systems – although the rate of compensation is capped at level IV of the Executive Schedule. The Board could contract with and compensate government and private agencies or persons to carry out its duties without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

Subsection (f) would authorize an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

The provision would be effective upon enactment, however, the enrollment and eligibility functions and implementation of parts C and E would be effective January 1, 2006.

Senate Bill

The section would amend title XVIII to add new section 1808, which, under subsection (a), would establish a new Center for Medicare Choices (CMC) within the Department of Health and Human Services by no later than March 1, 2004, to administer parts C and D of Medicare.

Subsection (b) would provide for an Administrator of CMC who would be appointed by the President with the advice and consent of the Senate for 5-year terms. The Administrator would be able to appoint a Deputy Administrator. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 5-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of CMC and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of CMC, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the CMC except for any unit, component, or provision provided by section 1808. The Administrator may assign duties, delegate, or authorize redelegations of authority to CMC officers and employees as needed. The Secretary of Health and Human Services shall ensure appropriate coordination between the Administrator of CMC

and the Administrator of the Centers for Medicare & Medicaid Services in administering the Medicare program.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the CMC. In administering parts C and D of Medicare, the Administrator would be required to negotiate, enter into and enforce contracts with MedicareAdvantage plans and with eligible entities for Medicare prescription drug plans. The Administrator would be required to carry out any duty provided for under part C or D of Medicare including demonstration programs (that are carried out in whole or in part under parts C or D). The Administrator of the agency, to the extent possible, would not be able interfere in any way with negotiations between eligible entities, MedicareAdvantage organizations, hospitals, physicians, other entities or individuals furnishing items and services under this title (including contractors for such items and services), and drug manufacturers, wholesalers, or other suppliers of covered drugs. The Administrator would be required to submit a report to Congress and the President on the administration of the voluntary prescription drug delivery program not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be able to employ management staff as determined appropriate. The Administrator would be able to compensate such managers up to the highest rate of basic pay for the Senior Executive Service. Any such manager would be required to have demonstrated, by their education and experience (either in the public or private sectors) superior expertise in the review, negotiation, and administration of health care contracts, the design of health care benefit plans, actuarial sciences, compliance and health plan contracts, consumer education and decision-making.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within CMC to make Medicare eligibility determinations, enroll beneficiaries into Medicare, provide Medicare benefit and appeals information, and carry out any other activities relating to Medicare beneficiaries under title XVIII. Within the Office of Beneficiary Assistance, a Beneficiary Ombudsman would be established who is appointed by the Secretary. The Ombudsman would be required to receive complaints, grievances, and requests for information submitted by a Medicare beneficiary regarding any aspect of the Medicare program; to provide assistance with the complaints, grievances and requests including assisting beneficiaries with appeals; and with problems arising from disenrolling from a MedicareAdvantage plan or a prescription drug plan. The Ombudsman would be required to submit annual reports to Congress, the Secretary, and the Medicare Competitive Policy Advisory Board describing the activities of the Ombudsman's office and including any recommendations for improvement in the administration of title XVIII. The Ombudsman would also be required to coordinate with state medical ombudsmen programs, and with state-and community-based consumer organizations to provide information about the Medicare program and to conduct education outreach regarding resolution or avoidance of disputes and problems under the Medicare program.

Subsection (e) would establish the Medicare Competitive Policy Advisory Board (the Board) within the CMC to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C and D. The Board would be required to report to Congress and to the Administrator of CMC such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C and D including: stability and solvency of the program, increasing competition, improving the quality

of benefits, incorporating disease management, improving competition and access to plans in rural areas, and improving beneficiary information and education for the entire Medicare program. The reports would be required to be published in the *Federal Register*. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the *Federal Register*. The Administrator of CMC is required to provide information and assistance to the Board as is requested to carry out its functions.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair. The Board is required to have an executive director who, with the approval of the Board, may appoint staff as appropriate.

Subsection (f) would authorize an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

The provision would also require that the Secretary provide 1-800-Medicare as a means by which individuals seeking information about or assistance with Medicare can receive assistance. The Secretary would be required to route calls to the appropriate entity to provide the assistance or information. The 1-800-Medicare number would be included in the Medicare handbook in place of the listing of phone numbers of individual contractors.

The Administrator of CMC would be added as Co-Secretary of the Board of Trustees of the Medicare Trust Funds. In addition, the pay level for the Administrator of CMS would be increased from level IV of the Executive Schedule to level III.

The CMC would be required to be established by the Secretary no later than March 1, 2004.

Conference Agreement

The conference agreement creates a new section 1808 of the Social Security Act establishing a center within the Centers for Medicare & Medicaid Services to administer Parts C and D of Medicare, provide notice and information to beneficiaries (as required under section 1804 of the Social Security Act), and other such duties as specified by the Secretary. The person heading the Center is required to report to the Administrator of CMS. The Secretary is required to ensure that the Center is carrying out these duties by no later than January 1, 2008.

The conference agreement permits the Secretary to employ management staff as he determines to be appropriate. If such staff are employed, the staff must have demonstrated superior expertise in at least one of the following areas: (1) the review, negotiation, and administration of health care contracts; (2) the design of health care benefit plans; (3) actuarial sciences; (4) consumer education and decision making; (5) any other area specified by the

Secretary that requires specialized management or other expertise. The Secretary is required to establish the rate of pay taking into account expertise, experience, and performance. The pay rate cannot exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code (currently ES-6). Such flexibility ensures those with private sector, real world experience managing benefit plans are hired and utilized to ensure the success of the new Medicare plans. This expertise will help mitigate against potential failure in coaxing integrated plans that promote coordinated care and modern health delivery into the Medicare program.

The conference agreement requires that an actuary within the office of the Chief Actuary of CMS have duties exclusively related to Parts C and D of Medicare and related provisions. The pay grade for the Administrator of CMS is increased to Executive Level III beginning January 1, 2004. The conferees strongly encourage the hiring of a separate actuary within the office of the actuary to assist the functions of the center. Because the analysis of the fee-for-service actuary can effect payment rates in private plan reimbursement, the two should be kept independent and answer directly to the Secretary.

In addition, the conference agreement changes statutory references from the Health Care Financing Administration to the Centers for Medicare & Medicaid Services.

Construction; Definition of Supplier (Section 901 of the Conference Agreement, Section 901 of the House Bill).

Present Law

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

House Bill

Nothing in this title would be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or impede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The provision also would clarify that consolidation of the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision would also clarify that the term “supplier” means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement provides that nothing in this title shall be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or impede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The conference agreement also clarifies that consolidating the Medicare

administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The agreement also clarifies that the term "supplier" means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare. The provision is effective upon enactment.

Issuance of Regulations (Section 902 of the Conference Agreement, Section 902 of the House Bill, Section 501 of the Senate Bill).

Present Law

The Secretary is required to prescribe regulations that are necessary to administer the Medicare program. The Secretary must publish proposed regulations in the Federal Register, with at least 30 days to solicit public comment before issuing the final regulation except in the following circumstances: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementing a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest. The Secretary must publish a list of all manual instructions, interpretative rules, statements of policy, and guidelines, which are promulgated to carry out Medicare law in the *Federal Register* no less frequently than every 3 months.

There is no explicit statutory instruction on logical outgrowth. The courts have repeatedly held that new matter in final regulations must be a "logical outgrowth of the proposed rule" and is an inherent aspect of notice and comment rulemaking.

House Bill

The provision would require the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established would not be permitted to be longer than three years, except under extraordinary circumstances. If the Secretary were to vary the timeline he established, the provision would require him to publish a notice in the *Federal Register* with the new timeline and an explanation of the variation. In the case of interim final regulations, the provision would require that if the Secretary did not meet his established timeframe, then the interim final regulation would not be able to continue in effect unless the Secretary published a notice of continuation of the regulation that included an explanation of why the regular time line had not been complied with. This provision regarding timelines would be effective upon enactment.

The provision also would require that a measure in a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation would be treated as a proposed regulation. The measure would not be able to take effect until public comment occurred and the measure was published as a final regulation. This provision would apply to final regulations published on or after the date of enactment.

Senate Bill

The Secretary would be required to publish a final regulation within 12 months of the publication of an interim final regulation or the interim final regulation would no longer be effective. Subject to appropriate notice, the Secretary would be able to extend this deadline for up to 12 additional months. The Secretary would be required to publish a notice in the *Federal Register* 6 months after the date of enactment providing the status of each interim final regulation for which no final regulation has been published and providing the date by which the final regulation is planned to be published. This provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established is not be permitted to be longer than 3 years, except under extraordinary circumstances. If the Secretary varies the timeline he established, he is required to publish a notice in the *Federal Register* with the new timeline and an explanation of the variation. In the case of interim final regulations, if the Secretary does not meet his established timeframe, then the interim final regulation cannot continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular time line was not complied with. This agreement regarding timelines is effective upon enactment.

The conference agreement also requires that a measure in a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation is to be treated as a proposed regulation. The measure could not take effect until public comment occurred and the measure is published as a final regulation. This agreement applies to final regulations published on or after enactment.

Compliance with Changes in Regulation and Policies. (Section 903 of the Conference Agreement, Section 903 of the House Bill, Sections 502 and 533 of the Senate Bill).

Present Law

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen v. Georgetown University Hospital*, the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

House Bill

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest, effective upon enactment. No substantive change would go into effect until 30 days after the change is issued or published unless it would be needed to comply with statutory changes or was in the public interest. Compliance actions would be able to be taken for items and services furnished only on or after the effective date of the change, effective upon enactment. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier would not be subject to penalty or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

Senate Bill

Same provisions.

Conference Agreement

The conference agreement bars retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. No substantive change could go into effect until 30 days after the change is issued or published unless it is needed to comply with statutory changes or in the public interest. Compliance actions could be taken for items and services furnished only on or after the effective date of the change, effective upon enactment. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier is not subject to penalty or interest (unless the inaccurate information was due to a clerical or technical operational error).

The conference agreement also makes clear that a provider or supplier is not subject to any penalty or interest on a repayment plan (including under section 1893 of the Social Security Act, relating to the Medicare Integrity Program, or otherwise) relating to the provision of such items or services or a claim if the provider or supplier reasonably relied on the guidance. The conference agreement applies to a sanction imposed with respect to guidance provided on or after July 24, 2003.

Reports and Studies Relating to Regulatory Reform. (Section 904 of the Conference Agreement, Section 904 of the House Bill, Section 503 of the Senate Bill).

Present Law

No provision.

House Bill

The GAO would be required to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report would be due to Congress 1 year after enactment.

The Secretary would be required to report to Congress every 2 years on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report would include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts. The first report would be due to Congress 2 years after enactment.

Senate Bill

Requires the Secretary to report to Congress in 2 years, and every 3 years thereafter, on the administration of Medicare and areas of inconsistency or conflict among various provisions

under law and regulation and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

Conference Agreement

The conference agreement requires the GAO to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report is due to Congress 1 year after enactment.

The Secretary is required to report to Congress in 2 years and every 3 years thereafter on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report is to include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

Increased Flexibility in Medicare Administration. (Section 911 of the Conference Agreement, Section 911 of the House Bill, Section 521 of the Senate Bill).

Present Law

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. For Medicare Part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross

negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

House Bill

This provision would add a new Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 5 years. All contracts would be required to be re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The provision would limit liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified, both in the contract and as the Secretary determines appropriate.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken. After enactment of the bill, but before October 1, 2005, the Secretary would be permitted to enter into new fiscal intermediary agreements without regard to any of the provider nomination provisions.

The Secretary would be required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2005.

Senate Bill

Same provision, containing three main differences: First, contracts would be required to be recompeted every 6 years. Second, a MAC with a contract to perform local coverage determinations would be required to designate at least 1 different individual to serve as a medical director for each state for which local coverage determinations are made; use the medical director in making the local coverage determinations; and appoint a contractor advisory committee for each state for which local coverage determinations are made to participate in an advisory capacity in the development of the local determinations. Finally, competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

Conference Agreement

The conference agreement adds a new Section 1874A to the Social Security Act into which the Medicare contractor authority is consolidated. The conference agreement permits the Secretary to competitively contract with any eligible entity to serve as a Medicare Administrative Contractor (MAC). The conference agreement eliminates the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and takes the separate authorities for fiscal intermediaries and carriers and merges them into a single authority for the new contractor. All the functions of the current fiscal intermediaries and carriers are assumed by the new MACs: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary is permitted to renew the MAC contracts annually for up to 5 years. All contracts must be re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) apply to MAC contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. (The conference agreement does not extend FAR provision to other contractors under title XVIII.) The Secretary is required to develop contract performance requirements to carry out the functions described in the provision and to develop standards for measuring the extent to which a contractor has met the requirements. The Secretary is required to consult with beneficiary and provider organizations, and organizations and agencies performing other Medicare functions. The Secretary is required to make the performance requirements and measurement standards available to the public and must include provider and beneficiary satisfaction levels as one of the requirements.

MAC performance requirements are required to be included in the contract and consistent with written statements of work and used for evaluating contractor performance. MACs are required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary may require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary is prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The conference agreement limits the liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. The standard does not limit liability for conduct that constitutes a violation of the False Claims Act. The conference agreement also establishes circumstances where contractors and their employees are indemnified, both in the contract and as the Secretary determines appropriate.

The conference agreement makes numerous conforming amendments as the statutory authorities for the fiscal intermediaries and carriers are stricken. After enactment of the bill, but before October 1, 2005, the Secretary is authorized to enter into new fiscal intermediary agreements without regard to any of the provider nomination provisions under section 1816 of the Social Security Act and may enter into new carrier contracts. The Secretary is required to take such steps as are necessary to provide for an appropriate transition from the fiscal intermediary agreements and carrier contracts to the MAC contracts. In addition, the Secretary is explicitly authorized to continue Medicare Integrity Program fiscal intermediary agreements and carrier contracts from the enactment of this provision through October 1, 2011.

The Secretary is required to submit a legislative proposal providing technical and conforming amendments to this provision to the appropriate committees of Congress within 6 weeks of enactment. The Secretary is required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within 6 months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008, on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin October 1, 2005 and all contracts should have been bid under the new structure by September 30, 2011.

Requirements for Information Security for Medicare Administrative Contractors (Section 912 of the Conference Agreement, Section 912 of the House Bill).

Present Law

No provision.

House Bill

Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) would be required to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program would be required to meet certain requirements for information security programs imposed on Federal agencies under title 44 of the United States Code. Medicare administrative contractors would be required to undergo an annual independent evaluation of their information security programs. Existing contractors

would be required to undergo the first independent evaluation within one year after the date of enactment and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The results of the independent evaluations would be submitted to the Secretary and the HHS Inspector General. The Inspector General of HHS would be required to report to Congress annually on the results of the evaluations. The Secretary would be required to address the results of the evaluations in required management reports.

Senate Bill

No comparable provision.

Conference Agreement

The conference agreement requires Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program is required to meet certain requirements for information security programs imposed on Federal agencies under title 44 of the United States Code. Medicare administrative contractors are required to undergo an annual independent evaluation of their information security programs. Current fiscal intermediaries and carriers are required to undergo the first independent evaluation within one year after the date of enactment and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The MACs are required to submit the results of the independent evaluations to the Secretary and the HHS Inspector General. The Inspector General of HHS is required to report to Congress annually on the results of the evaluations. The Secretary is required to address the results of the evaluations in required management reports.

Provider Education and Technical Assistance. (Section 921 of the Conference Agreement, Section 921 of the House Bill, Sections 531 and 532 of the Senate Bill).

Present Law

(a) Coordination of Education Funding.

Present Law

Medicare's provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

House Bill

The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding. The provision would be effective upon enactment. The Secretary would be required to report to

Congress on the steps taken to coordinate the funding of provider education under the provision by October 1, 2004.

Senate Bill

The provision would require the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers. The provision would be effective upon enactment.

Conference Agreement

The conference agreement adds section 1889 to the Social Security Act requiring the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding. The agreement is effective upon enactment. The Secretary is required to report to Congress on the steps taken to coordinate the funding of provider education under the provision by October 1, 2004.

(b) Incentives to Improve Contractor Performance.

Present Law

No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate-testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

House Bill

The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers. The provision would require the Comptroller General to submit to Congress and the Secretary a study and to make recommendations on the adequacy of the Secretary's methodology by October 1, 2004. The Secretary would be required to report to Congress by October 1, 2004 regarding how he intends to use the methodology in assessing Medicare contractor performance.

Senate Bill

The provision would require the Secretary to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers by October 1, 2004. The Conferees agree that any such methodology shall include non-responses in the measurement of the error rate. The Comptroller General would be required to study the adequacy of the methodology and make recommendations to the Secretary. The Secretary would be required to report to Congress regarding how he intends to use the methodology in assessing Medicare contractor performance.

Conference Agreement

The conference agreement requires the Secretary to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers. The Comptroller General is required to submit to Congress and the Secretary a study the adequacy of the methodology and to make recommendations. The Secretary is required to report to Congress by October 1, 2004 regarding how he intends to use the methodology in assessing Medicare contractor performance.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Present Law

No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

House Bill

The Secretary would be required to develop a strategy for communicating with beneficiaries, providers and suppliers. Medicare contractors would be required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the written inquiry. The Secretary would be required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers, and suppliers and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards. The provision would be effective October 1, 2004.

Senate Bill

Identical provision.

Conference Agreement

The conference agreement requires the Secretary to develop a strategy for communicating with beneficiaries, providers and suppliers, beginning October 1, 2004. Medicare contractors are required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the written inquiry. The Secretary is required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers,

and suppliers and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary is required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards. The conference agreement authorizes to be appropriated such sums as are necessary to carry out this subsection.

(d) Improved Provider Education and Training.

Present Law

In FY 2003, approximately $122 million was budget by CMS for provider education and training.

House Bill

The provision would authorize $25 million to be appropriated from the Medicare Trust Funds for fiscal years 2005 and 2006, and such sums as necessary for succeeding fiscal years for Medicare contractors to increase education and training activities for providers and suppliers. Medicare contractors would be required to tailor education and training activities to meet the special needs of small providers or suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

Senate Bill

The provision would provide increased funding for the Medicare Integrity Program of $35 million beginning with FY2004 for increased provider and supplier education. Also would require Medicare contractors to take into consideration the special needs of small providers or suppliers when conducting education and training activities and permits provision of technical assistance beginning January 1, 2004.

Conference agreement.

