

MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003

Section 1. Short Title; Amendments to Social Security Act; References to BIPA and Secretary; Table of Contents

Current Law

No provision.

Explanation of Provision

The provision specifies the title of the Act and includes a table of contents.

Title I - Medicare Prescription Drug Benefit

Section 101. Establishment of a Medicare Prescription Drug Benefit

Current 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 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 pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

Explanation of Provision

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. 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, and all costs borne by the individual above \$3,700. 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), Medicare Advantage plans, or Enhanced Fee-For-Service plans (MS-EFFS). 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 for drugs. A new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS) would administer the benefit.

New Section 1860D-1. Benefits; Eligibility; Enrollment; and Coverage Period

The new Section 1860A 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 under Medicare. Medicare Advantage (MA) organizations and enhanced fee-for-service (EFFS) plans would be required to offer qualified prescription drug coverage. An individual enrolled in a MA-EFFS plan would obtain their drug coverage through the plan. An individual not enrolled in either a Medicare Advantage 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-EFFS 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-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 November 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. 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.

The provision 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-EFFS could not be denied enrollment based on health status or other factor. 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 specify that PDP sponsors and MA-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 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 ERF 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.

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 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).

New Section 1860D-2. Requirements for Qualified Prescription Drug Coverage

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% cost-sharing up to the initial coverage limit (\$2,000); then no coverage until the beneficiary had out-of-pocket costs of \$3,700. Once the beneficiary reached the catastrophic (“stop loss”) limit, full coverage would be provided. 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% cost-sharing 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 only be considered incurred if they were incurred for the deductible, cost-sharing, or benefits not paid because of application of the initial coverage 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 or under the Medicaid program. Any costs for which the individual was

reimbursed by insurance or otherwise would not count toward incurred costs.

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 for individuals and \$120,000 for couples 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 \$3,700 divided by \$60,000 equaling 6.2%. 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 \$6,180 for an enrollee with an income of \$100,000 and \$12,380 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 product 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 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: the enrollee to provide the Secretary with the relevant portion of the more recent return; verification by the Secretary of the Treasury; and 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 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 Taxpayer Identification Numbers (TIMs) of enrollees in PDPs or MA-EFFS plans and request that the Secretary of the Treasury disclose income information. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. Criminal and civil penalties would apply to any unauthorized disclosure of information.

The provision would permit a PDP or MA-EFFS 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-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-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.

Covered outpatient drugs would be defined to include: 1) a drug which may only be dispensed subject to a prescription and which is 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 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 includes 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 MS-EFFS 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.

New Section 1860D-3. Beneficiary Protections for Qualified Prescription Drug Coverage.

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 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 a detailed explanation of benefits, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors and entities offering an MA-EFFS would be required to permit the participation of any pharmacy that met the plan's terms and conditions. A PDP and an MA-EFFS 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-EFFS 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 access 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-EFFS 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 is 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.

There is no requirement to use a formulary, however, if a PDP sponsor or a MA-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 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, pharmaco-economic 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 clinical basis for the coverage of any drug on the formulary. The committee would be required to establish policies and procedures to educate and inform health care providers concerning the formulary. Any removal of a drug from the formulary 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-EFFS would be required to have, as part of its appeals process, a process for appeals of coverage denials based on application of the formulary.

Each PDP sponsor and entity offering a MA-EFFS 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.

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, for years beginning with 2007, an electronic prescription drug 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 electronic prescription drug 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) and for provision of information to the prescribing health professional. 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 be required to provide for the development of national standards relating to the electronic prescription drug program. The standards would be compatible with those established for the administrative simplification program established under title XI of the Social Security Act. The Administrator would establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, technology experts, and pharmacy benefit experts of the Departments of Veterans Affairs, Defense and other appropriate Federal agencies. The task force would provide recommendations to the Administrator on standards including recommendations relating to: 1) range of available computerized prescribing software and hardware and their costs to develop and implement; 2) extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals; 3) efforts to develop uniform standards and a common software platform for the secure electronic transmission of medication history, eligibility, benefit and prescription information; 4) efforts to develop and promote universal connectivity and interoperability for the secure exchange of information; 5) cost of implementing such systems in hospital and physician office settings and pharmacies; and 6) implementation issues as they relate to administrative simplification requirements and current Federal and state prescribing laws and regulations and their impact on implementation of computerized prescribing. The Administrator would be required to establish the task force by April 1, 2004. It would be required to submit recommendations to the Administrator by January 1, 2005. The Administrator would be required to promulgate national standards by January 1, 2006.

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 provides 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 on the enrollee.

In general, PDP plans would be required to meet the requirements for independent review of coverage denials and appeals in the same manner that such requirements apply 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 apply to MA organizations.

New Section 1860D-4. Requirements for and Contracts With Prescription Drug Plan (PDP) Sponsors

New Section 1860D-4 would specify organizational plan requirements for entities seeking to become PDP plan sponsors. In general, the section would require PDP sponsors 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 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 Administrator under which the sponsor agrees 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 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.

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 a MA plan.

The new Section would permit the Administrator 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 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.

New Section 1860D-5. Process for Beneficiaries to Select Qualified Prescription Drug Coverage.

The new Section 1860D-5 would require the Administrator to establish a process for the selection of a PDP plan or a MA-EFFS 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-EFFS 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.

The section would specify that an EFFS Rx enrollee could only elect to receive drug coverage through the plan.

The Administrator would 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 is 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-EFFS 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.

New Section 1860D-6. 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 is 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.

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 72% 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.

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 plans could be used to reduce the premium otherwise applicable.

Under certain conditions, the PDP sponsor or entity offering an MA-EFFS 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.

New Section 1860D-7. Premium and Cost-Sharing Subsidies for Low-Income Individuals

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 (and assets below \$4,000) would have a subsidy equal to 100% of the value of standard drug coverage provided under the plan. (Beginning in 2007, these amounts would be increased by the percentage increase in per capita beneficiary drug costs) 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 both groups, 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 brand drug. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than \$5 per prescription. Sponsors and entities could reduce to zero the cost-sharing otherwise applicable for generic drugs.

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-EFFS 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 is equivalent). If a plan provides 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-EFFS 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.

Section 1860D-8. Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

New Section 1860D-8 would provide for subsidy payments to qualifying entities. The payments would reduce premiums for all beneficiaries consistent with an overall subsidy level of 72%, 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 or MA-EFFS plan, equal to 42% 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 EFFE Rx plan. The Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA Rx or EFFE Rx plans. Reinsurance payments would be provided for 30 percent 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 (\$3,700 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, 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 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.

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 and entitled to enroll under a PDP or MA-EFFS but elected not to. Subsidy payments would equal 28% of allowable costs over the \$250 deductible but not over \$5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.) The Administrator could adjust the percentage so that aggregate expenditures in a year were the same as aggregate expenditures that would have been made if the regular direct subsidy and reinsurance provisions (including adjustments) applied.

New Section 1860D-9. Medicare Prescription Drug Trust Fund.

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 account, 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.

Effective Date: Enactment

New Section 1860D-10. Definitions; Treatment of References to Provisions in Part C

New section 1860D-10 would include definitions of terms and specify how cross references to Part C would be applied. It would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions. The section would further require the Secretary to submit a report to Congress within 6 months of enactment that makes recommendations regarding providing benefits under Part D.

Also within 6 months of enactment, the Secretary 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.

Effective Date: Enactment

Section 102. Offering of Qualified Prescription Drug Coverage Under the Medicare Advantage and Enhanced Fee-For-Service Program

Current Law

Under current law, Medicare+Choice plans may elect to offer prescription drug coverage under Part C. The extent of these benefits vary and are not subject to any explicit standardization requirements. However, as with all Medicare+Choice benefit specifics, the financing and design of such benefits must meet the approval of the Secretary under the adjusted community rate (ACR) approval process. Generally, plans offering drugs must either finance such benefits from the differences between the applicable county payment rate and their costs in providing Medicare's basic benefits, or by assessing beneficiaries who enroll in the plan supplemental premiums.

Explanation of Provision

The provision would specify that, beginning January 1, 2006, a MA organization could not offer a coordinated care MA plan unless either that plan or another plan offered by the organization in the area included qualified drug coverage. It could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a MA plan offering such coverage.