The conference agreement authorizes such sums as necessary to be appropriated for fiscal years beginning with FY 2005 to be used to increase education and training activities for providers and suppliers regarding billing, coding, and other appropriate items and may be used to improve the accuracy, consistency, and timeliness of contractor responses. Beginning October 1, 2004, Medicare contractors are required to tailor education and training activities to meet the special needs of small providers or suppliers. Technical assistance is permitted to be included in the education and training activities. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

(e) Requirement to Maintain Internet Sites.

Present Law

No statutory provision. CMS and the Medicare contractors currently maintain internet sites.

House Bill

The provision would require that the Secretary and the Medicare contractors maintain Internet sites to answer frequently asked questions and provide published materials of the contractors beginning October 1, 2004.

Senate Bill.

No provision.

Conference agreement

Beginning October 1, 2004, the conference agreement requires the Secretary and the Medicare contractors to maintain Internet sites to answer frequently asked questions and provide published materials of the contractors.

(f) Additional Provider Education Provisions.

Present Law

No provision.

House Bill

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. The provision would not require Medicare contractors to disclose information that would compromise law enforcement activities or reveal findings of law enforcement-related audits. This provision would be effective upon enactment.

Senate Bill

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. The provision would not require Medicare contractors to disclose the screens used for identifying claims that will be subject to medical review or information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits. This provision would be effective upon enactment.

Conference agreement

The conference agreements bars Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. Nothing in section 1889 or 1893(g) shall be construed as providing for disclosure by a Medicare contractor of the screens used for identifying claims that will be subject to medical review or of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits. The agreement is effective upon enactment.

Small Provider Technical Assistance Demonstration Program. (Section 922 of the Conference Agreement, Section 922 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, to improve compliance with Medicare requirements. If errors are found, the Secretary would be barred from recovering any overpayments barring evidence of fraud and if the problem that is the subject of the compliance review has been satisfactorily corrected within 30 days and the problem remains corrected. Providers participating would be expected to pay 25 percent of the cost of the technical assistance. A GAO study would be required not later than 2 years after the demonstration program begins. Appropriations would be authorized for $1 million for FY 2005 and $6 million for FY 2006 to carry out the demonstration.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, in order to improve compliance with Medicare requirements. Technical assistance includes direct and in-person examination of billing systems and internal controls to determine program compliance and to suggest more efficient or effective means of achieving compliance. Providers participating are expected to pay 25 percent of the cost of the technical assistance. Appropriations of such sums as may be necessary to carry out this demonstration program are authorized from amounts not otherwise appropriated in the Treasury. The GAO is required to evaluate the demonstration no later than 2 years after it begins and submit a report to the Congress and the Secretary. The GAO is required to include in the report recommendations regarding the continuation or extension of the demonstration.

Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman. (Section 923 of the Conference Agreement, Section 923 of the House Bill, Sections 301 and 534 of the Senate Bill).

Present Law

No provision.

House Bill

A Medicare Provider Ombudsman would be required to be appointed by the Secretary and located within the Department of Health and Human Services. The Provider Ombudsman would be required to provide confidential assistance to providers and suppliers regarding complaints, grievances, requests for information, and resolution of unclear or conflicting guidance about Medicare. The Ombudsman would submit recommendations to the Secretary regarding improving the administration of Medicare, addressing recurring patterns of confusion

under Medicare, and ways to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums, as necessary, would be authorized and be appropriated for FY 2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. The Secretary would be required to appoint both ombudsmen not later than one year from the date of enactment. The Beneficiary Ombudsman would be required to have expertise and experience in health care, education of, and assistance to Medicare beneficiaries. The Beneficiary Ombudsman would be required to receive complaints, grievances, and requests for information submitted by Medicare beneficiaries. The Beneficiary Ombudsman would also be required to assist beneficiaries in collecting relevant information to seek an appeal of a decision or determination made by the Secretary, a Medicare contractor, or a Medicare+Choice organization and assisting a beneficiary with any problems arising from disenrolling in a Medicare+Choice plan and with presenting income information for purposes relating to the prescription drug benefit. The Beneficiary Ombudsman would be required to work with state Health Insurance Counseling Programs, to the extent possible.

Such sums as are necessary are authorized to be appropriated for FY 2004 and each succeeding fiscal year to carry out the ombudsmen provisions.

This provision would also require the use of 1-800-MEDICARE for all individuals seeking information about, or assistance with Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1-800-MEDICARE would be shown. The Comptroller General would be required to study the accuracy and consistency of information provided by the 1-800-MEDICARE line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study would be required to be submitted to Congress not later than one year after enactment.

Senate Bill

Same provisions.

Conference Agreement

The conference agreement creates a new section 1810 establishing a Medicare Beneficiary Ombudsman. The Secretary is required to appoint an Ombudsman with expertise and experience in the fields of health care and education of (and assistance to) Medicare beneficiaries not later than 1 year after the date of enactment. The Ombudsman will receive complaints, grievances, and requests for information from Medicare beneficiaries, and provide assistance in these matters and matters relating to appeals decisions made by Medicare contractors, Medicare+Choice organizations or the Secretary, as well as assistance to beneficiaries with any problems disenrolling from a Medicare+Choice plan. In addition, the Ombudsman will assist beneficiaries in presenting information relating to the income-related premium adjustment. The Beneficiary Ombudsman is required to work with State Health Insurance Counseling Programs, to the extent possible. The Ombudsman is prohibited from advocating for any increases in payment or new coverage of services, but may identify issues and problems in payment or coverage policies.

Appropriations are authorized to be appropriated in such sums as are necessary for FY 2004 and each succeeding fiscal year to carry out the Beneficiary Ombudsman provision.

The conference agreement also requires making 1-800-MEDICARE available to all individuals seeking information about, or assistance with, Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1-800-MEDICARE would be shown. The Comptroller General is required to study the accuracy and consistency of information provided on the 1-800-MEDICARE line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study is due to Congress not later than one year after enactment.

It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.

The conferees anticipate that disabled individuals will enroll in one of the many private sector prescription drug plans or MA-PD plans. Competition will necessitate plans offering the full complement of medicines, including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different.

Beneficiary Outreach Demonstration Program. (Section 924 of the Conference Agreement, Section 924 of the House Bill, Section 535 of the Senate Bill).

Present Law

No provision.

House Bill

The Secretary would be required to conduct a 3-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least 6 local Social Security offices (2 would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress. The provision would be effective upon enactment.

Senate Bill

Same provision

Conference Agreement

The conference agreement requires the Secretary to conduct a 3-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least 6 local Social Security offices (2 would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary is required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress. The agreement is effective upon enactment.

Inclusion of Additional Information in Notices to Beneficiaries About Skilled Nursing Facility Benefits. (Section 925 of the Conference Agreement, Section 925 of the House Bill, Section 551 of the Senate Bill).

Present Law

Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or skilled nursing facility (SNF) benefit or the spell of illness.

House Bill

The Secretary would be required to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits. The provision would be effective for notices provided during calendar quarters beginning more than 6 months after the date of enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement requires the Secretary to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits. The agreement applies to notices provided during calendar quarters beginning more than 6 months after the date of enactment.

Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans. (Section 926 of the Conference Agreement, Section 926 of the House Bill, Section 552 of the Senate Bill).

Present Law

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

House Bill

The Secretary would be required to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning would be required to evaluate a patient's need for SNF care.

The provision would apply to discharge plans made on or after the date specified by the Secretary, but not later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Senate Bill

Same provision.

Conference Agreement

The conference agreement requires the Secretary to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning is required to evaluate a patient's need for SNF care.

The agreement applies to discharge plans made on or after the date specified by the Secretary, but not later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Transfer of Responsibility for Medicare Appeals. (Section 931 of the Conference Agreement, Section 931 of the House Bill, Sections 511 and 519 of the Senate Bill).

Present Law

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an administrative law judge (ALJ). The ALJs that hear Medicare cases are employed by the Social Security Administration – a legacy from the inception of the Medicare program when Medicare was part of Social Security. BIPA section 522 requires that appeals of local coverage determinations be heard by ALJs of the Social Security Administration (SSA). As a result, if the ALJ function were moved from SSA to HHS, these local coverage determination appeals would still need to be heard by SSA ALJs.

House Bill

The Secretary and the Commissioner of the Social Security Administration (SSA) would be required to develop a plan to transfer the functions of the administrative law judges (ALJs) who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress not later than October 1, 2004. A GAO evaluation of the plan would be due within 6 months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department would be permitted to supervise the ALJs.

The Secretary would be required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and would be required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

Authorizes to be appropriated such sums as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

Senate Bill

The Secretary and Commissioner of Social Security would be required to develop and transmit to Congress and the Comptroller General a plan for transferring the functions of administrative law judges (ALJs) responsible for hearing cases under Medicare from the Social Security Administration to HHS no later than April 1, 2004. The plan would be required to include information on: workload; cost projections and financing; transition timetable; regulations; development of a case tracking system; feasibility of precedential authority; feasibility of electronic appeals filings and teleconference; steps needed to assure independence of ALJs, including assuring that they are in an office that is operationally and functionally separate from the Centers for Medicare & Medicaid Services and the Center for Medicare Choices; geographic distribution of ALJs; steps for hiring ALJs; performance standards of ALJs; sharing resources with Social Security regarding ALJs; training; and recommendations for further Congressional action. The GAO would be required to evaluate the Secretary's and Commissioner's plan and report to Congress on the result of the evaluation within 6 months of the receiving the plan. The Secretary would be prohibited from implementing the plan developed until no earlier than 6 month after the GAO report.

The statutory language that requires SSA ALJs be used to hear appeals of local coverage determinations would be eliminated. The requirement that these appeals be heard by ALJs would be retained. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary and the Commissioner of Social Security to develop a plan to transfer the administrative law judge function from SSA to HHS for Medicare appeals. Their plan is due to Congress and the Comptroller General not later than April 1, 2004. The plan is required to include information on: anticipated workload and staffing requirements; funding requirements; transition timetable; regulations; case tracking system; feasibility of developing a process to give Department Appeals Board decisions binding precedential authority; feasibility of filing appeals with ALJs electronically and conducing hearings using tele- or video-conferencing technologies; steps that should be taken to ensure the independence of ALJs; steps that should be taken to provide for an appropriate geographic distribution of ALJs throughout the United States; steps that should be taken to hire ALJs and support staff; appropriateness of establishing performance standards; steps that should be taken to carry out any needed shared resources with SSA; needed training; and any additional recommendations for further Congressional action.

A GAO evaluation of the plan is required within 6 months of the plan's submission. ALJ functions are required to be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary is required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department is permitted to supervise the ALJs. The Secretary is required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and is required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

In addition to any amounts otherwise appropriated, the agreement authorizes to be appropriated such sums as are necessary for FY 2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs, and to increase the staff of the Departmental Appeals Board (the final level of appeal).

The conference agreement strikes the statutory language that requires SSA ALJs be used to hear appeals of local coverage determinations. The requirement that these appeals be heard by ALJs is retained. This provision is effective upon enactment.

Process for Expedited Access to Review. (Section 932 of the Conference Agreement, Section 932 of the House Bill, Sections 512 and 513 of the Senate Bill).

Present Law

In general, administrative appeals must be exhausted prior to judicial review. The statute requires the automatic suspension of nurse aide training programs in skilled nursing facilities that have been subject to extended survey (that is, found to provide substandard care), have had serious sanctions imposed, or have waivers for required licensed nurse staffing.

House Bill

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain expedited access to judicial review when a 3-member review panel (composed of ALJs, members of the Departmental Appeals Board, or qualified individuals from qualified independent contractors designated by the Secretary) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would also be permitted for cases where the Secretary does not enter into or renew provider agreements.

Expedited review would also be established for certain remedies imposed against SNFs. The remedies in the provision are termination of participation, denial of payments, and imposition of temporary management. The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory 2-year disapproval period) if the only reason for the termination was the assessment of a civil money penalty of $5,000 or more. The appropriation of such sums as needed for FY2005 and subsequent years would be authorized to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the

DAB, and to educate these judges and their staffs on long-term care issues. This provision would be effective for appeals filed one or after October 1, 2004.

Senate Bill

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain expedited access to judicial review when a review entity (up to 3 qualified reviewers drawn from the ALJs or Departmental Appeals Board) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and is awarded by the reviewing court in favor of the prevailing party. Expedited access to judicial review would be permitted for cases where the Secretary does not enter into or renew provider agreements. The provision would be effective for appeals filed on or after October 1, 2004.

The Secretary also would be required to develop and implement a process to expedite review for certain remedies imposed against skilled nursing facilities (SNFs): termination of participation, immediate denial of payments, immediate imposition of temporary management, and suspension of nurse aide training programs.

This provision would authorize the appropriation of such sums as needed for FY2004 and subsequent years to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

The Comptroller General would be required to report to Congress on the access of Medicare beneficiaries and health care providers to judicial review of actions of the Secretary and HHS after February 29, 2000 (the date of the decision of *Shalala v. Illinois Council on Long Term Care, Inc.* (529 U.S. 1 (2000)). The report would be due not later than one year after enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a review entity (up to 3 qualified reviewers drawn from the ALJs or Departmental Appeals Board) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision is subject to review by the Secretary. Interest is assessed on any amount in controversy and is awarded by the reviewing court in favor of the prevailing party. Expedited access to judicial review is permitted for cases where the Secretary does not enter into or renew provider agreements. The conference agreement is effective for appeals filed on or after October 1, 2004.

The agreement requires the Secretary to establish a process to expedite appeals of provider terminations and certain other remedies imposed on skilled nursing facilities, including denial of payment for new admissions and temporary management, if imposed on an immediate basis. Providers who are subject to the remedies of denial of payment or temporary management may only access the expedited process when these remedies are imposed on an immediate basis and where the facility has no opportunity to correct the deficiency. The agreement would also allow an expedited appeal where a finding of substandard quality of care has resulted in the

disapproval of a skilled nursing facility's nurse aide training program. The agreement requires the Secretary to give priority to cases where termination has been imposed on a provider.

The agreement includes a provision allowing the Secretary to waive disapproval of a nurse aide training program, upon application by a nursing facility if the disapproval resulted from the imposition of a civil monetary penalty that was not related to quality of care provided to residents of the facility. Quality of care in such instances refers to direct, hands on care provided to residents of a facility. This agreement does not permit the Secretary to waive the CMP.

In addition to any amounts otherwise appropriated, the conference agreement authorizes the appropriation of such sums as needed for FY2004 and subsequent years in order to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

Revisions to Medicare Appeals Process. (Section 933 of the Conference Agreement, Section 933 of the House Bill, Section 514 of the Senate Bill).

(a) Requiring Full and Early Presentation of Evidence

Present Law

No provision. New evidence can be presented at any stage of the appeals process.

House Bill

The provision would require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QIC) unless good cause precluded the introduction of the evidence. The provision would be effective October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QIC) unless good cause precluded the introduction of the evidence. The conference agreement provision is effective October 1, 2004.

(b) Use of Patients' Medical Records

Present Law

No provision.

House Bill

The provision would provide for the use of beneficiaries' medical records in appeals reconsiderations by qualified independent contractors (QICs). The provision would be effective upon enactment.

Senate Bill

Beneficiaries' medical records would be able to be used in appeals reconsiderations by qualified independent contractors. The provision would be effective upon enactment.

Conference Agreement.

The conference agreement provides for the use of beneficiaries' medical records in appeals reconsiderations by QICs. The conference agreement is effective upon enactment.

(c) Notice Requirements for Medicare Appeals

Present Law

No statutory provision. Determinations and denials of appeals currently include the policy, regulatory, or statutory reason for the denial and information on how to appeal the denial. The Benefits Improvement and Protection Act (BIPA) of 2000, changed the appeals process and created a new independent review (the qualified independent contractors or QICs), which has not yet been implemented.

House Bill

The provision would require that when claims are denied the written notice of determination include the reasons for the determination, including whether a local medical review policy or a local coverage determination was used; the procedures for obtaining additional information concerning the determination including, when requested, the specific provision of the policy, manual, or regulation used in making the determination; and notification of the right to seek an appeal and instructions for appealing the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice would be required to include: the specific reasons for the redetermination; as appropriate, a summary of the clinical or scientific evidence used in making the redetermination; a description of the procedures for obtaining additional information concerning the redetermination. The notice would be required to be written in a manner calculated to be understood by a beneficiary. A beneficiary receiving such a notice would be permitted to request and receive information on the specific provision of the policy, manual, or regulation used in making the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice would be required to be written in a manner calculated to be understood by the beneficiary and information regarding appeal rights and processes provided.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision would be required to be in writing and written in a manner calculated to be understood by the beneficiary, to include the specific reasons for the determination, including to the extend appropriate a summary of the clinical or scientific evidence used in making the determination; the procedures for obtaining additional information regarding the decision; and notification of

the right to appeal and how to initiate such an appeal. The provision also requires that the qualified independent contractor submit information that is needed for an appeal of a decision.

Senate Bill

The provision would require that when claims are denied, the written notice of the decision at every level of the appeal or with the initial determination would be required to be written in a manner to be understood by the beneficiary and include notification of the right to appeal the decision and instruction on how to initiate an appeal.

In addition, the determination would be required to include the reasons for the determination including, as appropriate, the provision of the policy, manual, or regulation that resulted in the denial if requested; and the procedures for obtaining additional information concerning the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice would be required to include: the reasons for the decision and, as appropriate, the provision of the policy, manual, or regulation that resulted in the denial if requested, and a summary of the clinical or scientific evidence used in making the redetermination; and a description of the procedures for obtaining additional information concerning the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice would be required to include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making the decision, to the extent appropriate; and in the case of a decision regarding whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury, an explanation of the medical or scientific rationale for the decision.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision would be required to include the specific reasons for the determination including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination; and the procedures for obtaining additional information concerning the decision.

Conference Agreement.

The conference agreement requires that when claims are denied in either the initial determination or in subsequent appeals, a written notice of the decision is required and to be written in a manner calculated to be understood by the beneficiary and to include notification of the right to appeal the decision and instruction on how to initiate an appeal.

In addition, the determination is required to include the reasons for the determination, including whether a local medical review policy or a local coverage determination was used; and the procedures for obtaining additional information concerning the determination including, when requested, the specific provision of the policy, manual, or regulation used in making the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice is required to include: the specific reasons for the redetermination; as appropriate, a summary of the clinical or scientific evidence used in making the redetermination; a description of the procedures for obtaining additional information concerning the redetermination. A beneficiary

receiving such a notice is permitted to request and receive information on the specific provision of the policy, manual, or regulation used in making the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice is required to be written in a manner calculated to be understood by the beneficiary and information regarding appeal rights and processes provided.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision is required to be in writing and written in a manner calculated to be understood by the beneficiary, to include the specific reasons for the determination, including to the extend appropriate a summary of the clinical or scientific evidence used in making the determination; the procedures for obtaining additional information regarding the decision; and notification of the right to appeal and how to initiate such an appeal.

The conference agreement also requires that the qualified independent contractor submit information that is needed for an appeal of a decision. The conference agreement is effective upon enactment.

(d) Qualified Independent Contractors

Present Law

BIPA established a new and independent second level of appeal called the qualified independent contractors (QICs). BIPA called for at least 12 QICs. The QICs have not yet been implemented.

House Bill

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from not fewer than12 to not fewer than 4. The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

Senate Bill

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and prohibitions on compensation being linked to decisions rendered. The required minimum number of qualified independent contractors would be reduced from 12 to 4.

In addition, the provision would delay the effective date of certain appeals provisions until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. The provision would allow the transitional use of peer review organizations (now called quality improvement organizations by the Secretary) to conduct expedited determinations until the QICs are operating.

Conference Agreement

The conference agreement clarifies eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors is reduced from not fewer than 12 to not fewer than 4. The provisions regarding the eligibility requirements of QICs and QIC reviews are effective as if included in the enactment of BIPA.

Implementation of Certain BIPA Effective Dates

Present Law

The BIPA claims appeals provisions were effective October 1, 2002 but have not been implemented.

House Bill

No provision.

Senate Bill

The provision would delay the effective date of certain appeals provisions until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. The provision would allow the transitional use of peer review organizations (now called quality improvement organizations by the Secretary) to conduct expedited determinations until the QICs are operating.

Conference Agreement

No provision.

Prepayment Review. (Section 934 of the Conference Agreement, Section 934 of the House Bill, Section 541 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

House Bill

Medicare contractors would be permitted to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that were developed in consultation with providers and suppliers. Random prepayment review would only be permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only when there was a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates would be permitted depending upon the differences in the circumstances triggering prepayment review.

The Secretary would be required to issue the required regulations not later than one year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews would apply to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment). The remaining provisions would be effective one year after enactment.

Senate Bill

The conduct of random prepayment review would be limited only to those done in accordance with a standard protocol developed by the Secretary. Non-random reviews would be prohibited unless a likelihood of sustained or high level of payment error (as defined by the Secretary) existed and the Secretary would be required to establish protocols for terminating the non-random reviews within one year of enactment. The Secretary would be required to publish implementing regulations and develop and publish protocols not later than one year after enactment. The provision would be effective for random reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment).

Conference Agreement

The conference agreement permits Medicare contractors to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that are developed in consultation with providers and suppliers. Random prepayment reviews are only permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews are permitted only when there is a likelihood of sustained or high level of payment error. The Secretary is required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates is permitted depending upon the differences in the circumstances triggering prepayment review.

The Secretary is required to issue the required regulations not later than 1 year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews applies to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than 1 year after enactment). The remaining provisions are effective 1 year after enactment.

Recovery of Overpayments. (Section 935 of the Conference Agreement, Section 935 of the House Bill, Section 542 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

House Bill

In situations where repaying an Medicare overpayment within 30 days would be a hardship for a provider or supplier, the Secretary would be required to enter into an extended repayment plan of at least 6 months duration. The repayment plan would not be permitted to go

beyond 3 years (or 5 years in the case of extreme hardship, as determined by the Secretary). Interest would be required to accrue on the balance through the repayment period. Hardship would be defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship would be defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary would be required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, would not be taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary would not be obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary would be permitted to immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest would be required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation would be limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or documented educational intervention has failed to correct the payment error.

Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary would be able to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary would be required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary would be required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The

contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

In general the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is 1 year after the date of enactment. The Secretary would be required to establish the process for notice of overutilization of billing codes not later than 1 year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than 1 year after enactment.

Senate Bill

This provision would add a new subsection (h) to 1874A that would require establishment of at least a 1 year repayment plan – but not longer than three years – when a provider requests a repayment plan, unless the Secretary believes the provider may declare bankruptcy. If a provider or supplier fails to make a scheduled payment, the Secretary could immediately offset or recover the outstanding balance. The Secretary would be required to develop standards for the recovery of overpayments not later than one year after enactment.

The Secretary would be barred from recouping any overpayments until a reconsideration-level appeal was decided (if one were requested). The paragraph provides that interest would be required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

The provision would also require that if post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class. The process would be required not later than one year after enactment.

Not later than one year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

The Secretary would be authorized to use a consent settlement process to settle projected overpayments under certain specified conditions.

The provisions affecting post-payment audits and consent settlements would be effective to audits initiated and consent settlements entered into after the date of enactment. Other provisions would be effective for action taken 1 year after enactment.

Conference Agreement

In situations where repaying an Medicare overpayment within 30 days would be a hardship for a provider or supplier, the conference agreement requires the Secretary to enter into an extended repayment plan of at least 6 months duration. The repayment plan is not permitted to go beyond 3 years (or 5 years in the case of extreme hardship, as determined by the Secretary). Interest is required to accrue on the balance through the repayment period. Hardship is defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship is defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary is required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, are not taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary may immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary is prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest is required to be paid to the provider if the appeal is successful (beginning from the time the overpayment is recouped) or interest is required to be paid to the Secretary if the appeal is unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation is limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or document educational intervention has failed to correct the payment error.

Medicare contractors are permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary is permitted to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary is required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary is

required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary is required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits are conducted, the Medicare contractor is required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor is further required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary is required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

In general, the provisions are effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is 1 year after the date of enactment. The Secretary is required to establish the process for notice of overutilization of billing codes not later than 1 year after enactment. The Secretary is required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than 1 year after enactment.

Provider Enrollment Process; Right of Appeal. (Section 936 of the Conference Agreement, Section 936 of the House Bill, Section 515 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors.

House Bill

The Secretary would be required to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process would be required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary would be required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary would be required to consult with providers and suppliers. The provision would also establish hearing rights in cases where the applications have been denied.

The enrollment process would be required to be established within 6 months of enactment. The consultation process on provider enrollment forms would be required for changes in the form beginning January 1, 2004. The provision of hearing rights would apply to denials that occur 1 year after enactment or an earlier date specified by the Secretary.

Senate Bill

Same provisions

Conference Agreement

The conference agreement requires the Secretary to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process is required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary is required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary is required to consult with providers and suppliers. The conference agreement also establishes hearing rights in cases where the applications have been denied.

The enrollment process is required to be established within 6 months of enactment. The consultation process on provider enrollment forms is required for changes in the form beginning January 1, 2004. The provision of hearing rights applies to denials that occur 1 year after enactment or an earlier date specified by the Secretary.

Process for Correction of Minor Errors and Omissions without Pursuing Appeals Process. (Section 937 of the Conference Agreement, Section 937 of the House Bill, Section 543 the Senate Bill).

Present Law

No explicit statutory instruction. Administratively, the Medicare contractors send a claim's denial when a claim has been submitted that lacks required information. Amendments to cost reports are not allowed once a cost report is settled.

House Bill

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment. The provision would also require the Secretary to permit hospitals to correct wage data errors that affect geographic reclassification even if the cost report has been settled. For FY 2004 alone, resubmittal of the application for geographic reclassification would be permitted. The provision would be effective upon enactment.

Senate Bill

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment. The provision would require that the process be developed not later than 1 year after enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment within 1 year after enactment.

Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices. (Section 938 of the Conference Agreement, Section 938 of the House Bill, Section 535(b) of the Senate Bill).

Present Law

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for noncovered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the provider does not want to accept financial responsibility for the service. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

House Bill

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain categories of items and services before such services are provided. An eligible requestor would be a physician, but only in case of items and services for which the physician is paid directly and a Medicare beneficiary who receives an advance beneficiary notice from a physician would receive direct payment for that service. The provisions would establish (1) that such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions would not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process would be established in time to address such requests that are filed by 18 months of enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

Senate Bill

The Secretary would be required to establish a demonstration project to test the administrative feasibility of providing a process for beneficiaries and providers to request and receive a determination as to whether the item or service is covered under Medicare by reasons of Medical necessity, before the item or service involved is furnished to the beneficiary.

Conference Agreement

The conference agreement requires the Secretary to establish a prior determination process through regulation where physicians and beneficiaries can determine whether Medicare covers certain physician services before such services are provided. An eligible requestor is a physician, but only in case of services for which the physician is paid directly, or a Medicare beneficiary, who receives an advance beneficiary notice from a physician who would receive direct payment for that service. The provisions establishes (1) that such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions do not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process is required to be established in time to address such requests that are filed by 18 months after enactment and it sunsets 5 years later. For purposes of calculating the physician fee schedule sustainable growth rate, this provision is not to be considered to be a change in law or regulation. The Secretary is required to collect data on the advance beneficiary notices and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notices within 18 months of the implementation of the prior determination process. The GAO is also required to report on the use of the prior determination process within 36 months of the implementation of the prior determination process.

Appeals by Providers When There is No Other Party Available. (Section 939 of the Conference Agreement, Section 516 of the Senate Bill).

Present Law

Section 1870 of the Social Security Act provides for the recovery of overpayments and the settlement of claims for benefits on behalf of a deceased beneficiary

House Bill

No provision.

Senate Bill

In the case where a beneficiary dies before assigning appeal rights, a provider or supplier would be permitted to appeal a payment denial by a Medicare contractor. The provision would be effective for items and services furnished on or after enactment.

Conference Agreement

In the case where a beneficiary dies before assigning appeal rights, the conference agreement permits a provider or supplier to appeal a payment denial by a Medicare contractor. The provision is effective for items and services furnished on or after enactment.

Revisions to Appeals Timeframes and Amounts. (Section 940 of the Conference Agreement, Section 518 of the Senate Bill).

Present Law

BIPA revised the timeframes for Medicare appeals. For the first level of appeal, the "redetermination" level, the timeframe for decisions was reduced from 90 days for a part A appeal and 45 days for a part B appeal to 30 days; for the second level, the "reconsideration" level, the timeframe was reduced from 120 days for a part B appeal to 30 days (this is a new level of appeal for part A appeals); for the third level, appeals before administrative law judges, the timeframe was reduced from no time limit to 90 days; and the fourth level, appeals before the Department Appeals Board, the timeframe was reduced from no time limit to 90 days. BIPA also provided that a beneficiary could "escalate" his or her appeal to the next level if the appeal was not decided in a timely fashion.

To appeal a claim, the beneficiary must have an "amount in controversy" of $100 or more. Judicial review is available only for amounts in controversy of $1,000 or more. Claims are permitted to be aggregated in order to reach the amount in controversy if certain conditions are met.

House Bill

No provision.

Senate Bill

This provision would add 30 days to the timeframe for deciding an appeal at each of the four levels of appeal. No provision regarding the indexing of amounts in controversy.

Conference Agreement

The conference agreement adds 30 days to the timeframe for deciding an appeal at the redetermination and reconsideration levels of appeal (that is, the first two levels of appeal). The conference agreement also indexes the amount in controversy for appeals to the CPI-U, rounded to the nearest multiple of $10 beginning in 2005.

Mediation Process for Local Coverage Determinations (Section 940A of the Conference Agreement, Section 517 of the Senate Bill).

Present Law

Only beneficiaries have standing to appeal local coverage decisions by Medicare contractors. Mediation is not currently used in Medicare to resolve disputes.

House Bill

No provision.

Senate Bill

The parties that have standing to appeal local coverage decisions would be expanded to include providers or suppliers adversely affected by the determination. The Secretary would be required to establish a process whereby a provider or supplier may request a local coverage determination under certain circumstances. A provider or supplier could seek a local coverage determination if the Secretary determined that: (A) there have been at least five reversals by an ALJ of redeterminations made by a Medicare contractor in at least two different cases; (B) that each reversal involved substantially similar material facts; (C) each reversal involved the same medical necessity issue; and (D) at least 50% of the total claims submitted by the provider within the past year involving the requisite facts and medical necessity issue have been denied and then reversed by an ALJ. Such sums as necessary to carry out the provisions above would be authorized to be appropriated. Also the provision would require the Secretary to study and report to Congress on the feasibility and advisability of requiring Medicare contractors to track the subject and status of claims denials that are appealed and final determinations.

The expansion in standing would be effective for any review or request of any local coverage determination filed on or after October 1, 2003 and for any local coverage determination made on or after October 1, 2003. The requirement to establish a process for a provider or supplier to request a local coverage determination would be effective for requests filed on or after the date of enactment. The report would be due to Congress not later than one year after the date of enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a mediation process using a physician trained in mediation and employed by CMS. This process is to be used to mediate disputes between groups representing providers, physicians, and suppliers and the medical director for the Medicare contractor in any area that the relevant CMS regional administrator determines that there is a systematic pattern and a large volume of complaints from such groups regarding decisions of the medical director or there is a complaint from the co-chair of the advisory committee for that contractor. The Secretary is required to include in the contract with Medicare Administrative Contractors the performance duties expected of a medical director including professional relations. The provision is effective upon enactment.

Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines. (Section 941 of the Conference Agreement, Section 941 of the House Bill, Section 553 of the Senate Bill).

Present Law

No provision.

House Bill

The Secretary would not be permitted to implement any new documentation guidelines for, or clinical examples of, evaluation and management (E&M) physician services unless the Secretary: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines; (3) conducted pilot projects to test modifications to the guidelines; (4) finds the guidelines have met established objectives; and (5) established and

implemented an education program on the use of the guidelines with appropriate outreach. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The provision establishes objectives for modifications of the E&M guidelines:(1) identification of clinically relevant documentation needed to code accurately and assess coding levels accurately; (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the medical record; (3) increase accuracy of reviewers; and (4) education of physicians and reviewers.

The pilot projects would be required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and be of sufficient length to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project: using a physician peer review method, using an alternative method based on face-to-face encounter time with the patient, in a rural area, outside a rural area, and where physicians bill under physician services in a teaching setting and nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project and would last for as long as the provider participated in the project. Each pilot conducted would examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The Secretary would be required to submit periodic reports to Congress on these pilot projects.

The provision would require a study of an alternative system for documenting physician claims. Specifically the Secretary would be required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary would be required to consult with practicing physicians in designing and carrying out the study. This study would be due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary would also be required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary would be required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

Senate Bill

The Secretary would be required to ensure, before making changes in documentation guidelines for, or clinical examples of, or codes to report E&M physician services, that the process used in developing the guidelines, examples, or codes was widely consultative among physicians, reflects a broad consensus among specialties, and would allow verification of reported and furnished services.

Conference Agreement

The conference agreement does not permit the Secretary to implement any new or modified documentation guidelines (including clinical examples) for evaluation and management (E&M) physician services unless the Secretary has: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of

the proposed guidelines by the physician community; (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines; (3) conducted pilot projects to test modifications to the guidelines; (4) found the guidelines have met established objectives; and (5) established and implemented an education program on the use of the guidelines with appropriate outreach. The conference agreement requires the Secretary to make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The conference agreement establishes objectives for modifications of the E&M guidelines: (1) identification of clinically relevant documentation needed to code accurately and assess coding levels accurately; (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the medical record; (3) increase accuracy of reviewers; and (4) education of physicians and reviewers.

The pilot projects are required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and are of sufficient length (but, in no case longer than 1 year) to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project that: (1) uses a physician peer review method (that is not used by a Medicare contractor) that evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to codes used for billing purposes for these services; (2) uses an alternative method based on face-to-face encounter time with the patient; (3) is conducted for services furnished in a rural area and one for services furnished outside a rural area; and (4) is conducted in a setting where physicians bill under physician services in a teaching setting and one in a nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Each pilot conducted is required to examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The provision requires the Secretary to submit a report to Congress on these pilot projects within 6 months of completion of the pilots.

A study of an alternative system for documenting physician claims is also required. Specifically, the Secretary is required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary is required to consult with practicing physicians in designing and carrying out the study. This study is due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary is also required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary is required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

Improvement in Oversight of Technology and Coverage. (Section 942 of the Conference Agreement, Section 942 of the House bill, Section 554 of the Senate Bill).

(a) Council for Technology and Innovation

Present Law

No provision.

House Bill

The Secretary would be required to establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (CMS). The council would be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS administrator. The Chairperson would serve as the Executive Coordinator for Technology and Innovation would be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

Senate Bill

The provision would require the Secretary to establish a Council for Technology and Innovation composed of senior CMS staff and clinicians to coordinate coverage, coding, and payment processes under Title XVIII and the exchange of information on new technologies between CMS and other entities that make similar decisions.

Conference agreement

The conference agreement requires the Secretary establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (CMS). The council is to be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS administrator. The Chairperson will serve as the Executive Coordinator for Technology and Innovation and will be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council is required to coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

(b) Methods for Determining Payment Basis for New Lab Tests

Present Law

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes a cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1,2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

House Bill

The Secretary would be required to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the *Federal Register* on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and

recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary. Effective for codes assigned on or after January 1, 2005.

Senate Bill

No provision.

Conference agreement

The conference agreement requires the Secretary to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests are defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, is required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the *Federal Register* on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary sets forth the criteria for making these determinations, which include whether a test should be established through gap-filling or cross-walking to an existing code. In these cases, carriers and CMS cannot substitute an alternative service for a gap filled amount, the Secretary shall make public the available data considered in making such determinations; and convenes other public meetings as necessary. The provision is effective for codes assigned on or after January 1, 2005.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Present Law

No provision.

House Bill

The GAO would be required to study which external data can be collected in a shorter time frame by CMS to use in calculating payments for inpatient hospital services. The GAO could evaluate feasibility and appropriateness of using quarterly samples or special surveys and would include an analysis of whether other executive agencies are best suited to collect this information. The report would be due to Congress no later than October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the GAO to study which external data can be collected in a shorter time frame by CMS to use in calculating payments for inpatient hospital

services. The GAO may evaluate feasibility and appropriateness of using quarterly samples or special surveys and is required to include an analysis of whether other executive agencies are best suited to collect this information. The report is due to Congress no later than October 1, 2004.

(d) Process for Adoption of ICD Codes as Data Standard.