The organization would be required to meet beneficiary protections outlined in the new Section 1860D-3, including requirements relating to information dissemination and grievance and appeals. The organization would also be required to submit the same information required of PDP sponsors when submitting a bid. The Administrator could waive such requirements to the extent the Administrator determined they were duplicative of requirements otherwise applicable to the organization or plan. 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 nondrug coverage.

The same requirements would be applicable to an EFFS organization.

Effective Date: Applies to coverage provided on or after January 1, 2006

Section 103. Medicaid Amendments

Current 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.

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. QMBs are aged or disabled persons with incomes at or below the federal poverty level and 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. SLIMBs are persons who meet the QMB criteria, except that their income is over the QMB limit; the SLIMB limit is 120% of the federal poverty level. Medicaid protection for SLIMBs is limited to payment of the Medicare Part B premium. QMBs and SLIMBs 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 (QIs) are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits). QI-1s are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. Medicaid protection for QI-1s is limited to payment of the monthly Medicare Part B premium. QI-2s are persons who meet the QMB criteria, except that their income is between 135% and 175% of poverty. Medicaid protection for QI-2s is limited to payment of that portion of the Part B premium attributable to the gradual transfer of some home health visits from Medicare Part A to Medicare Part B. Expenditures under the QI-1 and QI-2 programs are paid for 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. Any expenditures beyond that level are paid by the state. Assistance under the QI-1 and QI-2 programs is available for the period January 1, 1998 to December 31, 2002.

Explanation of Provision

Section 103 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision requires 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 10 percent and in 2006 by 20 percent. In each subsequent year the percent would be increased by ten percentage points (but in no case could the rate exceed 100 percent). Beginning in 2013, 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.

Effective Date: Enactment

Section 104. Medigap Transition

Current 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.

Explanation of Provision

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. 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 2005 (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.

Effective Date: Enactment

Section 105. Medicare Prescription Drug Discount Card Endorsement Program

Current 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.

Explanation of Provision. The provision would require the Secretary or Administrator to establish a program to endorse prescription drug discount card programs meeting certain requirements and to make available information on such programs to beneficiaries. The Secretary would begin operation of the program within 90 days of enactment. The Secretary would provide for an appropriate transition and discontinuation at the time the drug benefits first become available under Part D.

The Secretary could not endorse a program unless it met certain requirements. The program would have to pass on to enrollees discounts on drugs, including discounts negotiated with manufacturers. The program could not be limited to mail order drugs. It would have to provide pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions. It would have to provide, through the Internet and otherwise, information to enrollees that the Secretary identified as being necessary to provide for informed choice by beneficiaries among endorsed programs. This would include information on enrollment fees, prices charged to beneficiaries, and services offered under the program. The entity operating the program would have to demonstrate experience and expertise in operating such a program or a similar program. The entity would have to have in place adequate procedures for assuring quality. The annual enrollment fee could not exceed \$30 (which could be paid in whole or in part by the State). Further, the program would be required to meet additional requirements identified by the Secretary to protect and promote the interest of Medicare beneficiaries, including requirements that assure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price.

The Secretary would provide for the dissemination of information which compared the costs and benefits of such programs. This activity would be coordinated with the dissemination of educational information on MA plans. The Secretary would provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including

verification of discounts, and services provided, the amount of dispensing fees, and audits. The Secretary would be required to provide, through the use of the Medicare toll free number, for the receipt and response to inquiries and complaints. The Secretary would be required to revoke the endorsement of any program the Secretary deemed no longer met requirements or engaged in false or misleading marketing practices. The provision would specify that a beneficiary could only be enrolled in one endorsed program at a time. A beneficiary could change enrollment, but not until he or she had been in a plan a minimum period, as specified by the Secretary.

Effective Date

Enactment

Section 106.

Current 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.

Explanation of Provision

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.

Effective Date

Enactment.

Section 107. State Pharmaceutical Assistance Transition Commission

Current 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.

Explanation of Provision

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 identifies as having a benefit package comparable to or more generous than the new Part D; 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 represent interests of participants, appointed by the Secretary; 4) representatives of Medicare Advantage 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.

Effective Date

Enactment.

TITLE II - Medicare Enhanced Fee-For-Service and Medicare Advantage Programs; Medicare Competition

Section 200. Medicare Modernization and Revitalization

Current Law

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plans contracts in the 1970s and the Medicare risk contract program in the 1980s. Then, in 1997, Congress passed the Balanced Budget Act of 1997 (BBA, P.L. 105-33), replacing the risk contract program with the Medicare+Choice (M+C) program.

Explanation of Provision

This title would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of EFFS plans that may include preferred provider networks. It would establish a Medicare Advantage (MA) program to offer improved managed care plans with coordinated care. It would also use competitive bidding, in the same style of the Federal Employees Health Benefits program (FEHBP) for the EFFS plans and MA plans beginning in 2010.

SUBTITLE A - Medicare Enhanced Fee-For-Service Program

Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare

Current Law

Payment. 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 one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- ! a minimum payment (or floor) rate,
- ! a rate calculated as a blend of an area-specific (local) rate and a national rate, or
- ! a rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This 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 costs of direct and indirect 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 payments 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 an additional 2% over the previous year's amount.

Eligibility. Medicare beneficiaries who are entitled to Part A of Medicare and enrolled in Part B may receive Medicare benefits through the original Medicare fee-for-service (FFS) program or they may enroll in a Medicare+Choice (M+C) plan.

Explanation of Provision

Beginning January 1, 2006 the Administrator would establish an EFFS program to offer EFFS plans to EFFS eligible individuals in one of not less than 10 regions established by the Administrator. EFFS plans would be required to provide either FFS or preferred provider coverage. Under FFS coverage, plans would: 1) be required to 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 are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions. Preferred Provider Organization (PPO) coverage plans would: 1) require 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.

EFFS eligible individuals would be those individuals who were entitled to Medicare Part A and enrolled in Part B. EFFS plans could only be offered in a region, if the plan was: 1) available to all EFFS beneficiaries in an entire region, 2) complied with statutory access requirements, 3) uniformly provided all required Parts A and B benefits, and other benefits as may be required 4) included a single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses, and 5) provided prescription drug coverage for each enrollee electing Part D drug coverage. The Administrator would not approve an EFFS plan if benefits were designed to substantially discourage enrollment by certain eligible individuals.

Each year, beginning in 2006, an EFFE organization would submit a monthly bid amount for each plan in each region, referred to as the “EFFE monthly bid amount”. The bid could not vary among EFFE eligible individuals in the EFFE region involved. The EFFE organization would be required to provide the following information: 1) the bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the region and the actuarial basis for determining such amount; 2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the “unadjusted EFFE statutory non-drug monthly bid amount”), statutory prescription drug benefits, and non-statutory benefits including the actuarial basis for determining these proportions; and 4) additional information as the Administrator may require. The Administrator could negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. The Administrator could enter into contract for up to three EFFE plans in any region.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The EFFE plan would provide the enrollee a monthly rebate equal to 75% of the average per capita savings, if any. (Calculation of average per capita savings is discussed below.) The rebate could be in the form of a credit towards the EFFE monthly prescription drug premium or the EFFE monthly supplemental beneficiary premium, a direct monthly payment, or other means approved by the Administrator.

The Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by region. For plans offered in the previous year, the Administrator could compute the average based on previous year risk adjustment. For plans entering a region, in which no plan was offered in the previous year, the Administrator would estimate the average, and could use factors applied in comparable regions or on a national basis.

For each EFFE plan, the Administrator would adjust the EFFE region -specific non-drug monthly benchmark amount and the unadjusted EFFE statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The EFFE region-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the average (weighted by the number of EFFE eligible individuals in each payment area) of the annual capitation rate calculated for that area.

The administrator would pay plans as follows. For plans below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted EFFE statutory non-drug monthly bid amount, with three adjustments. Payment would be adjusted for demographics factors including age, disability, gender, institutional status, health status, and other factors; 2) intra-regional geographic variations; and 3) the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the EFFE region-specific non-drug monthly benchmark amount, with the demographic and geographic adjustments. Additionally, for an EFFE enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

Beneficiary EFFE premiums are defined as follows. In the case where a plan provides a rebate, the EFFE monthly basic beneficiary premium would be zero. In the case where a plan does not provide a rebate (the plan’s unadjusted EFFE statutory non-drug bid is above the EFFE region specific non-drug benchmark), the EFFE monthly basic beneficiary premium would be the difference between the bid and the benchmark amount. The EFFE monthly prescription drug beneficiary premium would be the portion of the plan’s total monthly bid that the statutory drug benefit represents. The EFFE

monthly supplemental beneficiary premium would be the portion of the plan's total monthly bid that is attributable to the supplemental non-statutory benefits.