Present Law

The Secretary is required to rely on the recommendations from the National Committee on Vital and Health Statistics (NCVHS) before adopting health information standards and codes. The current standard for procedure codes is the International Classification of Diseases, 9th Revision, clinical modification (ICD-9-CM is the basis of the Medicare inpatient hospital PPS payment system). The NCVHS made a recommendation on November 5th to the Secretary about adopting the latest revision, the ICD-10-PCS (Procedure Coding System) or ICD-10-CM as a coding standard.

House Bill

The Secretary would be permitted to adopt the ICD-10-PCS and the ICD-10-CM within 1-year of enactment without receiving a recommendation from the National Committee on Vital and Health Statistics (NCVHS).

Senate Bill

No provision.

Conference Agreement

No provision. Because the NCVHS made a recommendation to the Secretary, Conferees believed the House provision was no longer necessary.

Conferees urge the Secretary, however, to accept the recommendation of the NCVHS and issue a notice of proposed rule making to initiate the regulatory process for the concurrent adoption of ICD-10-CM and ICD-10-PCS. ICD-10 would replace the 23-year-old ICD-9-CM coding classification system, which has highly limited reporting capabilities for today's needs and growth capacity for future needs, making it an unacceptable coding classification system for both inpatient and outpatient diagnosis. ICD-10 would be able to keep pace with advances in modern medicine, thus ensuring accurate reimbursement rates for emerging technologies and patient access to the highest quality care.

Since 1997, NCVHS has closely examined this issue and received testimonies and letters from more than 80 public- and private-sector groups representing the full range of interests in the health care community. NCVHS and other parties have commissioned numerous studies, all of which NCVHS also has carefully considered. The Committee finds that the recommendation made by NCVHS is based on sound evidence and is, in the words of NCVHS, "in the best interests of the country as a whole." Conferees encourage the Secretary to implement the recommendation as quickly as possible.

Treatment of Hospitals for Certain Services Under Medicare Secondary Payor (MSP) Provisions. (Section 943 of the Conference Agreement, Section 943 of the House Bill).

Present Law

In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payer is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

House Bill

The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Senate Bill

No provision.

Conference Agreement

The conference agreement prohibits the Secretary from requiring a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services are those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

EMTALA Improvements. (Section 944 of the Conference Agreement, Section 944 of the House Bill).

Present Law

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to any patient who comes to an emergency room requesting examination or treatment in order to determine whether an emergency medical situation exists.

Hospitals that are found to be in violation of Emergency Medical Treatment and Active Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. Prior to imposing a civil monetary penalty, the Secretary is required to request a peer review organization (PRO – currently called quality improvement organizations or QIOs) to assess whether the involved beneficiary had an emergency condition, which had not been stabilized and provide a report on its findings. Except in the case where a delay would

jeopardize the health or safety, the Secretary provides 60-day period for the requested PRO review.

House Bill

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated for Medicare's "reasonable and necessary" requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit. The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO would be required to provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment

Senate Bill

No provision.

Conference Agreement

The conference agreement requires emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, to be evaluated for Medicare's "reasonable and necessary" requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this includes the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary is prohibited from considering the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

The Secretary is required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary is required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO is required to provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision applies to terminations initiated on or after enactment.

Emergency Medical Treatment and Active Labor Act (EMTALA) Technical Advisory Group. (Section 945 of the Conference Agreement, Section 945 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to establish a 19-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the HHS Inspector General; 4 hospital representatives who have EMTALA experience, (2 of whom have not experienced EMTALA violations) 7 practicing physicians with specified experience; 2 patient representatives; 2 regional CMS staff involved in EMTALA investigations; 1 representative from a State survey organization and 1 from peer review organization. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations. The advisory group would be required to (1) elect a member to as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The Secretary would be required to establish the advisory group regardless of any limitation that may apply to the number of advisory committees that may be established within HHS.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a 19-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the HHS Inspector General; 4 hospital representatives who have EMTALA experience (2 of whom have not experienced EMTALA violations); 7 practicing physicians with specified experience; 2 patient representatives; 2 regional CMS staff involved in EMTALA investigations; 1 representative from a State survey organization and 1 from peer review organization. The Secretary is required to select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group will review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations. The advisory group is required to: (1) elect a member to as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The Secretary is required to establish the advisory group regardless of any limitation that may apply to the number of advisory committees that may be established within HHS.

Authorizing Use of Arrangements to Provide Core Hospice Services in Certain Circumstances. (Section 946 of the Conference Agreement, Section 946 of the House Bill, Section 406 of the Senate Bill).

Present Law

A hospice is a public agency or private organization that is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

House Bill

A hospice would be permitted to (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements. The provision would be effective for hospice care provided on or after the date of enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement permits a hospice to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements. The provision is effective for hospice care provided on or after the date of enactment.

Application of OSHA Bloodborne Pathogens Standard to Certain Hospitals. (Section 947 of the Conference Agreement, Section 947 of the House Bill).

Present Law

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

House Bill

Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare. The provision would apply to hospitals as of July 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires that public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement will be subject to a civil monetary penalty, but cannot be terminated from participating in Medicare. The provision applies to hospitals as of July 1, 2004.

BIPA-Related Technical Amendments and Corrections. (Section 948 of the Conference Agreement, Section 948 of the House Bill).

Present Law

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

House Bill

The statutory reference in BIPA would be changed from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from "policy" to "determinations." The provision is effective as if included in the enactment of BIPA.

Senate Bill

No provision.

Conference Agreement

The conference agreement changes the statutory reference in BIPA from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from "policy" to "determinations." The provision is effective as if included in the enactment of BIPA.

Conforming Authority to Waive a Program Exclusion. (Section 949 of the Conference Agreement, Section 949 of the House Bill, Section 544 of the Senate Bill).

Present Law

The Secretary is required to exclude individuals and entities from participation in federal health programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under state health programs; (2) convicted of a criminal offense related to patient abuse or neglect under federal or state law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program finance or operated by the federal, state or local government; or (4) convicted of a felony related to a controlled substance.

House Bill

The administrator of a federal health program would be permitted to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. The mandatory exclusions that could be waived would be those related to convictions associated with program-related crimes; health care fraud and controlled substance. The provision would be effective upon enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement permits the administrator of a federal health program to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community will impose a hardship. The mandatory exclusions that can be waived are those related to convictions associated with program-related crimes; health care fraud and controlled substance. The provision is effective upon enactment.

Treatment of Certain Dental Claims. (Section 950 of the Conference Agreement, Section 950 of the House Bill, Section 555 of the Senate Bill).

Present Law

The Medicare benefit does not include most dental services. Some insurers may require a claim denial from Medicare before accepting the dental claim for payment review, even if the service is not covered by Medicare.

House Bill

A group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for noncovered dental services before paying the claim. The provision would be effective 60 days after enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement provides that a group health plan providing supplemental or secondary coverage to Medicare beneficiaries cannot require dentists to obtain a claim denial from Medicare for dental services that are not covered by Medicare before paying the claim. The provision is effective 60 days after enactment.

Furnishing Hospitals with Information to Compute DSH Formula. (Section 951 of the Conference Agreement, Section 951 of the House Bill).

Present Law

Disproportionate share hospital (DSH) payments under Medicare are calculated using a formula that includes the number of patient days for patients eligible for Medicaid.

House Bill

The provision would require the Secretary to provide information that hospitals need to calculate the number of Medicaid patient days used in the Medicare DSH payment formula, not later than 1 year after enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to arrange for the provision of information that hospitals need to calculate the Medicare DSH payment formula not later than 1 year after enactment.

Revisions to Reassignment Provisions (Section 952 of the Conference Agreement, Section 952 of the House Bill, Section 434 of the Senate Bill).

Present Law

In general, Medicare Part B payments may be made only to a Medicare beneficiary or to physician or other person who provided the service. Section 1842(b)(6) of the Social Security Act establishes the Medicare reassignment prohibitions and does not permit physicians to reassign their Medicare payments to entities with which they have a relationship on an independent contractor basis. In order for an independent contractor to reassign Medicare benefits, the services must be performed on the premises of the entity to which the benefits will be reassigned.

House Bill

Medicare payment for Part B services would be permitted to be made to an entity, as defined by the Secretary, that has a contractual arrangement with the physician or other person who provided the service for the entity to bill for the service and the contractual arrangement meets program integrity and other safeguards specified by the Secretary.

The provision would be effective for payments made on or after one year after the date of enactment.

Senate Bill

Same provision, but would include a conforming amendment.

Conference Agreement

This provision amends the Social Security Act to allow physicians and non-physician practitioners to reassign payment for Medicare-covered services, regardless of where the arrangement (including but not limited to a hospital, clinic, medical group, a physician practice management organization, or a staffing company) so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such service. As a result, the Secretary could enroll these entities in the Medicare program. The Secretary may

also provide for other enrollment qualifications to assure program integrity, including joint and several liability.

This provision will streamline Medicare enrollment while also enhancing HHS' program integrity efforts. By permitting entities that retain independent contractors to enroll with the Medicare program and thereby directly bill the Medicare program, HHS will be able to monitor the claims submitted by the entities that retain independent contractors as well as those entities that employ physicians. The Committee supports appropriate program integrity efforts (e.g. joint and several liability) for any entities billing the Medicare program including entities with employees as well as independent contractors. Further, the Committee believes that physicians' and non-physician practitioners' should be entitled to unrestrictive access to billings submitted on their behalf by the entity with which they have contracted. The Committee intends that the Secretary will implement this provision via program instructions to the Medicare contractors. The changes made by this provision shall apply to Medicare payments made on or after date of enactment.

The provision is effective upon enactment.

Other Provisions. (Section 953 of the Conference Agreement, Section 953 of the House Bill).

Present Law

No provisions.

House Bill

GAO Report on Physician Compensation. No later than six months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequently. The report would examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The Secretary would be required to publish an annual list of nation coverage determinations made under Medicare in the previous year. Included would be information on how to get more information about the determinations. The list would be published to the public in an appropriate annual publication.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The GAO would be required to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report would be due no later than six month after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The Inspector General of HHS would be required to report to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report would also include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report would be due no later than one year after enactment.

Senate Bill

No provision.

Conference Agreement

GAO Report on Physician Compensation. The conference agreement requires that, no later than six months from enactment, the GAO report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequent years. The report will examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO is required to report to Congress on all aspects of physician compensation for Medicare services. The report is required to review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The conference agreement requires the Secretary publish an annual list of national coverage determinations made under Medicare in the previous year. Information on how to get more information about the determinations is required to be included in the publication. The list and the information are required to be published in an appropriate annual publication that is publicly available.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The conference agreement requires the GAO to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report is required to include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report is due no later than six month after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The conference agreement requires the Inspector General of HHS to report to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report is required to include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report is due no later than one year after enactment.

Streamlining and Simplification of Medicare Regulations (Section 504 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to analyze Medicare regulations for the purposes of determining how to streamline the regulation and reduce the number of words in the regulations by two-thirds by October 1, 2004. If the Secretary determines that the two-thirds reduction is infeasible, he would be required to inform Congress in writing by July 1, 2004 of the reasons and then establish a feasible reduction to be achieved by January 1, 2005. The provision would be effective upon enactment.

Conference Agreement

No provision.

Elimination of the Requirement for De Novo Review by the Departmental Appeals Board (Section 520 of the Senate Bill).

Present Law

BIPA section 521 requires that the Departmental Appeals Board (DAB), the fourth level of appeal, review appeals cases *de novo*. Prior to BIPA, the DAB reviewed appeals based on the record established during the previous three levels of appeal.

House Bill

No provision.

Senate Bill

The DAB would be required to review a decision and render a decision or remand the appeal to the ALJ within the 90-day period. The provision would be effective upon enactment.

Conference Agreement

No provision.

Title X– Medicaid and Miscellaneous Provisions

Subtitle A– Medicaid Provisions

Medicaid Disproportionate Share (DSH) Hospital Payments - Temporary Increase. (Section 1001(a) of the Conference Agreement, Section 1001 of the House Bill, and Section 601 of the Senate Bill)

Present Law

Hospitals that serve a large number of uninsured patients and Medicaid enrollees receive additional Medicaid disproportionate share hospital (DSH) payments. As established in the BBA 1997, the federal share of Medicaid DSH payments is capped at specified amounts for each state for FY1998 through FY2002. For most states, those specified amounts declined over the 5-year period. A state's allotment for FY2003 and for later years is equal to its allotment for the previous year increased by the percentage change in the consumer price index for urban consumers (CPI-U) for the previous year. In addition, each state's DSH payment for FY2003 and subsequent years is limited to no more than 12% of total spending for medical assistance in each state for that year.

BIPA provided states with a temporary reprieve from the declining allotments by establishing a special rule for the calculation of DSH allotments for 2 years, raising allotments for FY2001 and for FY2002. The provision also clarified that the FY2003 allotments were to be calculated as specified under BBA 1997, using the lower, pre-BIPA levels for FY2002 in those calculations.

DSH payments to each inpatient general hospital are limited to some percentage of the costs of providing inpatient and outpatient services to Medicaid and uninsured patients at that hospital, less payments received from or on behalf of Medicaid and uninsured patients. These costs are considered to be unreimbursed costs. DSH payments to private hospitals may be no greater than 100% of unreimbursed costs. Public hospitals, for the two state fiscal years beginning after September 2002, cannot receive DSH payments that exceed 175% of unreimbursed costs. Thereafter, those hospitals would be limited to DSH payments of no more than 100% of unreimbursed costs.

House Bill

The provision would establish a temporary increase in DSH allotments for FY2004 and for certain subsequent fiscal years. Allotments for FY2004 would be set at 120% of FY2003 allotments as under BIPA and would not be subject to the ceiling capping states' allotments at 12% of medical assistance payments. Allotments for subsequent years would be equal to the allotments for FY2004 unless the Secretary determines that the allotments as would have been calculated prior to the enactment of this bill would equal or exceed the FY2004 amounts. For such fiscal years, allotments would be equal to allotments for the prior fiscal year increased by the percentage change in the consumer price index for all urban consumers for the previous fiscal year. The provision would be effective upon enactment.

Senate Bill

The special DSH rule established by BIPA that raised DSH allotments, subject to the current law limit of 12% of spending for medical assistance, would be extended for FY2004 and FY2005. Allotments for FY2004 would be calculated to be equal to FY2004 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by BIPA 2000) increased by the percentage change in the CPI-U for each of fiscal years 2002 and 2003, and (b) FY2004 allotments (as established by BBA 1997). Allotments FY2005 would be calculated to be equal to FY2005 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by the BIPA 2000) increased by the percentage change in the CPI-U for each of fiscal years, 2002, 2003, and 2004, and (b) FY2005 allotments (as established by BBA 1997). For FY2006 and thereafter, DSH allotments would be calculated based on the previous years' amount (as established by BBA 1997 and subject to the current law limit of 12% of spending for medical assistance) increased by the percentage change in the CPI-U for the previous fiscal year. All allotments would remain subject to the current law limit of 12% of medical assistance spending.

A separate calculation of the DSH allotment for the District of Columbia for FY2004 would be specified. The DSH allotment for the District of Columbia for FY2004 would be raised, subject to the current law limit of 12% of spending for medical assistance, by multiplying $49 million by the percentage change in the CPI-U for each of FY2000, FY2001, FY2002, and FY2003. The provision would be effective upon enactment.

Conference Agreement

The conference agreement will establish a temporary increase in DSH allotments for FY2004 and for certain subsequent fiscal years. Allotments for FY2004 are to be set at 116% of FY2003 allotments as under BIPA and will not be subject to the ceiling capping states' allotments at 12% of medical assistance payments. Allotments for subsequent years will be equal to the allotments for FY2004 unless the Secretary determines that the allotments as would have been calculated prior to the enactment of this bill would equal or no longer exceed the FY2004 amounts. For such fiscal years, allotments will be equal to allotments for the prior fiscal year increased by the percentage change in the consumer price index for all urban consumers for the previous fiscal year. The provision is effective upon enactment.

Increase in the Floor for Treatment as an Extremely Low DSH States Under the Medicaid Program for Fiscal Years 2004 and 2005. (Section 1001(b) of the Conference Agreement, Section 602 of the Senate Bill)

Present Law

Extremely low DSH states are those states whose FY1999 federal and state DSH expenditures (as reported to CMS on August 31, 2000) are greater than zero but less than 1% of the state's total medical assistance expenditures during that fiscal year. DSH allotments for the extremely low DSH states for FY2001 would be equal to 1% of the state's total amount of expenditures under their plan for such assistance during that fiscal year. For subsequent fiscal years, the allotments for extremely low DSH states would be equal to their allotment for the previous year, increased by the percentage change in the CPI-U for the previous year, subject to a ceiling of 12% of that state's total medical assistance payments in that year.

House Bill

No provision.

Senate Bill

Allotments for certain extremely low DSH states for FY2004 and FY2005 would be increased. For states with DSH expenditures for FY2000 (as reported to CMS as of August 31, 2003) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year, the provision would raise the DSH allotments for FY2004 to 3% of the state's total amount of expenditures for such assistance during that fiscal year. States with DSH expenditures for FY2001 (as reported to CMS as of August 31, 2004) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year would have the DSH allotments for FY2005 equal to such state's DSH allotment for FY2004 increased by the percentage change in the CPI-U for FY2004.

A special DSH allotment adjustment for certain states would be specified for FY2004 and FY2005. For Tennessee, if its state-wide Section 1115 waiver is revoked or terminated during FY2004 and/or FY2005, the Secretary of HHS would permit the state to submit an amendment to its state plan that would describe the methodology to be used by the state to identify and make payments for disproportionate share hospitals (including children's hospitals, and institutions for mental diseases, or other mental health facilities – other than state-owned institutions or facilities), based on the proportion of patients served by such hospitals that are low-income patients with special needs. The state would be required to provide data for the computation of an appropriate DSH allotment that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated. The provision would be effective upon enactment.

Conference Agreement

The conference agreement will raise the temporary floor for extremely low DSH states as defined under current law for fiscal years 2004 through 2008 by 16% above current amounts.

Increased Reporting Requirements to Ensure the Appropriateness of Payment Adjustments to Disproportionate Share Hospitals Under the Medicaid Program. (Section 1001(c) of the Conference Agreement, Section 603 of the Senate Bill)

Present Law

BBA 1997 required each state to submit to the Secretary an annual report describing the disproportionate share payments made to each disproportionate share hospital (DSH) and the methodology used by the state for prioritizing payments to such hospitals.

House Bill

No provision.

Senate Bill

As a condition of receiving federal Medicaid payments for FY2004 and each fiscal year thereafter, the provision would require each state to submit to the Secretary an annual report (for

the previous fiscal year) identifying each disproportionate share hospital that received a payment, the amount such hospital received, as well as other information the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year. The provision would be effective upon enactment.

Conference Agreement

As a condition of receiving federal Medicaid payments for FY2004 and each fiscal year thereafter, the conference agreement will require each state to submit to the Secretary an annual report (for the previous fiscal year) identifying each disproportionate share hospital that received a payment, the amount such hospital received, as well as other information the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year. In addition, the conference agreement will require states to submit annually to the Secretary an independent certified audit verifying: the extent to which hospitals receiving DSH payments have reduced their uncompensated care costs to reflect DSH payments received; the states' compliance with the hospital-specific payment ceilings; the methodology used to calculate those ceilings; and the documentation maintained by the states regarding claimed costs, expenditures and payments under this section. The conference agreement will be effective upon enactment.

Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemptions for the Medicaid Drug Rebate Program. (Section 1002 of the Conference Agreement, Section 1002 of the House Bill, and Section 604 of the Senate Bill)

Present Law

Medicaid drug rebates are calculated based on the difference between the average manufacturer's price (AMP) and the manufacturer's "best price." In determining the "best price" for a drug sold by a manufacturer, certain discounted prices and fee schedules are disregarded. The special discounted prices for outpatient drugs negotiated by the Office of Pharmacy Affairs (of HHS) with drug manufacturers on behalf of certain clinics and safety net providers are one example of prices excluded from Medicaid's "best price" determination. Because of this exclusion from Medicaid's "best price" definition, the discounts available to safety net providers have no bearing on the calculation of drug rebates under the Medicaid program, allowing those providers to negotiate better rates with manufacturers, since Medicaid rebates will not change with the size of their negotiated discounts. Discounted prices for inpatient drugs for many safety net providers, however, are not disregarded in the Medicaid "best price" determination.

House Bill

The provision would modify the definition of "best price" for the purpose of calculating Medicaid drug rebates, to also disregard the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals would also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's "best price" determination. The provision would be effective upon enactment.

Senate Bill

The provision would modify the definition of "best price" for the purpose of calculating Medicaid drug rebates, to also exclude the discounted inpatient drug prices charged to certain

public safety net hospitals. Those hospitals would also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's "best price" determination. The provision would be effective October 1, 2003.

Conference Agreement

The conference agreement will modify the definition of "best price" for the purpose of calculating Medicaid drug rebates, to also exclude the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals will also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's "best price" determination. The provision will be effective upon enactment.

Assistance for States for Legal Immigrants

Present Law

"Qualified aliens" who entered the United States after the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, August 22, 1996) are not eligible to receive federally funded benefits under Medicaid or SCHIP for 5 years. Qualified aliens who entered the United States prior to the enactment of PRWORA are eligible for federally funded Medicaid coverage as a state option, as are qualified aliens arriving after August 22, 1996 who have been present in the United States for more than 5 years.

A person who executed an affidavit of support for an alien under Senate Section 213A of the Immigration and Nationality Act (INA) is liable to reimburse the federal or state government for the public benefits received by the sponsored alien until the alien naturalizes or has accumulated 40 quarters of work. Senate Section 213A was enacted as a part of PRWORA on August 22, 1996.

House Bill

No provision.

Senate Bill

The provision would lift the 5-year ban and would allow states the option to provide medical assistance to certain lawfully residing individuals under Medicaid (including under a waiver authorized by the Secretary) or SCHIP for any of fiscal years 2005 through 2007. Those eligible would include lawfully residing women during pregnancy and the 60-day period after delivery, and children otherwise eligible for Medicaid or SCHIP as defined by the state plan. States opting to provide coverage to such lawfully residing individuals under SCHIP must also provide coverage to such individuals under Medicaid. If services are provided under the Medicaid program, the alien's sponsor would not be liable to reimburse the federal or state government for the cost of such services. The provision would be effective upon enactment.

Conference Agreement

No provision.

GAO Study Regarding Impact of Assets Test for Low-income Beneficiaries. (Section 607 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would require the General Accounting Office (GAO) to conduct a study to determine the extent to which drug utilization and access to covered drugs differs between: (1) individuals who qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries (including qualified Medicare beneficiaries, specified low-income Medicare beneficiaries or qualifying individual under Senate Section 1860(D)), and (2) individuals who do not qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries solely as a result of the application of an assets test to the income eligibility requirements of such individuals. The GAO would be required to submit to Congress the final report (including recommendations for legislation) no later than September 30, 2007. The provision would be effective upon enactment.

Conference Agreement

No provision.

Clarification Regarding Non-Regulation of Transfers

Present Law

No specific provision

House bill

No provision

Senate bill

No provision

Conference Agreement

The final conference agreement permits the Secretary, in limited instances, to allow a publicly-owned regional medical center to utilize the disproportionate share hospital allotment of another State. This provision will apply through December 31, 2005.

Urban Health Provider Adjustment. (Section 625 of the Senate Bill)

Present Law

There are two other types of ceilings on DSH payments, in addition to the state-wide allotments. The "hospital-specific" ceiling limits payments to hospitals to some percentage of the each hospital's costs of providing inpatient and outpatient services to Medicaid and uninsured patients, less payments received from or on behalf of Medicaid and uninsured patients ("unreimbursed costs"). DSH payments to public hospitals are limited to 100% of these unreimbursed costs except in fiscal years 2003 and 2004 when the percentage of unreimbursed costs that can be covered by DSH rises to 175%. The hospital-specific ceiling for private hospitals is 100% of unreimbursed costs and for certain public hospitals in the state of California is 175% permanently.

House Bill

No provision.

Senate Bill

DSH payments made to hospitals that are owned and operated by the state of Indiana and located in Marion County would be made without regard to the state's DSH allotment limitation so long as those payment amounts, fit FY2004 and each fiscal year thereafter do not exceed 175% of the "unreimbursed costs" of furnishing hospital services.

Conference Agreement

No provision.

100% FMAP for Medical Assistance Provided to a Native Hawaiian Through a Federally-Qualified Health Center or a Native Hawaiian Health Care System Under the Medicaid Program. (Section 632 of the Senate Bill)

Present Law

The Medicaid program is jointly financed by the states and the federal government. The federal government share is based on each state's federal medical assistance percentage (FMAP). The FMAP for a state is calculated using a formula reflecting the state per capita income relative to the average U.S. per capita income. The formula is designed to give a higher FMAP to states with a per capita income below the U.S. average. No state can have an FMAP of less than 50% or more than 83%. Certain services including family planning are paid at an alternative FMAP rate, as are administrative expenses. In addition, the law provides that services provided through an Indian Health Service facility operated by the Indian Health Service or an Indian tribe or tribal organization have an FMAP of 100%.

The Jobs and Growth Tax Relief Reconciliation Act of 2003 (JEGTRRA, P.L. 108-026) altered the statutory calculation of the FMAPs by providing a hold harmless for declines from the prior year for each state FMAP, and a temporary increase of 2.95 percentage points for the last 2 quarters of fiscal year 2003 and the first three quarters of fiscal year 2004. The calculated statutory FMAPs for Hawaii would be 58.77% for fiscal year 2003 and 58.90% for fiscal year

2004. The JEGTRRA changes result in an FMAP of 61.75% for the last 2 quarters of fiscal year 2003, and 61.85% for the first three quarters of fiscal year 2004. The FMAP for services provided to a Native Hawaiian is the same as for services provided to other Medicaid beneficiaries in Hawaii.

House Bill

No provision.

Senate Bill

For services provided to a Native Hawaiian by a federally qualified health center or a Native Hawaiian health care system, the FMAP would be 100%. Services qualifying for the 100% FMAP would include those provided by referral, and under contract or other arrangement between a health care provider and the federally qualified health center or Native Hawaiian health care system. The provision would be effective for medical assistance provided on or after the date of enactment.

Conference Agreement

No provision.

Extension of Moratorium. (Section 633 of the Senate Bill)

Present Law

Medicaid payment for services provided by an institution for mental disease (IMD) may be made only for beneficiaries who are under age 21 or over 65. IMD means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. For two facilities in Michigan – Kent Community Hospital Complex and Saginaw Community Hospital - previous legislation has imposed a moratorium on determination of the facilities as IMDs through December 31, 2002.

House Bill

No provision.

Senate Bill

The moratorium on the determination of Saginaw Community Hospital as an IMD would be permanently extended. The provision would be effective as if included in the Balanced Budget Act of 1997.

Conference Agreement

The moratorium on the determination of Saginaw Community Hospital as an IMD would be extended for 2 years. The provision would be effective as if included in the Balanced Budget Act of 1997.

Subtitle B– Miscellaneous Provisions

Employer Flexibility. (Section 1011 of the Conference Agreement, and Section 631 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would amend the Age Discrimination in Employment Act of 1967 to allow an employee benefit plan that provides medical benefits to be offered to retirees who are not eligible for Medicare benefits or benefits provided under a State plan without offering medical benefits, or the same medical benefits, to Medicare-eligible retirees or retirees eligible for benefits under a State plan. Under the provision, an employee benefit plan that distinguishes between those retirees and other retirees would not violate the ADEA. The provision would be effective upon enactment.

Conference Agreement

No provision. However, the conferees reviewed the ADEA and its legislative history and believe the legislative history clearly articulates the intent of Congress that employers should not be prevented from providing voluntary benefits to retirees only until they become eligible to participate in the Medicare program.

Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens

Present Law

The Balanced Budget Act of 1997 (BBA97) provided $25 million in funding for state emergency health services furnished to undocumented aliens for each of FY1998 through 2001. Funds were distributed among the12 states with the highest number of undocumented aliens. In a fiscal year, each state's portion of the total funds available was based on its share of total undocumented aliens in all of the eligible states. The share of undocumented aliens in each state were based on the estimates provided by the Statistics Division of the Immigration and Naturalization Service (INS).

House Bill

No provision.

Senate Bill

For each of fiscal years 2005 through 2008 the provision would appropriate for allotment among states $250 million in funds for emergency health services furnished to undocumented aliens. Each such fiscal year the Secretary would distribute $167 million of $250 million among all states. Each state would receive an amount equal to the product of the total amount available in each fiscal year, and the proportion of the state's share of undocumented aliens to the total count of undocumented aliens residing in all states as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the decennial census.

For each of fiscal years 2005 through 2008, the Secretary would distribute $83 million of $250 million among the 6 states with the highest number of undocumented alien apprehensions for such fiscal year. Each such state would receive an amount that bears the same ratio to the total amount available for allotments to such states (in each fiscal year) as the ratio of the number of undocumented alien apprehensions in the state (in each fiscal year) to the total number of undocumented alien apprehensions for all such states (in each fiscal year) based on the four most recent quarterly apprehensions rates for undocumented aliens as reported by the Immigration and Naturalization Service.

From the state allotments described above, the Secretary would pay directly to local governments, hospitals, or other providers located in the state (including providers of services rendered through an Indian Health Service facility) for costs incurred in providing emergency health care services furnished to undocumented aliens during that fiscal year (even if the care is furnished to aliens who have been allowed to enter for the sole purpose of receiving emergency health care services). No later than September 1, 2004, the Secretary would be required to establish a process, that includes measures to protect against fraud and abuse, under which entities would apply for reimbursement from the state's allotments for claims associated with emergency health care services furnished to undocumented aliens. Advanced payments would be made quarterly based on the applicants projected expenditures. The Secretary would also be required to set up a process to allow for prior period adjustments resulting from underpayment or over payment to an entity in a prior quarter. Funds shall remain available until they are expended. The provision would be effective upon enactment.

Conference Agreement

For each of fiscal years 2005 through 2008 the Conference agreement appropriates for allotment among eligible providers in the 50 states and the District of Columbia $250 million in additional federal funding for emergency health services furnished to undocumented aliens. For each such fiscal year, the Secretary must distribute $167 million of $250 million among eligible providers in all states. Each state's share of this amount will be based on its proportion of total number of undocumented aliens in all states as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the decennial census.

For each of fiscal years 2005 through 2008, the Secretary must distribute $83 million of $250 million among eligible providers in the six states with the highest number of undocumented alien apprehensions for such fiscal year. Each state's share of this amount is equal to the product of the total amount available for allotments to such states (in each fiscal year), and the proportion of the number of undocumented alien apprehensions in the state (in each fiscal year) to the total number of undocumented alien apprehensions for all such states (in the preceding fiscal year) based on apprehensions rates for undocumented aliens as reported by the Immigration and Naturalization Service in the four consecutive-quarter period ending before the beginning of the fiscal year for which such information is available.

From the $250 million in state allotments described above, the Secretary will pay directly to eligible providers located in the state (including hospitals, physicians, or providers of ambulance services, and Indian Health Service facilities) for unreimbursed costs incurred by providing emergency health care services during that fiscal year to: (1) undocumented aliens; (2) aliens who have been paroled in the United States at a port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a specified identification card. In establishing a payment methodology, the Secretary may establish different methodologies for different types of eligible providers, may calculate payments to hospitals based on hospital-specific cost-to-charge ratios, and shall make quarterly payments to eligible providers. Hospitals may elect to receive payment for hospital and all physician services in which case they may pass on payments for physician services directly to physicians without charging hospital administrative fees. If the amount of funds allotted to a state is insufficient to ensure that each eligible provider receives the amount described above then the Secretary is required to reduce the amount of payment to eligible providers to ensure that each eligible provider is paid.

No later than September 1, 2004, the Secretary must establish a process that includes measures to protect against fraud and abuse to ensure that inappropriate, excessive or fraudulent payments are not made from allotments. Advance payments may be made quarterly based on the applicants projected expenditures. The Secretary is also required to set up a process to allow for prior period adjustments resulting from under payments or over-payments. Funds will remain available until they are expended. The provision will be effective upon enactment.

Commission on Systematic Interoperability. (Section 1013 of the Conference Agreement)

Pediatric Palliative Care Demonstration

Medicare is designed for aged and disabled individuals (typically people over 65 years of age). It was not designed with children in mind.

The conferees are aware of potential barriers in the current system for children with life-threatening illnesses. First, in order to qualify for hospice, a doctor must certify that a child has 6-months to live. Determining how long a child has to live is often difficult. Second, the current system does not allow a patient to receive curative and palliative care simultaneously. This means that children can either receive treatment for their disease or they can receive palliative care.

HHS should conduct a demonstration project in up to 6 geographically diverse sites to determine whether palliative care for children may be improved under circumstances where such barriers are reduced or eliminated. Such demonstration shall take place over at least a three year period.

The Secretary, in conducting such demonstration project, should take into account the recommendations of the Institute of Medicine in its report: "When Children Die: Improving Palliative and End-of-Life Care for Children and their Families."

In particular, the Secretary should consider including as part of the demonstration:

1. Waivers to Elect Hospice Care and Receive Curative Treatment
2. Care coordination from diagnosis to end of life.
3. Features to ensure that parents have information about existing pediatric hospice and palliative care programs to make decisions about the care of their child.
4. Bereavement counseling for the family and reimbursement to provider.

The conferees believe that it is important that the Secretary have flexibility when conducting such demonstration to provide additional benefits so long as they are consistent with the recommendations contained in the IOM Report and they are provided in budget neutral manner. The conferees also believe that the Secretary should provide reports to congress, as appropriate, that include an evaluation of the short and long-term costs and benefits of palliative care under traditional Medicare and the demonstration projects, determine the quality and duration of palliative care under the demonstration project, and evaluate whether there is an offset of savings by providing pediatric palliative care, and the projected cost of implementing the demonstrations on a national basis.

Present Law

No provision.

House Bill

No provision.

Senate Provision

No provision.

Conference Agreement

The conference agreement instructs the Secretary to establish a Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards. In developing its strategy, the Commission must consider the costs and benefits of the standards, the current demand on industry resources to implement these and other electronic standards (including the HIPAA administrative simplification standards), and the most cost-effective and efficient means for industry to implement the standards. The Commission must not interfere with any ongoing process of developing or adopting standards, nor shall it replicate activities related to such standards or to the HHS National Health Information Infrastructure initiative. Not later than October 31, 2005, the Commission must submit a report to the Secretary and the Congress describing its strategy.

The Commission shall be composed of 11 members. The President shall appoint three members, including a Chairperson; the Senate Majority Leader, the Senate Minority Leader, the Speaker, and the House Minority Leader shall each appoint two members. Commission membership must include nationally recognized experts in health finance and economics, health plans and integrated delivery systems, health care reimbursement, health care technology and information systems, and other related fields, as well as physicians, pharmacists, and other health care providers, who provide a mix of professionals, broad geographic representation, and a

balance between urban and rural representation. Each member shall be appointed for the life of the Commission.

Commission members shall be paid for each day (including travel days) of service at a rate not exceeding the rate of basic pay for level IV of the Executive Schedule. Each member shall also receive travel expenses and a per diem. Federal employees who serve on the Commission may not receive any financial compensation.

A majority of Commission members shall constitute a quorum but a lesser number may hold hearings. The Commission Chairperson must appoint a Director, to be paid at a rate not exceeding the rate of basic pay for level IV of the Executive Schedule. With the Commission's approval, the Director may appoint additional staff, as well as temporary experts and consultants. Employees of federal agencies may also be detailed to the Commission to assist in carrying out its duties.

The Commission may, as appropriate, hold hearings, take testimony, and receive evidence. Any Commission member or agent may, if so authorized by the Commission, take any action which the Commission is authorized to take. The Commission may obtain official information from a federal agency and may accept, use and dispose of gifts, bequests, or devises of services or property, both real and personal. Gifts, bequests, or devices or money and proceeds from sales of other property received as gifts, bequests, or devices shall be deposited in the Treasury and available for disbursement upon order of the Commission. The Commission may use the U.S. mail under the same conditions as other federal agencies and may enter into contracts as may be necessary to conduct its work. Upon the Commission's request, the Administrator of General Services must provide administrative support services to the Commission on a reimbursable basis.

The Commission shall terminate 30 days after submitting its report to the Secretary and the Congress. The conference report authorizes to be appropriated such sums as may be necessary to carry out this Section.