Most of the statutory requirements concerning payment rules (other than the requirements for rates, service areas and MSA payments), organization and financial requirements, the establishment of standards, and contracts, would apply to EFFE plans. However, unlike current law, EFFE plans would not be permitted to segment a region. No Medicare supplemental policy (with the exception of the 2 new plans offered under Section 104 of this bill) could provide coverage of the single deductible or more than 50% of the other cost-sharing imposed under an EFFE plan under Part E.

Subtitle B-Medicare Advantage Program

CHAPTER 1-Implementation of Program

Section 211. Implementation of Medicare Advantage Program

Current Law

See Section 200. *Medicare Modernization and Revitalization* and Section 201. *Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.*

Explanation of Provision

This provision would establish the Medicare Advantage (MA) program under Part C of Medicare and make changes in the payments for these plans. It would be replaced with 100% of fee-for-service (the adjusted average per capita cost for the year, for MA payment area for services covered under Parts A and B for individuals entitled to benefits under Part A, enrolled under Part B and who are not enrolled in a MA plan). This payment would be adjusted 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) hadn't used those services. The minimum payment (floor) would be increased as under current law, and would include indirect medical education (IME), but exclude direct medical education (DME). Further the minimum percentage increase amount would also be changed. For 2004 and beyond, the minimum percent increase would be the greater of: 1) a 2% increase over the previous year, as under current law; or 2) the annual MA capitation rate for the area for the previous year, increased by the national per capita MA growth percentage increase. There would be no adjustment to the national growth percentage for prior years errors before 2004, for purposes of calculating the minimum percentage increase. For 2005, the annual rate equals the previous year's rate increased by the national growth percentage.

No later than 18 months after enactment of this legislation, 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.

No later than July 1, 2006, the Administrator would submit a report to Congress that

describes the impact of additional financing provided under the Act and other Acts, including BBRA and BIPA) on the availability of MA plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

Chapter 2- Implementation of Competition Program

Section 221. Competition Program Beginning in 2006

Current Law

See Section 200. *Medicare Modernization and Revitalization* and Section 201. *Establishment of Enhanced Fee-For-Service (EFS) Program under Medicare.*

Explanation of Provision

Each year, beginning in 2006, an MA organization would be required to provide the following information: 1) the 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 basis 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 4) additional information as the Administrator may require. The Administrator could negotiate the bid amount and could also reject the bid or proportion, if it was not supported by the actuarial basis. Private Fee-for-Service (PFFS) plans would be exempt from this negotiation.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The MA plan would provide the enrollee a monthly rebate equal to 75% of the average per capita savings, if any, as discussed below. The rebate could be in the form of a credit towards the MA monthly supplementary beneficiary premium or the MA monthly prescription drug premium, a direct monthly payment, or other means approved by the Administrator.

The Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by state, or on a basis other than the state. For plans offered in the previous year, the Administrator could compute the average based on the previous year's risk adjustment. For plans entering a state, in which no plan was offered in the previous year, the Administrator would estimate the average, and could use factors applied in comparable states or on a national basis.

For each MA plan, the Administrator would adjust the FFS area-specific non-drug monthly benchmark amount and the unadjusted MA statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The FFS area-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the annual MA capitation rate calculated for that area.

Beginning in 2006, the administrator would pay plans as follows. For plans below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted MA statutory non-drug monthly bid amount, with two adjustments. Payment would be adjusted for demographic factors including age, disability, gender, health status, and other factors and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the FFS

area-specific non-drug monthly benchmark amount, with the demographic adjustments. Additionally, for an MA enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

The Administrator would not approve a plan if benefits were designed to substantially discourage enrollment by certain MA eligible individuals. The MA monthly bid amount, the MA monthly basic and supplemental beneficiary premium and the MA monthly MSA premium, would not vary among individuals enrolled in the plan.

Chapter 3 - Additional Reforms

Section 231. Making Permanent Change in Medicare Advantage Reporting Deadlines and Annual, Coordinated Election Period

Current 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: 1) the plan deadline for submitting ACRs and other information moved from no later than July 1 to no later than the second Monday in September for 2002, 2003, and 2004, 2) the annual coordinated election period moved from the month of November to November 15 through December 31 for 2002, 2003, and 2004, and 3) the M+C payment rate announcement moved from no later than March 1 to no later than the second Monday in May for 2003 and 2004. The Secretary is required to mail information to enrollees at least 15 days before each annual open season, including a list of plan and plan options.

Explanation of Provision

This provision would permanently 1) move the plan deadline for submitting information to the second Monday in September, 2) change the annual coordinated election period to November 15 through December 31, and 3) move the annual payment rate announcement to no later than the second Monday on May. The requirement for providing information comparing plan options would be amended to require that the information would be provided to the extent possible at the time of preparation of material for the mailing.

Section 232. Avoiding Duplicative State Regulations

Current 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).

Explanation of Provision

This provision would stipulate that Federal standards established by this legislation would supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

Section 233. Specialized Medicare Advantage Plans for Special Needs Beneficiaries

Current 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 adjusted average per capita costs (AAPCC), for all nursing home resident Medicare enrollees.

Explanation of Provision

This provision would establish a new MA option – specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. 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 need beneficiaries on the cost and quality of services provided to enrollees. No later than 6 months after enactment of this Act, the Secretary of HHS would be required to issue final regulations to establish requirements for special needs beneficiaries.

Section 234. Medicare MSAs

Current Law

M+C plans must have a quality assurance program that: 1) stresses health outcomes and provides data permitting measurement of outcomes and other indices of quality; 2) monitors and evaluates high volume and high risk services and the care of acute and chronic conditions; 3) evaluates the continuity and coordination of care that enrollees receive; 4) is evaluated on an ongoing basis as to its effectiveness; 5) includes measures of consumer satisfaction, and 6) provides the Secretary with certain information to monitor and evaluate the plan's quality. Only certain coordinated care plans (excluding non-network MSAs, PPOs and PFFS plans) have to comply with other quality assurance requirements, such as providing for internal peer review, establishing written protocols for utilization review, and establishing mechanisms to detect under and over utilization.

Medicare MSAs were available on a demonstration basis, and no one could join a Medicare MSA after January 1, 2003 or earlier, if enrollment reached a capacity limit of 390,000.

Explanation of Provision

The provision would permanently extend Medicare MSAs and remove the enrollment cap. It would eliminate the requirement that Medicare MSA plans report on enrollee encounters, Non-contract providers furnishing services to enrollees of MSAs would be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

Section 235. Extension of Reasonable Cost Contracts

Current Law

Cost-based plans are reimbursed by Medicare for the actual cost of furnishing covered services, less the estimated value of beneficiary cost-sharing. The Secretary may

not extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

Explanation of Provision

This provision would allow reasonable cost contracts to be extended or renewed indefinitely, with an exception that would begin January 1, 2008. These contracts could not be extended or renewed for a service area, if during the entire previous year, the area had 2 or more coordinated care MA plans or 2 or more EFS plans which meet the following minimum enrollment requirements: 1) at least 5,000 enrollees for the portion of the area within a MSA with a population of more than 250,000 and counties contiguous to such MSA, and 2) at least 1,500 enrollees for any other portion of such area.

Subtitle C - Application of FEHBP Style Competitive Reforms

Section 241. Application of FEHBP-Style Competitive Reform Beginning in 2010

Current Law

See Section 200. *Medicare Modernization and Revitalization* and Section 201. *Establishment of Enhanced Fee-For-Service (EFS) Program under Medicare.*

Explanation of Provision

Beginning in 2010, this provision would create the new payment system for a “competitive EFS region” defined as a region that during the open season offers at least 2 EFS plans by different organizations, each meeting minimum enrollment requirements as of March of the previous year.