Research on Outcomes of Health Care Items and Services. (Section 1014 of the Conference Agreement)

Present Law

The Agency for Healthcare Research and Quality (AHRQ) is an agency within the Department of Health and Human Services. AHRQ's mission is to support, conduct, and disseminate research that improves access to care and the outcomes, quality, cost, and utilization of health care services. The research agenda is designed to be responsive to the needs of its customers, including patients, clinicians, institutions, plans, purchasers, and federal, state and local governments. The research conducted by AHRQ is used to inform medical practice, educate consumer understanding of health care, and expand policymakers' ability to monitor and evaluate the impact of system changes on outcomes, quality, access, cost, and use of health care, and to devise policies to improve system performance.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement authorizes and appropriates $50 million for fiscal year 2004 for the Secretary through the Agency for Healthcare Research and Quality to conduct research to address the scientific information needs and priorities identified by the Medicare, Medicaid, and State Children Health Insurance Programs. The information needs and priorities will relate to the clinical effectiveness and appropriateness of specified health services and treatments, and the health outcomes associated with such services and treatments. The needs and priorities also will address strategies for improving the efficiency and effectiveness of those health care programs. The Secretary is required to establish a process for developing research priorities. Not later than 6 months after the date of enactment, the Secretary must establish an initial list of priorities. The Secretary must complete the evaluation and synthesis of the scientific evidence related to that initial list within 18 months after development of such a list and disseminate the research findings to the public, prescription drug plans, and other plans. Not later than18 months after the date of enactment, the Secretary is required to identify voluntary options that could be undertaken by public and private entities to improve information sharing regarding outcomes and quality of care, adopt innovative quality improvement strategies, develop management tools to improve oversight by state officials, support federal and state initiatives to improve the quality, safety, and efficiency of services, and provide a basis for estimating the fiscal and coverage impact of federal or state policy changes of the Medicare, Medicaid, and State Children's Health Insurance Programs. The Administrator for the Center for Medicare and Medicaid Services may not use data from the research conducted to withhold coverage of a prescription drug, to mandate a national standard, or require a specific approach to quality measurement and reporting.

Health Care that Works for All Americans-Citizens Health Care Working Group. (Section 1015 of the Conference Agreement, and Section 620 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The bill would authorize $3 million for each of the fiscal years 2005 and 2006 for the Secretary of HHS, acting through the Agency for Healthcare Research and Quality, to establish a group that would be called the "Citizens' Health Care Working Group." The 25 members of the group would come from health care stakeholders and would be appointed by Congressional leaders. Working Group member appointments could not be made from elected officials. Appointments would be for a 2-year period. Once all the members of the Working Group have been appointed, Congressional leaders would appoint a chairperson from among the members. The Working Group would be responsible for holding hearings and producing public reports regarding expanding coverage options, the cost of health care, innovative state and community

strategies to expand coverage or reduce costs, and the role of evidence-based medicine and technology in improving quality and lowering costs. The first hearing would be required to be held within 90 days after the chairperson was appointed and additional hearings would be permitted. Within 90 days of completing hearings, the Working Group would be required to prepare a report that discusses numerous health care issues including health care and related services used by individuals throughout their lifetimes, the cost of health care services, sources of coverage and payment, and reasons for uninsurance and underinsurance.

In addition to hearings, the Working Group would be required to hold community meetings throughout the United States in sufficient number to reflect geographic differences, diverse populations, and a balance among urban and rural populations. The Working Group would be required to prepare an interim set of recommendations on health care coverage and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings within 180 days after the conclusion of the community meetings. There would be a 90-day public comment period on the recommendations. Not later than 120 days after the end of the public comment period, the Working Group would be required to submit to Congress and the President a final set of recommendations. Not later than 45 days after receiving the final recommendations, the President would be required to submit a report to Congress with additional views and comments on the recommendations and recommendations for legislation and administrative actions. Each congressional committee of jurisdiction would be required to hold at least one hearing on the report and the final recommendations.

The Working Group would be staffed by an Executive Director appointed by the chairperson, up to 20 Federal Government employees on detail, and could procure temporary or intermittent services of individuals. The Working Group would be required to report to Congress annually a detailed description of the expenditures of the Working Group used to carry out its duties. The Working Group would terminate when the report with the final recommendations is submitted to Congress, but not later than two years after the date on which Working Group members were appointed. The provision would be effective upon enactment.

Conference Agreement

The conference agreement authorizes $3 million for each of the fiscal years 2005 and 2006 for the Secretary of HHS, acting through the Agency for Healthcare Research and Quality, to establish a group called the "Citizens' Health Care Working Group." The working group will be composed of 15 members; one member will be the Secretary and the other 14 members will be appointed by the Comptroller General. Appointments will include certain consumers of heath services, and individuals with expertise in the health care industry. Appointment will not include elected officials. The duration of appointments will be for the life of the Working Group. Not later than 15 days after which all appointments have been made, the Comptroller General will designate a chairperson from the members. The Working Group will be responsible for holding hearings and producing public reports regarding expanding coverage options, the cost of health care, innovative state and community strategies to expand coverage or reduce costs, and the role of evidence-based medicine and technology in improving quality and lowering costs. The first hearing must be held within 90 days after designation of the chairperson, and additional hearings would be permitted as long as such hearings do not delay the Working Group's other activities. Within 90 days of completing hearings, the Working Group will prepare a report that discusses numerous health care issues including health care and related services used by individuals throughout their lifetimes, the cost of health care services, sources of coverage and payment, and reasons for uninsurance and underinsurance.

In addition to hearings, the Working Group will hold community meetings throughout the United States in sufficient number to reflect geographic differences, diverse populations, and a balance among urban and rural populations. The Working Group will prepare an interim set of recommendations on health care coverage, and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings within 180 days after the conclusion of such meetings. There will be a 90-day public comment period on the recommendations.

Not later than 120 days after the end of the public comment period, the Working Group will submit to Congress and the President a final set of recommendations. Not later than 45 days after receiving the final recommendations, the President will submit a report to Congress with additional views and comments on the recommendations, and recommendations for legislative and administrative actions. Each congressional committee of jurisdiction will hold at least one hearing on the report and the final recommendations.

The Working Group will be staffed by an Executive Director appointed by the chairperson, up to 20 Federal Government employees on detail, and could procure temporary or intermittent services of individuals. The Working Group will report annually to Congress a detailed description of the expenditures used by the Working Group to carry out its duties. The Working Group will terminate within 2 years after the date on which all members of the Working Group were appointed.

Establishment of Consumer Ombudsman Account. (Section 606 of the Senate Bill)

Present Law

The Omnibus Budget Reconciliation Act of 1990 established State Health Insurance Counseling Assistance grants to states to provide education and information to Medicare beneficiaries. Funding has been subject to annual appropriations.

House Bill

No provision.

Senate Bill

A Consumer Ombudsman Account would be established in the Medicare Trust Fund and $1 for every Medicare beneficiary would be appropriated to the account from the Trust Fund beginning with fiscal year 2005. The account would be used to make grants to State Health Insurance Counseling Programs. The provision would be effective upon enactment.

Conference Agreement

No provision.

Health Care Infrastructure Improvement. (Section 1016 of the Conference agreement and Section 608 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

A loan program would be established to improve the cancer-related health care infrastructure in certain geographic areas of the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital, medical research facility or other medical facility or the purchase of any equipment to be used in a hospital, research facility or other medical research facility. In order to receive assistance, the project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute (NCI) or be designated by the state as the sole official comprehensive cancer effort for the state; and (3) be located in a state that on the date of enactment of this title has a population of less than 3 million individuals. $49 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, $2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the projects that have received assistance under this program, including recommendations on the future operation of the program. The provision would be effective upon enactment.

Conference Agreement

A loan program would be established to improve the cancer-related health care hospital infrastructure in the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital. In order to receive assistance, the project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute (NCI) or be designated by the state as the sole official comprehensive cancer effort for the state. $200 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, $2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the projects that have received assistance under this program, including recommendations on the future operation of the program. The provision would be effective upon enactment.

Capital Infrastructure Revolving Loan Program. (Section 609 of the Senate Bill)

Present Law

The Public Health Services Act establishes a fund in the Treasury from which the Secretary of HHS can make loans or loan guarantees in the amounts that have been specified in appropriations Acts from time to time. Under the Medicare Rural Hospital Flexibility Program established as part of Title XVIII, the Secretary may award grants to rural hospitals to cover the implementation costs associated with data systems needed to meet the BBA 97 requirements.

House Bill

No provision.

Senate Bill

The Secretary would be able to make loans to any rural entity to acquire land, renovate buildings, and purchase major moveable equipment or other appropriate projects. A rural entity would include rural health clinics, a medical facility with less than 50 beds in a county that is not part of a metropolitan statistical area or is in a rural census tract of such area, a hospital that is a rural referral center or a sole community hospital. An entity that has been geographically reclassified for the purposes of Medicare reimbursement would not be precluded from being considered a rural provider. Loan guarantees and interest subsidies of up to 3% of the net effective interest rate would be authorized. The total of the government's exposure with respect to this program would not exceed $50 million per year. The total of the principal amount of all loans directly made or guaranteed in any year may not exceed $250 million per year. In addition, rural providers could apply to receive $50,000 planning grants to help assess capital and infrastructure needs. The grants awarded in any year would not exceed $2.5 million. The program would expire after September 30, 2008. The provision would be effective upon enactment.

Conference Agreement

No provision.

Increase in Appropriation to the Health Care Fraud and Abuse Control Account. (Section 611 of the Senate Bill)

Present Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, PL.104-91) established the Health Care Fraud and Abuse Control (HCFAC) Program which is administered by the HHS Office of Inspector General and the Department of Justice. Funds for the HCFAC program are appropriated from the Federal Hospital Insurance Trust Fund. HIPAA provided for annual increases of 15% in HCFAC funding through 2003, after which the appropriation for HCFAC and the amount earmarked for HHS-OIG remains the same. In FY2003 the available appropriation for HCFAC was $240,558,320 of which $150 million to $160 million was available to the HHS-OIG.

House Bill

No provision.

Senate Bill

Additional appropriations to HCFAC would be authorized. In FY2004, the increase would be $10 million over the FY2003 appropriation limit; in FY2005 the increase would be $15 million over the FY2003 limit; in FY2006 the increase would be $25 million above the FY2003 limit. Subsequent years appropriations would be at the 2003 limit. The HHS-OIG earmarked

appropriations would increase as well: to $170 million in FY2004, $175 million in FY2005, $185 million in FY2006. In subsequent years, it would be not more than $150 million and not more than $160 million. The provision would be effective upon enactment.

Conference Agreement

No provision.

Increase in Civil Penalties Under the False Claims Act. (Section 612 of the Senate Bill)

Present Law

The False Claims Act imposes a liability on those who knowingly present or cause to be presented a false or fraudulent claim for payment by the government. In certain instances, the person may be liable for a civil penalty of not less than $5,000 and not more than $10,000, plus treble damages.

House Bill

No provision.

Senate Bill

For violations occurring on or after January 1, 2004, the minimum amount of the civil penalty would be increased from $5,000 to $7,500 and the maximum amount would increase from $10,000 to $15,000. The provision would be effective for violations occurring on or after January 1, 2004.

Conference Agreement

No provision.

Increase in Civil Monetary Penalties under the Social Security Act. (Section 613 of the Senate Bill)

Present Law

The Office of the Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs) on any person (including an organization or other entity, but not a beneficiary) who knowingly presents, or causes to be presented, to a state or federal government employee or agent certain false or improper claims for medical or other items or services. CMPs may also be imposed for other fraudulent activities such as inflating charges for services, providing services when not a properly licensed physician, billing for medically unnecessary services, falsely certifying that an individual meets the requirements for home health services, and offering or soliciting remuneration to influence the provision of medical services. Depending upon the violation, Section 1128A of the SSA authorizes the imposition of CMPs up to $10,000 for each item or service involved, up to $15,000 for individuals who provide false or misleading information in certain instances, and up to $50,000 per act in other instances as well as treble damages.

House Bill

No provision.

Senate Bill

The amount of penalties would be increased for violations that occur on or after January 1, 2004. In instances where penalties are limited to $10,000 would be increased to $12,500; those penalties that are limited to $15,000 would be increased to $18,750; and those that are limited to $50,000 would be increased to $62,500. The provision would be effective for violations occurring on or after January 1, 2004.

Conference Agreement

No provision.

Extension of Customs User Fees. (Section 614 of the Senate Bill)

Present Law

The U.S. Customs Service, the federal government's oldest revenue collecting agency is responsible for regulating the movement of persons, carriers, merchandise, and commodities between the United States and other countries. Its authority to impose user fees for certain services lapsed on September 30, 2003, but was subsequently restored.

House Bill

No provision.

Senate Bill

The authority to impose user fees would be extended until September 30, 2013.

Conference Agreement

No provision.

Provision of Information on Advance Directives. (Section 616 of the Senate Bill)

Present Law

Information about advance directives is required to be given to patients in hospitals, skilled nursing facilities, and served by home health agencies. The Secretary is required to provide Medicare beneficiaries annual information about Medicare benefits, limitations on payment, and a description of the limited benefits for long-term care. This information is provided to Medicare beneficiaries in the Medicare & You handbook that is mailed annually to all beneficiaries.

House Bill

No provision.

Senate Bill

The Secretary would be required to provide information on advance directives in the Medicare & You handbook. The information would be required to be presented in a separate Senate section on advance directives and would include specific information about living wills and durable power of attorney for health care. The Secretary would further be required to note the inclusion of this information in the introductory letter that accompanies the handbook. The provision would be effective upon enactment.

Conference Agreement

No provision.

Sense of the Senate Regarding Implementation of the Prescription Drug and Medicare Improvement Act of 2003. (Section 617 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision expresses a sense of the Senate that the Committee on Finance should hold at least four hearings to monitor implementation of the Prescription Drug and Medicare Improvement Act of 2003. The first hearing should be held within 60 days after enactment of the Act, the remaining hearings should be held May 2004, October 2004, and May 2005. The provision would be effective upon enactment.

Conference Agreement

No provision.

Extension of Municipal Health Service Demonstration Projects. (Section 618 of the Senate Bill)

Present Law

Under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, the Municipal Health Service Demonstration projects will expire on December 31, 2004. The municipal health services demonstration program is a multi-site demonstration intended to improve access to primary care services in underserved urban areas and to reduce the cost of health care. BBA 1997 authorized the Secretary to extend the project through December 31, 2000, but only with respect to persons who had received at least one service for the period of January 1, 1996-August 7, 1997 (the enactment date of BBA 97). Sites who wanted the

demonstration project extended were required to submit plans for the orderly transition of participants to a non-demonstration health care delivery system. Subsequent legislation extended the project through December 31, 2004.

House Bill

No provision.

Senate Bill

This provision would extend these demonstration projects to December 31, 2009, for individuals who reside in the city in which the project is operated. The provision would be effective upon enactment.

Conference Agreement

No provision.

Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually Impaired Individuals. (Section 619 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to study how to make prescription drug information, including drug labels and usage instructions, accessible to blind and visually impaired individuals. The study would be required to include a review of existing and emerging technologies. A report would be required within 18 months of enactment and would include recommendations for implementing usable formats and an estimate of the associated costs. The provision would be effective upon enactment.

Conference Agreement

No provision.

GAO Study of Pharmaceutical Price Controls and Patient Protections in the G-7 Countries. (Section 621/Duplicative Provision 634 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The GAO would be required to study price controls on pharmaceuticals in France, Germany, Italy, Japan, the United Kingdom, and Canada to review the impact they have on consumers, including American consumers, and on innovation in medicine. The provision would be effective upon enactment.

Conference Agreement

No provision.

Safety Net Organizations and Patient Advisory Commission. (Section 624/Duplicative Provision 635 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would establish the Safety Net Organizations and Patient Advisory Commission that would conduct an ongoing review of the health care safety net programs including Medicaid, the State Children's Health Insurance Program (SCHIP), Maternal and Child Health Services Block Grant Programs, Federally qualified health center (FQHC) programs, rural health clinic (RHC) programs, disproportionate share hospital (DSH) payment programs, and the Emergency Medical Treatment and Active Labor Act (EMTALA). The Commission would review a variety of issues and data related to the safety net programs.

The Commission would be required to submit annual reports to the appropriate committees of Congress on the health care needs of the uninsured and the financial and infrastructure stability of the Nation's core health care safety net. The first report would be due June, 2005. Additional reports could be made if requested by the chairpersons or ranking minority members of appropriate committees of Congress or if the Commission deems such additional reviews and reports appropriate.

The Commission would have 13 members appointed by the Comptroller General of the United States in consultation with the appropriate committees of Congress. Members would be drawn from health professionals, employers, third-party payers, researchers, recipients of care from core health care safety net and individuals who provide and manage the delivery of care by the core health care safety net. The term of the members would be 3 years, although the initial appointments would be on a staggered basis. The Comptroller General would be required to establish a system for public disclosure of financial and other potential conflicts of interest by members of the Commission. The Commission could hire an executive director and other

personnel without regard to the provisions of Title V of the United States Code. The Comptroller General would be required to appoint the initial members of the Commission by June 1, 2004.

Conference Agreement

No provision.

Committee on Drug Compounding. (Section 626 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a committee on drug compounding within the Food and Drug Administration to ensure that patients are receiving necessary, safe, and accurate dosages of compounded drugs. The members of the committee would be appointed by the Secretary and would include representatives from the National Association of Boards of Pharmacy; pharmacy groups; physician groups; consumer and patient advocate groups; the United States Pharmacopoeia; and other individuals determined appropriate by the Secretary. The Committee would be required to submit a report with recommendations of the Committee to improve and protect patient safety within 1 year of enactment. The Committee would terminate 1 year after enactment.

Conference Agreement

No provision.

Sense of the Senate Concerning the Structure of Medicare Reform and the Prescription Drug Benefit. (Section 627 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision provides a sense of the Senate that Medicare reform legislation should achieve certain principles.

Conference Agreement

No provision.

Sense of the Senate Regarding the Establishment of a Nationwide Permanent Lifestyle Modification Program for Medicare Beneficiaries. (Section 628 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision provides a sense of the Senate that coronary disease is expensive, the Medicare Lifestyle Modification Program has been operating in 12 states as a demonstration program, and such program of behavior modification should be conducted on a national basis for those beneficiaries who elect to participate. The provision would be effective upon enactment.

Conference Agreement

No provision.

TITLE XI -- Access to Affordable Pharmaceuticals

Current Law

Section 804 of the Federal Food, Drug, and Cosmetic Act – Importation of Covered Products – was established under the medicine Equity and Drug Safety Act of 2000 (P.L. 106-387). This section of current law has not been implemented.