The competitive EFS non-drug benchmark amount is equal to the sum of: 1) the EFS component, and 2) the FFS component. The EFS component is calculated as the product of: 1) the weighted average of the EFS plan bids for the region and year, and 2) 1 minus the FFS market share percentage for the region and year. The FFS component is calculated as the product of: 1) the EFS region-specific non-drug monthly benchmark amount for the region and the year, and 2) the FFS market share percentage for the region and the year. The weighted average of EFS plan bids is calculated by summing the following for each EFS plan in a region - the unadjusted EFS statutory non-drug monthly bid amount multiplied by the number of individuals who reside in the region and who were enrolled in the EFS plan during March of the previous year, divided by the total number of such individuals for all EFS plans for that region for the year. The FFS market share percentage is the proportion of EFS eligible individuals who were residents of the region during March of the previous year and were not enrolled in an EFS or MA plan, or if greater, the same proportion determined on a national basis. Plans not offered in the previous year are excluded.

Similarly, beginning in 2010, this provision would also create a new payment system for “competitive MA areas” (CMA area) defined as an area that during the open season offers at least two MA plans by different organizations, each meeting the minimum enrollment requirements as of March of the previous year.

The CMA non-drug benchmark amount is equal to the sum of: 1) the MA component, and 2) the FFS component. The MA component is calculated as the product of: 1) the weighted average of the MA plan bids for the region and year, and 2) 1 minus the FFS market share percentage for the region and year. The FFS component is calculated as the product of: 1) the FFS area-specific non-drug monthly bid amount for the area and the year, and 2) the FFS market share percentage for the area and the year. The weighted average of MA plan bids is calculated by summing the following for each

MA plan in an area - the unadjusted MA statutory non-drug monthly bid amount multiplied by the number of individuals who reside in the area and who were enrolled in the MA plan during March of the previous year, divided by the total number of such individuals for all MA plans for that area for the year. The FFS area-specific non-drug monthly bid is defined as the weighted average of the FFS area-specific non-drug monthly benchmark amounts (defined above) for the MA payment area or areas included in the area for the year. The FFS market share percentage is the proportion of MA eligible individuals who were residents of the area during March of the previous year and were not enrolled in an EFS of MA plan, or if greater, the same proportion determined on a national basis. Plans not offered in the previous year are excluded. The Administrator would compute the benchmark for each CMA area before the beginning of each annual election period, beginning in 2010.

Similar to the rebates under the EFS and MA programs for non-competitive areas, beneficiaries in competitive areas would receive a rebate equal to 75% of the average per capita monthly savings

Beginning in 2010, the Secretary would announce on a yearly basis the FFS area-specific non-drug benchmark and if applicable the competitive MA non-drug benchmark for the year and competitive MA area involved and the FFS market share, the adjustment factor, relating to demographic adjustments, ESRD, and health status, and in the case of a competitive MA area, the projected FFS area-specific non-drug bid.

Beneficiaries enrolling in plans with bids below the benchmark would receive seventy-five percent of the difference between the benchmark and bid, and the government would receive twenty-five percent of the difference. Beneficiaries enrolling in plans with bids above the benchmark would pay the excess.

To carry out this section, the Administrator would transmit the name, social security number and adjustment amount to the Commissioner of Social Security at the beginning of each year and periodic updates throughout the year. Effective January 1, 2010.

TITLE III B COMBATTING WASTE, FRAUD AND ABUSE

Section. 301. Medicare Secondary Payer (MSP) Provisions.

Current 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 and Medicare determines that the payment will not be made promptly, as determined in accordance with regulations).

Explanation of Provision

The Secretary would be able to make a Medicare payment if a primary plan --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.

The list of primary plans for which conditional payment could be made would be expanded; an entity engaging in a business, trade, or profession would be deemed as

having a self-insured plan if it carries its own risk. Failure to obtain insurance would be required as evidence of carrying 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.

Effective Date

Subsection (a) 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). Subsection (b) would be effective upon enactment.

Section 302. Competitive Acquisition of Certain Items and Services.

Current Law

In general, durable medical equipment is paid under a set of local (or state) fee schedules subject to certain floors and ceilings as well as limited to the lower of the actual charge for the equipment or the fee schedule amount. Fee schedule amounts received an update of the full consumer price index for urban consumers (CPI-U) in 2003.

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.

Explanation of Provision

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, parental nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. 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 one-third of the areas implemented each year. 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.

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 supplies 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 3 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 are to the number needed to meet projected demand for covered items and services. 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 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 ordering the tests. 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. GAO would be required to report to Congress on the differences in reimbursement between public and private payors for clinical diagnostic services. The Secretary would be required to study whether suppliers of DME are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

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 included 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. In this instance, the regular payment rules established by regulation, including the inherent reasonableness rule, would not be applied.

Effective Date

Upon enactment

Section 303. Competitive Acquisition of Covered Outpatient Drugs and Biologicals.

(a) Adjustment to the Physician Fee Schedule.

Current 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 include 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.

Explanation of Provision

The Secretary would be required to establish the practice expense relative value for the physician fee schedule in CY2004 using the survey data provided by entities and organizations if consistent with the Secretary's criteria for acceptable survey data. The Secretary would be required to consult with GAO and groups representing the affected physician specialties before publishing the notice of proposed rulemaking. The increase in expenditures resulting from this provision would be exempt from the budget-neutrality requirement for CY2004. The Secretary would not be prevented from adjusting the practice expense relative values in subsequent years. The resulting adjustments in practice expense relative value units for CY2004 would not be subject to administrative or judicial review. Also, the Secretary would be required to adjust the nonphysician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

Effective Date

Upon enactment.

(b) Payment Based on Competition.

Current Law

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is specifically 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, including those which must be put directly into the 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 based on 95% of the average wholesale price (AWP). The term "AWP" is not defined in statute or regulation, but generally, the AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on reported prices as 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. To differing degrees, the published prices on which Medicare payment's are based are higher than the amounts actually paid to acquire a given prescription drug.

Because covered outpatient prescription drugs are Part B services, Medicare pays 80% of the recognized amount and the beneficiary is liable for the remaining 20% coinsurance amount, except in the case of vaccines where no beneficiary cost-sharing is imposed. Also, beneficiaries cannot be charged for any amounts in excess of the recognized payment amount.

Explanation of Provision

A new section 1847A would be established and 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 required to select a contractor who would deliver covered drugs and biologicals to the physician. 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) that would be implemented beginning in 2005, and the non-oncology category that would be implemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o) of the Social Security Act (SSA) which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, drugs and biologicals other than erythropoetin furnished as treatment for end-stage renal disease (ESRD), and radiopharmaceuticals would not be considered covered drugs under the competitive acquisition program. Nothing in the section would affect the carrier invoice pricing method used to pay for radiopharmaceuticals. 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, 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 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. 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 insure product integrity, customer service, past experience with drug distribution, and other factors. All drugs dispensed under this program would be acquired directly from the manufacturer. Contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. The bid prices in an area would be effective for that area throughout the 2-year contract period. The Secretary would not be able to accept a contract for an area if its aggregate average prices exceed those established by the interim payment method. The interim payment method would be based on the cost at which drugs are reasonably available in the market, including discounts, rebates and chargebacks; and established by regulation, effective no later than January 1, 2004 (subject to the implementation of the physician practice expense adjustment previously established in this legislation). Interim payments would not apply to drugs in the oncology category after December 31, 2004 or to other drugs after December 31, 2005. Under the program, the Secretary would be required to compute an area average of the submitted bid prices. The Secretary would be able to establish alternative payment rules for new drugs and biologicals and other exceptional cases as long as the payment amounts did not exceed the interim payment amount or other specified market price based payment methodology. Beneficiary liability would be limited to 20% of the payment basis for the covered drug or biological.

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 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 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. These drugs would be those that would be immediately required, not reasonably foreseen as immediately required, and not able to be delivered by the contractor in a timely manner. 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 provider satisfaction under the competitive acquisition program. These reports would be due each year from 2004 through 2006 and every 5 years thereafter. GAO would be required to assess the impact of this program on the delivery of services, particularly with respect to beneficiary access to drugs and the site of delivery. MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors in its 2004 annual report.

Under this section, the Secretary would not be able to pay a dispensing fee to a pharmacy.

Effective Date

Upon enactment.

Section. 303. Demonstration Project for Use of Recovery Audit Contractors.

Current Law

No provision.