House Bill

Section 1121(a) of H.R. 1 would replace the existing Section 804 entirely. The House bill directs the Secretary to establish, upon certification of safety and cost savings, a program that would allow for the importation of drugs from Canada by pharmacists, wholesalers, and individuals. The House bill incorporates new safety measures such as: (1) the use of tamper-resistant and counterfeit-proof packaging; (2) a new requirement that drugs must contain a statement informing the consumer that the drug has left the country; (3) any drug may only be shipped back to the country by the first Canadian recipient; (4) new authority to the Secretary of HHS to limit importation to certain ports of entry; (5) the importer would be required to keep detailed records and to conduct drug testing; and (6) a manufacturer must provide the importer with approved labeling of the drug. This provision applies to prescription drugs as subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug that the Secretary determines poses a threat to the public health.

Senate Bill

Section 801(a) of S. 1 would replace the existing Section 804 entirely. The Senate bill directs the Secretary to establish, upon certification of safety and cost savings, a program that would allow for the importation of drugs from Canada by pharmacists, wholesalers, and individuals. The Senate bill incorporates new safety provisions as well as provides new authority to the Secretary of HHS to suspend the program if public safety is compromised. Specifically, between 12 and 18 months after the regulations are implemented, if the Secretary certifies to Congress that, based on substantial evidence, the benefits of the implementation of the importation program do not outweigh any detriment, drug imports under this section would cease 30 days after the certification is submitted. However, the certification may not be submitted unless, after a public hearing, the Secretary finds it is more likely than not that implementation will result in an increased risk to the public health. This provision applies to prescription drugs as subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, or a drug that is inhaled during surgery that the Secretary determines poses a threat to the public health.

Conference Agreement

The Conference agreement, virtually identical to Section 801(a) of S. 1, gives the Secretary, upon certification of safety and cost savings, authority to create a system for the importation of drugs from Canada by pharmacists, wholesalers, and individuals.

The agreement directs the Secretary of HHS, in consultation with appropriate government agencies, to conduct a comprehensive study that identifies current problems with the implementation of existing law as well as examines a range of issues associated with the importation of drugs. In conducting the study, the Secretary shall take into account the distinctions between—

drugs that are biological products with licenses under section 351 of the Public Health Service Act; and
drugs with approved applications under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act.

The details of the study shall include the following:

Identification of the limitations, including limitations in resources and, if applicable, in current law authorities that may inhibit the Secretary's ability to certify the safety of pharmaceutical products imported into the US.

Assessment of the pharmaceutical distribution chain and the need for, and feasibility of, modifications, in order to assure the safety of products that may be imported into the US.

Analysis of whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that could be imported from foreign nations. This analysis shall identify the types of technologies, if available, and assess the limitations of these technologies to the distribution chain.

Estimate of costs borne by entities within the pharmaceutical distribution chain to utilize any new technologies identified in paragraph (3).

Assess the scope, volume, and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment. This assessment should include the percentage of drugs commercially available in other countries that conform in all respects to FDA requirements, and the limitations of visual inspection, sampling, and other testing methods to determine its quality.

The extent to which foreign health agencies are willing and/or able to ensure the safety of drugs being exported from their country into the United States, including drugs that are transshipped through their countries.

Assessment of the potential short and long-term impacts on drug prices and prices for consumers and other system costs associated with importation of pharmaceuticals from Canada and other countries into the U.S.

Assessment of the impact on the research and development of drugs--and the associated impact on consumers and patients--if importation were permitted.

Estimation of agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceutical products entering into the country. This estimate shall detail the number of field personnel needed in order to appropriately secure all ports of entry on a daily basis.

Identification of liability protections, if any, that should be in place, if importation is permitted, for entities within the pharmaceutical distribution chain.

Identify the ways in which importation could violate United States and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to assure the effective enforcement of these rights.

The Conference agreement directs the Secretary to submit a report providing the findings of the study under this section to the appropriate committees of Congress no later than 12 months after the date of enactment of this Act.

Report on Trade in Pharmaceuticals.

The Conference agreement directs the Secretary of Commerce, in consultation with the International Trade Commission, the Secretary of Health and Human Services and the United States Trade Representative, to conduct a study and report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development and whether those practices utilize nontariff barriers with respect to trade in pharmaceuticals. The study shall include an analysis of the use of price controls, reference pricing, and other actions that affect the market access of United States pharmaceutical products.

The study shall include the following:

Identification of the countries that use price controls or other such practices with respect to pharmaceutical trade.

Assessment of the price controls and other such practices used by the countries identified.

Estimate of additional costs to U.S. consumers because of such price controls and other such practices, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices are reduced or eliminated.

Estimate of the impact such price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and research and development in the United States and each country identified.

Not later than 9 months after the date of enactment of this Act, the report shall be submitted to the Committees on Finance, the Judiciary, and Health, Education, Labor, and Pensions of the Senate, and the Committees on Ways and Means, the Judiciary, and Energy and Commerce of the House of Representatives.

In addition, the United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services shall analyze whether bilateral or multilateral trade or other negotiations present an opportunity to address these price controls and other such practices and shall develop a strategy to address such issues in appropriate negotiations. In so doing, these agencies shall bear in mind the negotiating objective set forth in the Bipartisan Trade Promotion Authority Act of 2002 to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address

negotiations to establish a U.S.-Australia Free Trade Agreement and, as appropriate, other current negotiations.

Provisions Related to Hatch-Waxman Law

Amendments and Supplements

In including this provision, Congress does not intend this provision to alter current U.S. Food and Drug Administration's ("FDA") practice regarding acceptance of supplements to approved new drug applications ("NDAs"), or amendments and supplements to pending and approved abbreviated new drug applications ("ANDAs"). Instead, Congress intends this provision to reflect the FDA's current practice regarding those changes and variations to both innovator and generic drugs that may be approved under amendments and supplements to previously filed NDAs and ANDAs, and expects the Agency to maintain its current policy in designating "listed drugs." The conferees intend that FDA continue to use its existing scientific discretion to determine whether different polymorphs present safety, effectiveness, or bioavailability differences and therefore should be considered the same or different active ingredients.

The single 30-month stay provisions are a centerpiece of this legislation, allowing lower-priced generic products to enter the market more quickly. As a result, this provision must not be construed as requiring an ANDA applicant to file a new application where, before its enactment, the applicant would have been allowed to file an amendment or supplement to an existing application. Such a construction would run directly contrary to Congress' intent.

Declaratory Judgments

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., Fina Oil and Chemical Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002). In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

<u>Counterclaims</u>

Section 1101 of the Conference agreement prohibits the recovery of damages resulting from a successful counterclaim in a paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book. It is not the intent of Congress to prohibit the recovery by a counterclaimant in a paragraph IV suit of anti-trust or any other damages as a result of the improper listing of a patent in the Orange Book. The language found in this section simply

means that in the absence of any other cause of action, a ruling in favor of the counterclaimant resulting in the removal of the patent does not entitle the counterclaimant to recover damages.

TITLE XII. HEALTH SAVINGS INCENTIVES

Health Savings Accounts and Health Savings Security Accounts (sec. 1202 of the House bill and new sec. 223 of the Code)

Present Law

Overview

Present law contains a number of provisions dealing with the Federal tax treatment of health expenses and health insurance coverage.

Employer-provided health coverage

In general, employer contributions to an accident or health plan are excludable from an employee's gross income (and wages for employment tax purposes).[1] This exclusion generally applies to coverage provided to employees (including former employees) and their spouses, dependents, and survivors. Benefits paid under employer-provided accident or health plans are also generally excludable from income to the extent they are reimbursements for medical care.[2] If certain requirements are satisfied, employer-provided accident or health coverage offered under a cafeteria plan is also excludable from an employee's gross income and wages.[3] Present law provides for two general employer-provided arrangements that can be used to pay for or reimburse medical expenses of employees on a tax-favored basis: flexible spending arrangements ("FSAs") and health reimbursement arrangements ("HRAs"). While these arrangements provide similar tax benefits (i.e., the amounts paid under the arrangements for medical care are excludable from gross income and wages for employment tax purposes), they are subject to different rules. A main distinguishing feature between the two arrangements is that while FSAs are generally part of a cafeteria plan and contributions to FSAs are made on a salary reduction basis, HRAs cannot be part of a cafeteria plan and contributions cannot be made on a salary-reduction basis.[4]

Amounts paid or accrued by an employer within a taxable year for a sickness, accident, hospitalization, medical expense, or similar health plan for its employees are generally deductible as ordinary and necessary business expenses.[5]

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[1] Secs. 106, 3121(a)(2), and 3306(b)(2). All "section," "sec.," and "Code" references are to the Internal Revenue Code of 1986, as amended.

[2] Sec. 105. In the case of a self-insured medical reimbursement arrangement, the exclusion applies to highly compensated employees only if certain nondiscrimination rules are satisfied. Sec. 105(h). Medical care is defined as under section 213(d) and generally includes amounts paid for qualified long-term care insurance and services.

[3] Secs. 125, 3121(a)(5)(G), and 3306(b)(5)(G). Long-term care insurance and services may not be provided through a cafeteria plan.

[4] Notice 2002-45, 2002-28 I.R.B. 93 (July 15, 2002); Rev. Rul. 2002-41, 2002-28 I.R.B. 75 (July 15, 2002).

[5] Sec. 162.

Self-employed individuals

The exclusion for employer-provided health coverage does not apply to self-employed individuals. However, under present law, self-employed individuals (i.e., sole proprietors or partners in a partnership)[6] are entitled to deduct 100 percent of the amount paid for health insurance for themselves and their spouse and dependents.[7]

Itemized deduction for medical expenses

Under present law, individuals who itemize deductions may deduct amounts paid during the taxable year (to the extent not reimbursed by insurance or otherwise) for medical care of the taxpayer, the taxpayer's spouse, and dependents, to the extent that the total of such expenses exceeds 7.5 percent of the taxpayer's adjusted gross income.[8]

Archer medical savings accounts

In general

In general, an Archer medical savings account ("MSA") is a tax-exempt trust or custodial account created exclusively for the benefit of the account holder that is subject to rules similar to those applicable to individual retirement arrangements.[9]

Within limits, contributions to an Archer MSA are deductible in determining adjusted gross income if made by an eligible individual and are excludable from gross income and wages for employment tax purposes if made by the employer of an eligible individual. Earnings on amounts in an Archer MSA are not includible in gross income in the year earned (i.e., inside buildup is not taxable). Distributions from an Archer MSA for qualified medical expenses are not includible in gross income. Distributions not used for qualified medical expenses are includible in gross income and subject to an additional 15-percent tax unless the distribution is made after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

Qualified medical expenses are generally defined as under section 213(d), except that qualified medical expenses do not include expenses for health insurance other than long-term care insurance, premiums for health coverage during any period of continuation coverage required by Federal law, and premiums for health care coverage while an individual is receiving unemployment compensation under Federal or State law. For purposes of determining the

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[6] Self-employed individuals include more than two-percent shareholders of S corporations who are treated as partners for purposes of fringe benefit rules pursuant to section 1372.

[7] Sec. 162(l).

[8] Sec. 213. The adjusted gross income percentage is 10 percent for purposes of the alternative minimum tax. Sec. 56(b)(1)(B).

[9] Sec. 220.

itemized deduction for medical expenses, distributions from an Archer MSA for qualified medical expenses are not treated as expenses paid for medical care under section 213.

Eligible individuals

Archer MSAs are available only to employees of a small employer who are covered under an employer-sponsored high deductible health plan and to self-employed individuals covered under a high deductible health plan.[10] An employer is a small employer if it employed, on average, no more than 50 employees on business days during either of the two preceding calendar years. An individual is not eligible for an Archer MSA if he or she is covered under any other health plan that is not a high deductible health plan (other than a plan providing certain limited types of coverage). Individuals entitled to benefits under Medicare are not eligible individuals. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

Treatment of contributions

Individual contributions to an Archer MSA are deductible (within limits) in determining adjusted gross income (i.e., "above-the-line"). In addition, employer contributions are excludable from gross income and wages for employment tax purposes (within the same limits), except that this exclusion does not apply to contributions made through a cafeteria plan. In the case of an employee, contributions can be made to an Archer MSA either by the individual or by the individual's employer, but not by both.

The maximum annual contribution that can be made to an Archer MSA for a year is 65 percent of the annual deductible under the high deductible health plan in the case of self-only coverage and 75 percent of the annual deductible in the case of family coverage.

If an employer provides a high deductible health plan coupled with Archer MSAs for employees and makes employer contributions to the Archer MSAs, the employer must make available a comparable contribution on behalf of all employees with comparable coverage during the same period. Contributions are considered comparable if they are either of the same amount or the same percentage of the deductible under the high deductible health plan. If employer contributions do not satisfy the comparability rule during a period, then the employer is subject to an excise tax equal to 35 percent of the aggregate amount contributed by the employer to Archer MSAs of the employer for that period.

Definition of high deductible health plan

A high deductible health plan is a health plan with an annual deductible of at least $1,700 and no more than $2,500 in the case of self-only coverage and at least $3,350 and no more than $5,050 in the case of family coverage. In addition, the maximum out-of-pocket expenses with respect to allowed costs must be no more than $3,350 in the case of self-only coverage and no

[10] Self-employed individuals include more than two-percent shareholders of S corporations who are treated as partners for purposes of fringe benefit rules pursuant to section 1372.

more than $6,150 in the case of family coverage.[11] Out-of-pocket expenses include deductibles, co-payments, and other amounts (other than premiums) that the individual must pay for covered benefits under the plan. A plan does not fail to qualify as a high deductible health plan merely because it does not have a deductible for preventive care as required under State law. A plan does not qualify as a high deductible health plan if substantially all of the coverage under the plan is certain permitted insurance or is coverage (whether provided through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

Treatment of death of account holder

Upon death, any balance remaining in the decedent's Archer MSA is includible in his or her gross estate. If the account holder's surviving spouse is the named beneficiary of the Archer MSA, then, after the death of the account holder, the Archer MSA becomes the Archer MSA of the surviving spouse and the amount of the Archer MSA balance may be deducted in computing the decedent's taxable estate, pursuant to the estate tax marital deduction.[12] If, upon the account holder's death, the Archer MSA passes to a named beneficiary other than the decedent's surviving spouse, the Archer MSA ceases to be an Archer MSA as of the date of the decedent's death, and the beneficiary is required to include the fair market value of the Archer MSA assets as of the date of death in gross income for the taxable year that includes the date of death. The amount includible in gross income is reduced by the amount in the Archer MSA used, within one year after death, to pay qualified medical expenses incurred prior to the death. If there is no named beneficiary for the decedent's Archer MSA, the Archer MSA ceases to be an Archer MSA as of the date of death, and the fair market value of the assets in the Archer MSA as of such date is includible in the decedent's gross income for the year of the death.

Limit on number of MSAs; termination of MSA availability

The number of taxpayers benefiting annually from an Archer MSA contribution is limited to a threshold level (generally 750,000 taxpayers). The number of Archer MSAs established has not exceeded the threshold level.

After 2003, no new contributions can be made to Archer MSAs except by or on behalf of individuals who previously had Archer MSA contributions and employees who are employed by a participating employer.

House Bill

In general

The House bill creates health savings accounts ("HSAs") and health savings security accounts ("HSSAs"), which provide tax-favored treatment for current medical expenses as well as the ability to save on a tax-favored basis for future medical expenses. In general, HSAs and HSSAs are tax-exempt trusts or custodial accounts created exclusively to pay for the qualified

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[11] The deductible and out-of-pocket expenses dollar amounts are for 2003. These amounts are indexed for inflation in $50 increments.

[12] Sec. 2056.

medical expenses of the account holder and his or her spouse and dependents that are subject to rules similar to those applicable to individual retirement arrangements.[13] Unless otherwise provided, the following description applies to both HSAs and HSSAs (jointly referred to as "health accounts").

Within limits, contributions to health accounts are deductible if made by an eligible individual and are excludable from gross income and wages for employment tax purposes if made by the employer of an eligible individual. In the case of HSSAs only, family members may make nondeductible contributions on behalf of an eligible individual. Distributions from health accounts for qualified medical expenses are not includible in gross income. Distributions that are not for qualified medical expenses are includible in gross income and subject to an additional 15 percent tax. The additional 15 percent tax does not apply after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

Eligible individuals

HSAs

Eligible individuals for HSAs are individuals who are covered by a high deductible health plan and no other health plan that is not a high deductible health plan. Individuals entitled to benefits under Medicare are not eligible to make contributions to an HSA. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

An individual with other coverage in addition to a high deductible health plan is still eligible for an HSA if such other coverage is certain permitted insurance or permitted coverage. Permitted insurance is: (1) insurance if substantially all of the coverage provided under such insurance relates to (a) liabilities incurred under worker's compensation law, (b) tort liabilities, (c) liabilities relating to ownership or use of property (e.g., auto insurance), or (d) such other similar liabilities as the Secretary may prescribe by regulations; (2) insurance for a specified disease or illness; and (3) insurance that provides a fixed payment for hospitalization. Permitted coverage is coverage (whether provided through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

A high deductible health plan is a health plan that in the case of self-only coverage has an annual deductible between $1,000 and $2,500 and in the case of family coverage has an annual deductible between $2,000 and $5,050 (for 2003).[14] The maximum out-of-pocket expenses must be no more than $3,350 in the case of self-only coverage and no more than $6,150 in the case of family coverage. The annual deductible maximum and minimum and out-of-pocket expense amounts are indexed for inflation. A plan is not a high deductible health plan if substantially all of the coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above.

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[13] As under Archer MSAs, the House bill provision provides that the present-law requirement applicable to insurance companies that certain policy acquisition expenses must be capitalized and amortized (sec. 848) does not apply in the case of any contract that is a health account.

[14] Special rules apply for determining whether a health plan that is a preferred provider organization plan meets the requirements of a high deductible plan.

HSSAs

Individuals eligible for HSSAs are individuals who (1) are covered under a health plan meeting minimum deductible requirements and no other health plan that does not meet the minimum deductible requirements, or (2) are uninsured. Individuals entitled to benefits under Medicare are not eligible to make contributions to an HSSA. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

An individual with other coverage in addition to a plan meeting the minimum deductible requirements is still eligible for an HSSA if such other coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above. In addition, an individual is treated as uninsured if his or her only coverage is permitted coverage or coverage that may be provided by permitted insurance.

A plan meets the minimum deductible requirements if the plan is a health plan with an annual deductible of at least $500 in the case of self-only coverage and at least $1,000 in the case of family coverage. These dollar amounts are indexed for inflation. There are no maximum deductible requirements and no limits on out-of-pocket expenses. A plan is not a minimum deductible plan if substantially all of the coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above.