Explanation of Provision

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 and 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 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.

Effective Date

Upon enactment.

TITLE IV B RURAL HEALTH CARE IMPROVEMENTS

Section 401. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds.

Current 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.

Explanation of Provision

Starting for discharges after October 1, 2003, a hospital that is not a large urban hospitals that qualifies for a DSH adjustment would receive its DSH payments using the current DSH adjustment formula, subject to a limit. The DSH adjustment for any of these hospitals, except for rural referral centers, would be increased to a maximum of 10%. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Effective Date

The provision would apply to discharges occurring on or after October 1, 2003

Section 402. Immediate Establishment of Uniform Standardized Amount in Rural and

Small Urban Areas.

Current Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6% larger than the standardized amount used to reimburse 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 December 31, 2003, will be paid on the basis of the large urban area amount.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 403. Establishment of Essential Rural Hospital Classification.

Current Law

No provision in current law

Explanation of Provision

An essential rural hospital would be a new designation for the purposes of Medicare reimbursement. An essential rural hospital would apply for such a classification, would have more than 25 beds, and would be located in a rural area as defined by the inpatient prospective payment system (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 specific 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. A essential rural hospital 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.

Effective Date

The provision would apply to cost reporting periods beginning on or after October 1, 2004.

Section 404. More Frequent Update in Weights Used in Hospital Market Basket.

Current Law

Medicare's standardized amounts, which serve as the basis of its payment per discharge from acute hospital, are increased annually using an update factor which 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 hospitals purchased 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 in using 1997 cost data for use in the FY2003 Medicare hospital payment rates.

Explanation of Provision

The Secretary would be required to revise the market basket cost weights including the labor share to reflect the most currently available data and to establish a schedule for revising the cost 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.

Effective Date

Upon enactment.

Section 405. Improvements to the Critical Access Hospital (CAH) Program.

(a) Increase in Payment Amounts.

Current Law

Generally, a critical access hospital (CAH) receives reasonable, cost based reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient service payment or an all-inclusive rate which is equal to a reasonable cost payment 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.

Explanation of Provision

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.

Effective Date

This provision would apply to cost reporting periods beginning on or after October 1, 2003.

(b) Coverage of Costs For Certain Emergency Room On-Call Providers.

Current 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.

Explanation of Provision

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.

Effective Date

This provision would apply to costs for services provided on or after January 1, 2004.

(c) Modification of the Isolation Test for Cost-Based CAH Ambulance Services.

Current 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.

Explanation of Provision

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.

Effective Date

This provision would apply to ambulance services furnished on or after the first cost reporting periods that begins after the date of enactment.

(d) Reinstatement of Periodic Interim Payment (PIP).

Current 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.

Explanation of Provision

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.

Effective Date

This provision would apply to payments made on or after January 1, 2004.

(e) Condition for Application of Special Physician Payment Adjustment.

Current 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.

Explanation of Provision

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.

Effective Date

This provision would be effective as if it had been included as part of BBRA.

(f) Flexibility in Bed Limitation for Hospitals.

Current 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.

Explanation of Provision

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 than 10 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 only 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment.

Effective Date

These provisions would only apply to CAH designations made before, on or after January 1, 2004.

(g) Additional 5-Year Provisions Related to Certain Rural Grants.

Current Law

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. The authorization to award the grants expired in FY2002.

Explanation of Provision

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up to \$25 million each year.

Effective Date

Upon enactment.

Section 406. Redistribution of Unused Resident Positions.

Current 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. 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 nonhospital 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 nonhospital 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 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.

Explanation of Provision

A teaching hospital's 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 to 75% of the difference between the hospital's 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 hospital's reference period would be the 3 most recent consecutive cost reporting periods for which a hospital's 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 hospital's 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, 2003 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital has applied for such an increase by December 1, 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 hospital's resident count established under this section would affect a hospital's 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, including recommendations, on whether to extend the application deadline for increases in resident limits no later than July 1, 2005.

Effective Date

Upon enactment

Section 407. Two-Year Extension of Hold Harmless Provisions for Small Rural Hospitals Under Prospective Payment System for Hospital Outpatient Department Services.

Current 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.

Explanation of Provision

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be extended to 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 exceeds 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.

Effective Date

Upon enactment.

Section 408. Exclusion of Certain Rural Health Clinic and Federally Qualified health Center Services from the Prospective Payment System for Skilled Nursing Facilities.

Current 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.

Explanation of Provision

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 a physician or practitioner who was not affiliated with a RHC or FQHC.

Effective Date

The provisions would apply to services furnished on or after January 1, 2004.

Section 409. Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients.

Current 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.

Explanation of Provision

A beneficiary 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.

Effective Date

Upon enactment.

Section 410. Improvement in Payments to Retain Emergency Capacity for Ambulance Services in Rural Areas.

Current 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.

Explanation of Provision

The Secretary would be required to increase the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area to account for the higher average costs incurred by providers furnishing a low volume of services. The Secretary may provide for a greater increase for providers in frontier areas based on findings of even higher average costs because of an even lower volume of services furnished. A qualified urban area is county that has not been assigned to a metropolitan statistical area (MSA) with a population density of Medicare beneficiaries in the lowest 1 quartiles of all rural county populations.

Effective Date

Upon enactment.

Section 411. Two-Year Increase for Home Health Services Furnished in a Rural Area.

Current 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.

Explanation of Provision

The provision would extend a 5% additional payment for home health care services furnished in a rural area during FY 2004 and 2005 without regard to certain budget-neutrality requirements.

Effective Date

Upon enactment.

Section 412. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations.

Current Law

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.

Explanation of Provision

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) 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 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.

Effective Date

Upon enactment

Section 413. GAO Study of Geographic Differences in Payments for Physicians' Services.

Current Law

No provision.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 414. Treatment of Missing Cost Reporting Periods for Sole Community Hospitals.

Current 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 standardize 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.

Explanation of Provision

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.

Effective Date

The provision would apply to cost reporting periods beginning on or after January 1, 2004.

TITLE V B PROVISIONS RELATING TO PART A

Subtitle A B Inpatient Hospital Services

Section 501. Revision of Acute Hospital Payment Updates.

Current 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.

Explanation of Provision

Acute hospitals would receive an operating update of, on average, 3.1 percents for FY2004 through FY2006.

Effective Date

Upon enactment

Section 502. Recognition of New Medical Technologies Under Inpatient Hospital PPS.

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. These 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.

Medicare pays hospitals additional amounts for atypical cases (known as "outliers") that have extraordinarily high costs compared to most discharges classified in the same DRG. The additional payment amount is equal to 80% of the difference (90% for certain DRGs for burn victims) between the hospital's entire cost for the stay and the threshold amount.

Explanation of Provision

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year that 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 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 provides 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 Secretary would be directed to automatically reconsider an application as a new technology that was denied for FY2003 as a FY2004 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.

Effective Date

These provisions would be effective for classifications beginning in FY2004.

Section 503. Phase-in of Federal Rate for Hospitals in Puerto Rico.

Current 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.

Explanation of Provision

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 between federal and local amounts before October 1, 2003. From FY2004 through 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.

Effective Date

Upon enactment

Section 504. Wage Index Adjustment Reclassification Reform.

Current 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 standardized amount, wage index, or both. 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 are met: (1) an urban hospital 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 MGCRB and withdraws or terminates its reclassification.

Explanation of Provision

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 terminates its payment. A hospital that receives a commuting wage adjustment would not be eligible for reclassification into another area by the MGCRB for the purposes of using its wage index or standardized amount. 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.

Enactment Date

Upon enactment.

Section 505. MedPAC Report on Specialty Hospitals.

Current Law

No provision.

Explanation of Provision

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.

Enactment Date

Upon enactment.

SUBTITLE B B Other Services

Section 511. Payment for Covered Skilled Nursing Facility Services.

Current 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.

Explanation of Provision

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.

Enactment Date

The provision would be effective for services on or after October 1, 2003.

Section 512. Coverage of Hospice Consultation Services.

Current Law

Current law authorized coverage of hospice services, in lieu of certain other Medicare

benefits, for terminally ill beneficiaries who elect such coverage.

Explanation of Provision

Coverage of certain physicians' 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 physicians' 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.

Effective Date:

The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

TITLE VI PROVISIONS RELATING TO PART B

Subtitle A Physicians Services

Section 601. Revision of Updates for Physicians Services.