Tax treatment of and limits on contributions

Contributions to a health account made by an eligible individual are deductible (within limits) in determining adjusted gross income (i.e., "above-the-line"). In addition, employer contributions to a health account (including salary reduction contributions made through a cafeteria plan) are excludable from gross income and wages for employment tax purposes to the extent the contribution would be deductible if made by the employee (e.g., in the case of an HSSA, subject to the adjusted gross income limits).[15] Nondeductible contributions may be made to an HSSA by a family member of an eligible individual. In the case of an employee, contributions to a health account may be made by both the individual (and family members in the case of an HSSA) and the individual's employer. All contributions are aggregated for purposes of the maximum annual contribution limit.

The maximum aggregate annual contribution that can be made to an HSA is 100 percent of the annual deductible under the high deductible plan.[16]

The maximum aggregate annual contribution that can be made to an HSSA is (1) $2,000 for (a) persons with self-only coverage and (b) uninsured individuals with no dependents[17] who

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[15] Employer contributions to a health account are excludable from wages for employment tax purposes if, at the time of payment, it is reasonable to believe that the employee will be able to exclude such payment from income (e.g., a reasonable basis to believe that the employee's income is within the applicable adjusted gross income limits for an HSSA).

[16] The annual contribution limit for a health account is the sum of the limits determined separately for each month, based on the individual's status and health plan coverage as of the first day of the month.

do not file a joint return, and (2) $4,000 for (a) individuals with family coverage and (b) uninsured individuals with dependents or who file a joint return. In the case of individuals age 55 and older, the $2,000 and $4,000 HSSA annual contribution limits are increased by $500 in 2004, $600 in 2005, $700 in 2006, $800 in 2007, $900 in 2008, and $1,000 in 2009 and thereafter.

The maximum allowable contribution to an HSSA is phased out for taxpayers with adjusted gross income[18] above certain levels. In the case of individuals with self-only coverage (other than individuals filing a joint return), the phase-out range is $75,000 to $85,000. For individuals with family coverage and individuals filing a joint return, the phase-out range is $150,000 to $170,000. The adjusted gross income limits apply to HSSA contributions from all sources (e.g., both individual and employer contributions).

The maximum annual contribution limits for the health accounts are coordinated so that contributions to one type of health account reduce the annual contribution limit for the other type of health account.[19]

An excise tax applies to contributions in excess of the maximum contribution amount for the health account. The excise tax is generally equal to six percent of the cumulative amount of excess contributions that are not distributed from the health account to the contributor.[20]

Amounts can be rolled over into a health account from an Archer MSA or a health FSA on a tax-free basis. Amounts can be rolled over into an HSA from another HSA or HSSA and into an HSSA from another HSSA on a tax-free basis. Rollovers from an HSA into an HSSA are not permitted. Amounts transferred from another health account or Archer MSA are not taken into account under the annual contribution limits.

If an employer makes contributions to employees' health accounts, the employer must make available comparable contributions on behalf of all employees with comparable coverage during the same period. Contributions are considered comparable if they are either of the same amount or the same percentage of the deductible under the plan. The comparability rule is applied separately to part-time employees (i.e., employees who are customarily employed for fewer than 30 hours per week). The comparability rule does not apply to amounts transferred from an employee's health account, health FSA, or Archer MSA or to contributions made through a cafeteria plan.

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[17] Written declarations releasing a claim to a dependency exemption under section 152(e)(2) are disregarded in determining whether an individual has dependents.

[18] Adjusted gross income is defined generally as under the rules relating to individual retirement arrangements ("IRAs"), and is computed after the deduction for contributions to IRAs and before the deductions provided by the provision.

[19] The contribution limits are also coordinated with contributions to Archer MSAs.

[20] Ordering rules apply to determine the nature of any distributed excess contributions (e.g., nondeductible family contributions in the case of an HSSA or employer contributions).

If employer contributions do not satisfy the comparability rule during a period, then the employer is subject to an excise tax equal to 35 percent of the aggregate amount contributed by the employer to health accounts of the employer for that period. The excise tax is designed as a proxy for the denial of the deduction for employer contributions. In the case of a failure to comply with the comparability rule which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed to the extent that the payment of the tax would be excessive relative to the failure involved. For purposes of the comparability rule, employers under common control are aggregated.

Taxation of distributions

Distributions from a health account for qualified medical expenses of the individual and his or her spouse or dependents generally are excludable from gross income. In general, amounts in a health account can be used for qualified medical expenses even if the individual is not currently eligible for contributions to the health account.[21]

Qualified medical expenses generally are defined as under section 213(d) and include expenses for diagnosis, cure, mitigation, treatment, or prevention of disease, including prescription drugs, transportation primarily for and essential to such care, and qualified long-term care expenses. Qualified medical expenses do not include expenses for insurance other than for (1) long-term care insurance, (2) premiums for health coverage during any period of continuation coverage required by Federal law, and (3) premiums for health care coverage while an individual is receiving unemployment compensation under Federal or State law. In the case of HSSAs, qualified medical expenses also include (1) health insurance meeting the minimum deductible requirements if no portion of the cost of the insurance is paid by the employer or former employer of the individual or the individual's spouse,[22] and (2) health insurance for individuals who are older than age 65 (including Medicare expenses). For purposes of determining the itemized deduction for medical expenses, distributions from a health account for qualified medical expenses are not treated as expenses paid for medical care under section 213.

Distributions from a health account that are not for qualified medical expenses are includible in gross income (except to the extent that the distribution is attributable to a return of nondeductible family contributions in the case of an HSSA).[23] Distributions includible in gross income are also subject to an additional 15-percent tax unless made after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

Tax treatment of HSAs and HSSAs after death.

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[21] However, in any year for which a contribution is made to an HSA, withdrawals from the HSA maintained by that individual generally are excludable from income only if the individual for whom the expenses were incurred was covered under a high deductible plan for the month in which the expenses were incurred. The rule does not apply for continuation coverage or coverage while the individual is receiving unemployment compensation even if for an individual who is not an eligible individual.

[22] Amounts paid by the employer include salary reduction contributions.

[23] Ordering rules apply to determine the extent to which distributions are attributable to nondeductible contributions.

Upon death, any balance remaining in the decedent's health account is includible in his or her gross estate.

If the health account holder's surviving spouse is the named beneficiary of the health account, then, after the death of the health account holder, the health account becomes the health account of the surviving spouse and the amount of the health account balance may be deducted in computing the decedent's taxable estate, pursuant to the estate tax marital deduction.[24] The surviving spouse is not required to include any amount in gross income as a result of the death; the general rules applicable to the health account apply to the surviving spouse's health account (e.g., the surviving spouse is subject to income tax only on distributions from the health account for nonqualified expenses). The surviving spouse can exclude from gross income amounts withdrawn from the health account for expenses incurred by the decedent prior to death, to the extent they otherwise are qualified medical expenses.

If, upon death, the health account passes to a named beneficiary other than the decedent's surviving spouse, the health account ceases to be a health account as of the date of the decedent's death, and the beneficiary is required to include the fair market value of health account assets as of the date of death in gross income for the taxable year that includes the date of death. The amount includible in income is reduced by the amount in the health account used, within one year after death, to pay qualified medical expenses incurred by the decedent prior to the death. As is the case with other health account distributions, whether the expenses are qualified medical expenses is determined as of the time the expenses were incurred. In computing taxable income, the beneficiary may claim a deduction for that portion of the Federal estate tax on the decedent's estate that was attributable to the amount of the health account balance.[25]

If there is no named beneficiary of the decedent's health account, the health account ceases to be a health account as of the date of death, and the fair market value of the assets in the health account as of such date is includible in the decedent's gross income for the year of the death.

This rule applies in all cases in which there is no named beneficiary, even if the surviving spouse ultimately obtains the right to the health account assets (e.g., if the surviving spouse is the sole beneficiary of the decedent's estate).

Reporting requirements

Employer contributions are required to be reported on the employee's Form W-2. Trustees of health accounts may be required to report to the Secretary of the Treasury amounts with respect to contributions, distributions, and other matters as determined appropriate by the Secretary. In addition, providers of health insurance are required to report information as may be prescribed by the Secretary.

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[24] Sec. 2056.

[25] The deduction is calculated in accordance with the present-law rules relating to income in respect of a decedent set forth in section 691(c).

Effective date.--The House bill provision is effective for taxable years beginning after December 31, 2003.

Senate Amendment

No provision.

Conference Agreement

The conference agreement does not include the House bill provision relating to HSSAs. The conference agreement includes the HSA provision from the House bill, with the following modifications.[26]

The conference agreement modifies the definition of a high deductible health plan applicable to HSAs by removing the limitation on the maximum amount of the deductible and increasing the limit on out-of-pocket expenses. Under the conference agreement, a high deductible health plan is a health plan that has a deductible that is at least $1,000 for self-only coverage or $2,000 for family coverage[27] and that has an out-of-pocket expense limit that is no more than $5,000 in the case of self-only coverage and $10,000 in the case of family coverage.[28] As under present law, out-of-pocket expenses include deductibles, co-payments, and other amounts (other than premiums) that the individual must pay for covered benefits under the plan.

Under the conference agreement, the maximum aggregate annual contribution[29] that can be made to an HSA is the lesser of (1) 100 percent of the annual deductible under the high deductible health plan, or (2) the maximum deductible permitted under an Archer MSA high deductible health plan under present law, as adjusted for inflation. For 2004, the amount of the maximum high deductible is estimated to be $2,600 in the case of self-only coverage and $5,150 in the case of family coverage.

Under the conference agreement, contributions made by or on behalf of an eligible individual are deductible by the individual. Thus, for example, contributions made by an eligible individual's family members are deductible by the eligible individual to the extent the

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[26] The rules for HSAs generally follow those of Archer MSAs unless otherwise provided.

[27] The $1,000 limit is indexed for inflation. The family coverage limit will always be twice the individual limit (as indexed for inflation).

[28] In the case of the plan using a network of providers, the plan does not fail to be a high deductible health plan (if it would otherwise meet the requirements of a high deductible health plan) solely because the out-of-pocket expense limit for services provided outside of the network exceeds the $5,000 and $10,000 out-of-pocket expense limits. In addition, such plan's deductible for out-of-network services is not taken into account in determining the annual contribution limit (i.e., the deductible for services within the network is used for such purpose).

[29] The maximum annual contribution limit is calculated as the sum of limits determined for each month based on the individual's health plan coverage on the first day of the month.

contributions would be deductible if made by the individual.[30] As under the House bill, all contributions by or on behalf of an eligible individual are aggregated for purposes of the maximum annual contribution limit. Contributions to Archer MSAs reduce the annual contribution limit for HSAs.

The conference agreement increases the annual contribution limits for individuals who have attained age 55 by the end of the taxable year. In the case of policyholders and covered spouses who are age 55 or older, the HSA annual contribution limit is greater than the otherwise applicable limit by $500 in 2004, $600 in 2005, $700 in 2006, $800 in 2007, $900 in 2008, and $1,000 in 2009 and thereafter.[31] As under the House bill, contributions, including catch-up contributions, cannot be made once an individual is eligible for Medicare.

Under the conference agreement, qualified medical expenses are expanded to include health insurance premiums for individuals eligible for Medicare, other than premiums for Medigap policies. Qualified health insurance premiums include, for example, Medicare Part A and Part B premiums, Medicare HMO premiums, and the employee share of premiums for employer-sponsored health insurance including employer-sponsored retiree health insurance.

Except as otherwise provide by the Secretary, preventative care is defined as under section 1871 of the Social Security Act. It is intended that the Secretary of the Treasury will amend the definition of preventative care if the definition used under the Social Security Act is inconsistent with the purposes of the provision.

Under the conference agreement, the additional tax on nonqualified distributions is reduced to 10 percent (rather than 15 percent as in the House bill).

Under the conference agreement, amounts can be rolled over into an HSA from another HSA or from an Archer MSA.

The conference agreement also clarifies information reporting requirements in the House bill.

Effective date.--The provision is effective for taxable years beginning after December 31, 2003.

Disposition of Unused Health Benefits in Flexible Spending Arrangements (sec. 1203 of the House bill and sec. 125 of the Code)

Present Law

A flexible spending arrangement ("FSA") is defined under the Code as a benefit program which provides employees with coverage under which specified incurred expenses may be reimbursed and the maximum amount of reimbursement which is reasonably available to a participant for such coverage is less than 500 percent of the value of such coverage.[32] A health

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[30] Under present law, contributions made on behalf of another individual are generally treated as gifts. The present-law gift tax rules apply to contributions made on behalf of another individual.

[31] As in determining the general annual contribution limit, the increase in the annual contribution limit for individuals who have attained age 55 is also determined on a monthly basis.

[32] Sec. 106(c).

FSA is an FSA that provides for reimbursement of medical expenses.[33] Health FSAs are typically part of a cafeteria plan and may be funded through salary reduction.[34] Health FSAs are commonly used, for example, to reimburse employees for medical expenses not covered by insurance. There is no special exclusion for benefits provided under an FSA. Thus, health benefits provided under an FSA are excludable from income only if they qualify for exclusion under sections 105 or 106.

FSAs that are part of a cafeteria plan must comply with the rules applicable to cafeteria plans generally. One of these rules is that a cafeteria plan may not offer deferred compensation except through a qualified cash or deferred arrangement.[35] Under proposed Treasury regulations, a cafeteria plan is considered to permit the deferral of compensation if it includes a health FSA which reimburses participants for medical expenses incurred beyond the end of the plan year.[36] Thus, amounts in an employee's health account that are not used for medical expenses incurred before the end of a plan year must be forfeited. This rule is often referred to as the "use it or lose it" rule.

House Bill

The House bill allows up to $500 of unused health benefits in an employee's health FSA to be carried forward to the employee's health account for the next plan year of the health FSA or transferred to an HSA or HSSA maintained for the benefit of the employee.[37] Amounts transferred to an HSA or HSSA are treated as employer contributions for purposes of the HSA and HSSA rules. Under the House bill, if an individual is not eligible to contribute to an HSA or HSSA for the taxable year, the individual may transfer up to $500 of unused health benefits in the employee's health FSA to a tax-qualified retirement plan, a tax-sheltered annuity (section 403(b)), an individual retirement arrangement ("IRA"), or an eligible deferred compensation plan of a State or local government (section 457). An employee's unused health benefit is the excess of the maximum amount of reimbursement allowable to the employee over the actual amount of reimbursement made during the year. Amounts transferred are subject to the rules and limits on contributions that would otherwise apply to contributions to the transferee plan.

Effective date.--The House bill provision applies to taxable years beginning after December 31, 2003.

Senate Amendment

No provision.

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[33] FSAs may also be used to provide certain other nontaxable benefits, such as dependent care.

[34] Long-term care insurance cannot be offered through a cafeteria plan. Sec. 125(f).

[35] Sec. 401(k).

[36] Prop. Treas. Reg. sec. 1.125-2 Q&A-5(a).

[37] Section 2 of the bill provides the eligibility rules for contributions to an HSA or HSSA.

Conference Agreement

The conference agreement does not include the House bill provision.

Exclusion from Gross Income of Certain Federal Subsidies for Prescription Drug Plans (new sec. 139A of the Code)

Present Law

Gross income includes all income from whatever source derived unless a specific exclusion applies.[38]

House Bill

No provision.

Senate Amendment

No provision.

Conference Agreement

The conference agreement provides that gross income does not include any special subsidy payment received under section 1860D-22 of the Social Security Act. The exclusion applies for purposes of both the regular tax and the alternative minimum tax (including the adjustment for adjusted current earnings).

The exclusion is not taken into account in determining whether a deduction is allowable with respect to costs taken into account in determining the subsidy payment. Accordingly, a taxpayer could claim a deduction for prescription drug expenses incurred even though the taxpayer also received an excludible subsidy related to the same expenses.

Effective date.--The provision is effective for taxable years ending after the date of enactment.

Exception to Information Reporting Requirements for Certain Health Arrangements (sec. 1204 of the House bill and sec. 6041 of the Code)

Present Law

Any person in a trade or business who, in the course of that trade or business, makes specified payments to another person totaling $600 or more in a year, must provide an information report to the IRS (as well as a copy to the recipient) on the payments.[39] Reporting is

[38] Sec. 61.

[39] Sec. 6041.

required to be done on Form 1099. In general, these information reports remind taxpayers of amounts of income that should be reflected on their tax returns and assist the IRS in verifying that taxpayers have correctly reported these amounts.

Treasury regulations specify that fees for professional services, including the services of physicians, must be reported.[40] Treasury regulations also provide a general exception from these information reporting requirements for payments made to corporations, except that this exception is inapplicable if the corporation is "engaged in providing medical and health care services."[41] Earlier this year, the IRS issued a revenue ruling describing whether employer-provided expense reimbursements made through debit or credit cards or other electronic media are excludible from gross income.[42] The ruling states that "payments made to medical service providers through the use of debit, credit, and stored value cards are reportable by the employer on Form 1099-MISC under section 6041."[43]

House Bill

The House bill provides an exception from the generally applicable information reporting provisions for payments for medical care made under either: (1) a flexible spending arrangement,[44] or (2) a health reimbursement arrangement that is treated as employer-provided coverage.

Effective date.--The House bill provision applies to payments made after December 31, 2002.

Senate Amendment

No provision.

Conference Agreement

The conference agreement follows the House bill.

Tax Complexity Analysis

Section 4022(b) of the Internal Revenue Service Reform and Restructuring Act of 1998 (the "IRS Reform Act") requires the Joint Committee on Taxation (in consultation with the Internal Revenue Service and the Department of the Treasury) to provide a tax complexity

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[40] Treas. Reg. sec. 1.6041-1(d)(2).

[41] Treas. Reg. sec. 1.6041-3(p)(1). These regulations also provide an exception from these information reporting requirements if the payment is made to a hospital that is tax-exempt or that is owned and operated by a governmental entity.

[42] Rev. Rul. 2003-43, 2003-21 I.R.B. 935 (May 27, 2003).

[43] *Id.*

[44] This term is defined in sec. 106(c)(2).

analysis. The complexity analysis is required for all legislation reported by the Senate Committee on Finance, the House Committee on Ways and Means, or any committee of conference if the legislation includes a provision that directly or indirectly amends the Internal Revenue Code (the "Code") and has widespread applicability to individuals or small businesses.

The staff of the Joint Committee on Taxation has determined that a complexity analysis is not required under section 4022(b) of the IRS Reform Act because the bill contains no provisions that amend the Code and that have "widespread applicability" to individuals or small businesses