Current 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 physician 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.

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) 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 to correct for faulty data for the number of fee-for-service beneficiaries in 1998 and 1999. 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.

Explanation of Provision

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 of -0.2 percent in 2004 and 0.8 percent in 2005.

The formula for calculating the sustainable growth rate would be modified. Starting in 2003, the GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average.) The current GDP factor measures the 1-year change from the preceding year.

Effective Date

Upon enactment. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

Section 602. Studies on Access to Physicians Services.

Current 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 is not available for a subsequent period; however, several surveys have showed a decline in the percentage of physicians accepting new Medicare patients.

Explanation of Provision

GAO would be required to conduct a study on access of Medicare beneficiaries to physicians' 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 include a determination whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would also include a determination 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.

Effective Date

Upon enactment

Section 603. MedPAC Report on Payment for Physicians Services.

Current 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.

Explanation of Provision

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component in the case of services for which there are no physician work relative value units. The report is to examine the following by specialty: 1) the effects 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.

Effective Date

Upon enactment.

Subtitle B Preventative Services

Section 611. Coverage of An Initial Preventative Physical Examination.

Current Law

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

Explanation of Provision

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 physicians fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams.

Effective Date

The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

Section 612. Coverage of Cholesterol and Blood Lipid Screening.

Current Law

Medicare covers a number of preventive services. However, it does not cover cholesterol and blood lipid screening

Explanation of Provision

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.

Effective Date

The provision would apply to services furnished on or after January 1, 2005.

Section 613. Waiver of Deductible for Colorectal Cancer Screening Tests.

Current 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.

Colorectal cancer screening tests are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount.

Explanation of Provision

The Part B deductibles would be waived for colorectal cancer screening tests.

Effective Date

The provision would apply to items and services furnished on or after January 1, 2004.

Section 614. Improved Payment for Certain Mammography Services.

Current 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 nonphysician 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).

Explanation of Provision

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.

Effective Date

The provision would apply to mammography performed on or after January 1, 2004.

Subtitle C Other Services

Section 611. Hospital Outpatient Department (HOPD) Payment Reform.

(a) Payment for Drugs

Current Law

Under hospital outpatient department (HOPD) prospective payment system (PPS), 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 certain 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 radiopharmaceutical 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 AWP and the payment rate for the comparable dose of the associated drug APC.

Hospital costs for these drugs are used to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying the average wholesale price (AWP) for the drug by the applicable cost to charge ratio which varies by the class of drug. Although transitional pass through payments are subject to an budget neutrality requirement, the applicable budget neutrality requirement (2.5% through CY2003) was not effective until April, 2002.

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.

Temporary HCPCS codes are used exclusively to bill pass-through payments for new technology items paid under the hospital outpatient PPS. These codes cannot be used to bill other Medicare payment systems. These codes are added, changed or deleted on a quarterly basis to expedite the processing of requests for pass-through status.

Explanation of Provision

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 radiopharmaceuticals 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 cost drugs from \$150 to \$50. 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.

(b) Special Payment for Brachytherapy.

Current 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. 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.

Explanation of Provision

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to costs. 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.

Effective Date

Upon enactment.

(c) Functional Equivalence.

Current Law

In the November, 1 2002 *Federal Register*, CMS decided that a new anemia treatment for cancer patients was no longer eligible for pass-through payments, because it was functionally equivalent (although not structurally identical or therapeutically equivalent) to an existing treatment. The transitional pass-through rate for the drug was reduced to zero starting for services in 2003.

Explanation of Provision

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 identical to another drug and therefore ineligible for pass-through payment status without first developing these standards by regulation. The regulation would be required to be published after public comment period and contain criteria that provides for the coordination with the Federal Food and Drug Administration and is based on scientific studies that show the clinical relationship between the drugs in question.

Effective Date

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.

(d) Hospital Acquisition Cost Study.

Current Law

CMS estimates hospital costs to establish beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying the average wholesale price (AWP) for the drug by the applicable cost to charge ratio which varies by the class of drug.

Explanation of Provision

The Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost \$50 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 appropriated 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.

Effective Date

Upon enactment.

Section 622. Payment for Ambulance Services.

Current 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.

Explanation of Provision

The phase-in methodology and schedule for full implementation of the ambulance fee schedule would be modified. The calculation of ambulance fees in 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.

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 by January 1, 2004.

Effective Date

The provision would apply to ambulance services furnished on or after January 1, 2004.

Section 623. Renal Dialysis Services.

(a) Demonstration of Alternative Delivery Models

Current Law

The Secretary announced a demonstration project establishing a disease-management program that will allow organizations experienced with treating 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.

Explanation of Provision

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 end-stage renal disease services, economists, and researchers.

Effective Date

Upon enactment.

(b) Restoring Composite Rate Exceptions for Pediatric Facilities

Current Law

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).

Explanation of Provision

The prohibition on exceptions 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.

Effective Date

Upon enactment.

(c) Increase in Renal Dialysis Composite Rate for Services Furnished in 2004.

Current 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. BBRA increased the composite rates by 1.2% for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the mandated 2001 update to 2.4%, an increase that was to be implemented on the following schedule in order to avoid a disruption in claims processing: for services furnished from January through March, 2001, the 1.2% increase specified by BBRA applied; for the remainder of 2001, a transition increase of 2.79% applied. Effective January 1, 2002, the composite rates reflected the 2.4% increase. There is no rate increase scheduled for ESRD composite payment rate in 2004.

Explanation of Provision

The provision would increase the ESRD composite payment rate by 1.6% for 2004.

Effective Date

Upon enactment.

Section 624. One Year Moratorium on Therapy Caps; Provisions Relating to Report.

Current 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 are not yet being enforced. Implementation of the therapy caps is scheduled for July, 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.

Explanation of Provision

Application of the therapy caps would be suspended during CY 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.

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.

Effective Date

Upon enactment

Section 625. Adjustment to Payments for Services Furnished in Ambulatory Surgical Centers.

Current Law

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ACS. 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.

Explanation of Provision

The update would be reduced two percentage points for five years. ASC's 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.

Effective Date

Upon enactment

Section 626. Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics.

Current 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 is 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.

Explanation of Provision

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 or a carrier would be able to establish lower payment limits than these amount 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.

Effective Date

The provision would apply to items furnished on or after January 1, 2004.

Section 627. Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period.

Current Law

A late enrollment penalty is imposed on beneficiaries who do not enroll in Medicare part B upon becoming eligible for Medicare.

Explanation of Provision

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and over. 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 in the TRICARE for Life program during 2001, 2002, 2003, or 2004.

The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. For the individual who enrolls during the special enrollment period, coverage will begin on the first day of the month, following the month in which the individual enrolled.

Effective Date

The provision would apply to premiums for months beginning with January 2001. A method will be established to provide rebates of premium penalties paid for by military retirees for months on or after January 2001.

Section 628. Part B Deductible.

Current 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 set at \$100 since 1991.

Explanation of Provision

Each year after January 1, 2003, the Medicare Part B deductible would be increased annually by the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance Trust Fund. The Part B deductible would grow at the same rate as expenditures per capita for Part B services. The amount would be rounded to the nearest dollar.

Effective Date

Upon enactment.

TITLE VII PROVISIONS RELATING TO PARTS A AND B
Subtitle A B Home Health Services

Section 701. Update in Home Health Services.

Current 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.

Explanation of Provision

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.

Effective Date

Upon enactment

Section 702. Establishment of Reduced Copayment for a Home Health Service Episode of Care for Certain Beneficiaries.

Current Law

The home health benefit does not have any cost sharing requirement.
Explanation of Provision

This provision would establish a beneficiary copayment for each 60-day episode of care beginning January 1, 2004. The amount of the copayment would be 1.5% of the national average payment per episode in a calendar year as projected by the Secretary before the beginning of the year. The copayment amount would be rounded to the nearest multiple of \$5. For 2004, the copayment would be \$40 unless the Secretary provides the results of the statutory formula in a timely manner. Medicare payment for each episode would be reduced to reflect the amount of the copayment. Qualified Medicare beneficiaries (low income beneficiaries for whom Medicaid pays the Medicare premiums, deductibles, and coinsurance), beneficiaries dually eligible for Medicare and Medicaid,

and beneficiaries receiving four or fewer home health visits in an episode of care would not face any cost sharing requirements. Administrative and judicial review of the calculated copayment amounts would be prohibited.

Effective Date

Upon enactment.

Section 703. MedPAC Study of Medicare Margins of Home Health Agencies.

Current Law

No provision.

Explanation of Provision

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare 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.

Effective Date

Upon enactment.

Subtitle B Direct Graduate Medical Education

Section 711. Extension of Update Limitation on High Cost Programs.

Current Law

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospitals 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.

Explanation of Provision

The hospitals with per resident amounts above 140% of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

Effective Date

Upon enactment

Subtitle C B Chronic Care Improvement

Section 721. Voluntary Chronic Care Improvement Under Traditional Fee-For-Service.

Current Law

No provision.

Explanation of Provision

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, 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 would be able to 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 and subcontractors would be able to 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, including a description of advantages in participating and that the contractor could contact the beneficiary directly concerning participation, the voluntary nature of program participation, and a means of declining to participate 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 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 able to 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 three-year period. Contracts for chronic care improvement programs would be treated as a risk-sharing arrangement. In addition, payment to contractors would be required to 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 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.

Effective Date

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than one-year after enactment.

Section. 722. Chronic Care Improvement Under Medicare Advantage and Enhanced Fee-For-Service Programs.

Current Law

Under the Medicare+Choice program, organizations are required to have quality assurance programs that includes 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.

Explanation of Provision

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, stroke 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 able to 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.

Effective Date

The provision would apply for contract years beginning on or after one year after enactment.

Section. 723. Institute of Medicine Report.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to contract with the Institute of Medicine of the National Academy of Sciences to study the barriers to effective integrated care improvement for Medicare beneficiaries with multiple or severe chronic conditions across settings and over time. The study would be required to examine the statutory and regulatory barriers to coordinating care across setting for Medicare beneficiaries in transition from one setting to another. The Institute of Medicine would be required to submit the report of the study to the Secretary and Congress no later than 18 months after enactment.

Effective Date

Upon enactment.

Section 724. Extension of Treatment for Certain Physician Pathology Services Under Medicare

Current 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 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.

Explanation of Provision

Medicare would make direct payments for the technical component for these pathology services. A change in hospital ownership would not affect these direct billing arrangements.

Effective Date

The provision would be effective January 1, 2004.

Subtitle D Other Provisions

Section 731. Modifications to Medicare Payment Advisory Commission (MedPAC).

Current 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.

Explanation of Provision

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, 2003. 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.

Effective Date

Upon enactment.

Section 732. Demonstration Project for Medical Adult Day Care Services.

Current Law

No provision

Explanation of Provision

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.

Effective Date

Upon enactment

Section. 723. Improvements in National and Local Coverage Determination Process

To Respond to Changes in Technology.

(a) National and Local Coverage Determination Process.

Current Law

No provision.

Explanation of Provision

Subsection (a) would require the Secretary to establish the general guidelines used in making national coverage determinations under Medicare, including the way in which evidence is considered by the Secretary regarding whether a procedure or device is reasonable or necessary. The provision would establish a time frame for decisions regarding national coverage determinations of six months after a request when a technology assessment is not required and 12 months when a technology assessment is required and in which a clinical trial is not requested. Following the six- or 12-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; and make the clinical evidence and data used in making the decision available to the public. 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.

Effective Date

The provision would be effective for determinations as of January 1, 2004.

(b) Medicare Coverage of Routine Costs Associated with Certain Clinical Trials

Current Law

No provision.

Explanation of Provision

Subsection (b) would provide for the coverage of the routine costs of care for Medicare 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.

Effective Date

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.

(c) Issuance of Temporary National Codes

Current Law

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.

Explanation of Provision

Subsection (c) would require that the Secretary implement revised procedures for the issuance of temporary national HCPCS codes. The provision would further require the Secretary to use data reflecting prices and costs of products in the United States in setting payment rates.

Effective Date

The provision would be effective not later than one year after enactment, effective as if it had been included in BIPA.

Title VIII Medicare Benefits Administration

Section 801. Establishment of Medicare Benefits Administration.

Current 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. Codes 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.

Explanation of Provision

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 5-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 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 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. 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 B other than sections 3110, the prohibition against officials hiring relatives, and 3112, the hiring preferences given to veterans. 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 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 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 may 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 B although the rate of compensation is capped at level IV of the Executive Schedule. The Board may 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) authorizes 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.

Effective Date

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.

[(c) Miscellaneous Administrative Provisions.]

Current Law

The Board of Trustees of the Medicare Trust Funds is composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services and two members of the public. The Administrator of the Centers for Medicare & Medicaid Services serves as the Secretary of the Board of Trustees.

Title 5 of the U. S. Codes sets the Administrator's salary at level IV of the Executive Schedule.

Explanation of Provision

Paragraph (1) would add the Administrator of MBA as an ex officio member of the Board of Trustees of the Medicare Trust Funds.

Paragraph (2) would increase the pay level for the Administrator of CMS from level IV of the Executive Schedule to level III.

Title IX Regulatory Relief

Subtitle A - Regulatory Reform

Section 901. Construction; Definition of Supplier.

Current Law

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

Explanation of Provision

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. A supplier means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare.

Effective Date

Upon enactment.

Section 902. Issuance of Regulations.

Current Law

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.

Explanation of Provision

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* 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 timeline had not been complied with.

The provision also would require that a provision of 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 provision would not be able to take effect until public comment occurred and the provision published as a final regulation.

Effective Date

The provision regarding the establishment of regulatory timeframes would be effective upon enactment and would require the Secretary to provide for an appropriate transition to take into account the backlog of previously published interim final regulation. The provision regarding logical outgrowth would be effective for final regulations published on or after enactment.

Section 903. Compliance with Changes in Regulations and Policies.

Current 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.

Explanation of Provision

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. 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. 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 sanction or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

Effective Date

The prohibition of retroactive application of substantive changes would apply to changes issued on or after the date of enactment. The provisions affecting compliance with substantive changes would apply to compliance actions undertaken on or after the date of enactment. The reliance on guidance would take effect upon enactment but would not apply to any sanction for which notice was provided on or before the date of enactment.

Section 904. Reports and Studies Relating to Regulatory Reform.

Current Law

No provision.

Explanation of Provision

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 one year after enactment.

The Secretary would be required to report to Congress every two 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 two years after enactment.

Effective Date

Upon enactment.

SUBTITLE B CONTRACTING REFORM

Section 911. Increased Flexibility in Medicare Administration.

Current 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 (FIs) 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.

Explanation of Provision

This provision would add 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.

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, 2011.

Effective Date

Upon enactment.

Section 912. Requirements for Information Security for Medicare Administrative Contractors.

Current Law

No provision.

Explanation of Provision

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 the contractor begins implementing the information security program 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.

Effective Date

Upon enactment.

SUBTITLE C EDUCATION AND OUTREACH

Section 921. Provider Education and Technical Assistance.

(a) Coordination of Education Funding.

Current Law. Medicare 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.

Explanation of Provisions. The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate the 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.

Effective Date. Upon enactment.

(b) Incentives to Improve Contractor Performance.

Current 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.

Explanation of Provisions. 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 and would require the Comptroller General to study the adequacy of the methodology and make recommendations to the Secretary and the Secretary to report to Congress regarding how he intends to use the methodology in assessing Medicare contractor performance.

Effective Date

Upon enactment.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Current 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.

Explanation of Provisions. 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 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 supplier 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.

Effective Date. The provision would be effective October 1, 2004.

(d) Improved Provider Education and Training.

Current Law

In FY2003, approximately \$122 million was budget by CMS for provider education and training.

Explanation of Provision

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.

Effective Date

Upon enactment.

(e) Requirement to Maintain Internet Sites.

Current Law

No statutory provision. CMS and the Medicare contractors currently maintain Internet sites.

Explanation of Provision

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.

Effective Date

The provision would be effective October 1, 2004.

(f) Additional Provider Education Provisions.

Current Law

No provision.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 922. Small Provider Technical Assistance Demonstration Program.

Current Law

No provision.

Explanation of Provision

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. A GAO study is 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.

Effective Date

Upon enactment.

Section 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

Current Law

No provision.

Explanation of Provision

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 to be appropriated for FY2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. 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 disembedding in a Medicare Choice plan. The Beneficiary Ombudsman would be required to work with state Health Insurance Counseling Programs, to the extent possible.

Appropriations would be authorized to be appropriated in such sums, as are necessary for fiscal year 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 to use. 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.

Effective Date

The Secretary would be required to appoint both ombudsmen not later than one year from the date of enactment.

Section 924. Beneficiary Outreach Demonstration Program.

Current Law

No provision.

Explanation of Provision

Subsection (a) would require the Secretary to conduct a three-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least six local Social Security offices (two 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.

Subsection (b) would require that the Secretary establish a demonstration project to test the administrative feasibility of providing a process for Medicare beneficiaries, providers, suppliers and other individuals or entities furnishing items or services under Medicare 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. The Secretary would be required to evaluate the demonstration and report to Congress by January 1, 2006.

Effective Date

Upon enactment.

Section 925. Inclusion of Additional Information in Notices to Beneficiaries about Skilled Nursing Facility Benefits.

Current 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.

Explanation of Provision

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.

Effective Date

The provision would apply to notices provided on and after the calendar quarter beginning more than 6 months after enactment.

Section 926. Information on Medicare-certified Skilled Nursing Facilities in Hospital Discharge Plans.

Current Law

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

Explanation of Provision

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.

Effective Date

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.

Subtitle D B Appeals and Recovery

Section 931. Transfer of Responsibility for Medicare Appeals.

Current 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 B a legacy from the inception of the Medicare program when Medicare was part of Social Security.

Explanation of Provision

The Commissioner of the Social Security Administration (SSA) and the Secretary 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).

Effective Date

Upon enactment.

Section 932. Process for Expedited Access to Review.

Current Law

In general, administrative appeals must be exhausted prior to judicial review.

Explanation of Provision

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain 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 including denied 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). 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.

Effective Date

This provision would be effective for appeals filed one or after October 1, 2004.

Section 933. Revisions to Medicare Appeals Process.

(a) Requiring Full and Early Presentation of Evidence

Current Law

No provision. New evidence can be presented at any stage of the appeals process.

Explanation of Provision

The provision would require providers and suppliers to present all evidence at the reconsideration that is conducted by a QIC unless good cause precludes the introduction of the evidence.

Effective Date

October 1, 2004.

(b) Use of Patients' Medical Records

Current Law

No provision.

Explanation of Provision

The provision would provide for the use of beneficiaries' medical records in qualified independent contractors reconsiderations.

Effective Date

Upon enactment.

(c) Notice Requirements for Medicare Appeals

Current 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.

Explanation of Provision

The provision would require that notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision and notice of the right to appeal decisions and the process for further appeal. The initial determination of a claim would also be specifically required to include: the reasons for the determination, including whether a local review policy or coverage determination was used and the procedures for obtaining additional information (including, upon request, the specific provision of the policy manual, or regulation used in making the determination). Redeterminations, the first level of appeal, would also

specifically be required to include: the specific reasons for the decision; as appropriate 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 (including, upon request, the specific provision of the policy manual, or regulation used in making the determination).

Effective Date

Upon enactment.

(D) Qualified Independent Contractors

Current Law

BIPA established a new and independent second level of appeal called the qualified independent contractors. BIPA called for at least 12 QICs. The QICs have not yet been implemented.

Explanation of Provision

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 than 12 to not fewer than four.

Effective Date

The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

Section 934. Prepayment Review.

Current 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.

Explanation of Provision

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.

Effective Date

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.

Section 935. Recovery of Overpayments.

Current Law

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

Explanation of Provision

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 six months duration. The repayment plan would not be permitted to go beyond three years (or five 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 document 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.

Effective Date

In general the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is one 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 one year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than one year after enactment.

Section 936. Provider Enrollment Process; Right of Appeal.

Current Law

No explicit statutory instruction. Under administrative authorities, CMS has

established provider enrollment processes in instructions to the contractors.

Explanation of Provision

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.

Effective Date

The enrollment process would be required to be established within six 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 one year after enactment or an earlier date specified by the Secretary.

Section 937. Process for Correction of Minor Errors and Omissions on Claims Without Pursuing Appeals Process.

Current Law

No provision.

Explanation of Provision

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.

Effective Date

The proposal would require that the process be developed not later than one year after enactment.

Section 938. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices

Current 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.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 949. Authority to Waive a Program Exclusion.

Current Law

The Secretary has the authority to waive exclusion from participation in any Federal health program when the provider is the sole source of care in a community, at the request of a state.

Explanation of Provision

The Secretary would be permitted to waive a program exclusion at the request of an administrator of a federal health care program (which includes state health care programs), after consulting with the Inspector General of HHS.

Effective Date

Upon enactment.

Subtitle V Miscellaneous Provisions

Section 941. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines.

Current Law

No provision.

Explanation of Provision

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) identify clinically relevant documentation needed to code accurately and assess coding levels accurately; (2) decrease the non-clinically pertinent documentation in the medical record; (3) increase reviewers accuracy; and (4) educate 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.

Effective Date

Upon enactment.

Section 942. Improvement in Oversight of Technology and Coverage.

(a) Council for Technology and Innovation

Current Law

No provision.

Explanation of Provision

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.

Effective Date

Upon enactment.

(b) Methods for Determining Payment Basis for New Lab Tests

Current Law

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes cap on the payment amounts, which is currently set at 74% of the median for all fee schedules for that test. The cap is set at 100% 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.

Explanation of Provision

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 Date

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.

Current Law

No provision.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 943. Treatment of Hospitals for Certain Services Under Medicare Secondary Payer (MSP) Provisions.

Current 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.

Explanation of Provision

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 it that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date

Upon enactment.

Section. 944. EMTALA Improvements.

Current Law

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exist prior to asking about insurance status of the patient.

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 B currently called quality improvement organizations or Quos) 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.

Explanation of Provisions

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary 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 shall provide a copy of the report on its findings to the hospital or physician that is consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment

Effective Date

Upon enactment.

Section 945. Emergency Medical Treatment and Active Labor (EMTALA) Task Force.

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a 17-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the OIG; 4 hospital representatives who have EMTALA experience, (including 1 person from a public hospital and 2 of whom have not experienced EMTALA violations) 5 practicing physicians with EMTALA experience; 2 patient representatives; 2 regional CMS staff involved in EMTALA investigations; 1 representative from a State survey organization and 1 from PRO. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

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; (3) terminate 30 months after the date of its first meeting; and (4) be exempt from the Federal Advisory Committee Act. 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.

Effective Date

Upon enactment.

Section 946. Authorizing Use of Arrangements with Other Hospice Programs to Provide the Core Hospice Services in Certain Circumstances.

Current Law

A hospice is a public agency or private organization, which is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

Explanation of Provisions

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.

Effective Date

For hospice care provided on or after enactment.

Section 947. Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals.

Current Law

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

Explanation of Provision

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.

Effective Date

The provision would apply to hospitals as of July 1, 2004.

Section 948. BIPA-Related Technical Amendments and Corrections.

Current 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.

Explanation of Provision

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 a policy to a determinations.

Effective Date

The provision would be effective as if included in BIPA.

Section 949. Conforming Authority to Waive A Program Exclusion.

Current 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.

Explanation of Provisions

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.

Effective Date

Upon enactment.

Section 950. Treatment of Certain Dental Claims.

Current 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.

Explanation of Provision

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.

Effective Date

The provision would be effective 60 days after enactment.

Section 951. Furnishing Hospitals with Information to Compute DSH Formula.

Current 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.

Explanation of Provision

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.

Effective Date

Upon enactment.

Section 952. Revisions to Reassignment Provisions.

Current Law

Under certain circumstances, a person or entity other than the individual providing the service may receive Medicare payments.

Explanation of Provision

Entities, as defined by the Secretary, could receive Medicare payments for services provided by a physician or other person if the service was provided under a contractual arrangement and if the arrangement included joint and several liability (liability for several parties) for overpayment and the entities meet program integrity specifications determined by the Secretary.

Effective Date

The provision would be effective for payments made on or after one year after the date of enactment.

Section 953. Other Provisions.

Current Law

No provisions.

Explanation of Provision

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 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 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.

Effective Date

Upon enactment.