

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 that are *not usually 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 pneumococcal 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.

New Section 1860A. Benefits; Eligibility; Enrollment; and Coverage Period

The new Section 1860A would specify that each individual entitled to Medicare Part A and enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage. An individual enrolled in a Medicare+Choice (M+C) plan providing qualified prescription drug coverage could obtain coverage through the plan. An individual not enrolled in a M+C plan providing qualified prescription drug coverage could enroll under Part D 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 a M+C with qualified drug coverage, 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 M+C, including annual coordinated election periods and special election periods. An individual discontinuing a M+C 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, 2004, would be established for persons enrolled under Part B on that date. For persons first enrolling in Part B after that date, an initial election period, which is 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 M+C 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 M+C could not be denied enrollment based on health status or other factors. Existing M+C 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 M+C 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 is considered to have had continuous prescription drug coverage if the individual establishes that he or she has had coverage under one of the following (and coverage in one plan occurs no more than 63 days after termination of coverage in another plan): 1) qualified prescription drug coverage under a PDP or M+C plan; 2) Medicaid prescription drug coverage; 3) prescription drug coverage under a group health plan, but only if benefits are 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, 2005, and only if the benefits are at least equivalent to benefits under a qualified PDP; 5) state pharmaceutical assistance program, but only if benefits are at least equivalent to benefits under a qualified PDP; and 6) veterans coverage for prescription drugs, but only if benefits are 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 prohibit PDP sponsors from establishing a service area in a manner that would discriminate based on the health or economic status of potential enrollees.

The provision would provide that elections would take effect at the same time that elections take effect for M+C plans. However, no election could take effect before January 1, 2005. The Secretary would provide for the termination of an election in the case of termination of Part B coverage or termination of an election by the M+C for cause (including failure to pay the required premium).

New Section 1860B. Requirements for Qualified Prescription Drug Coverage

The new Section 1860B specifies the requirements for qualified prescription drug coverage. Qualified coverage is defined as either a standard coverage or actuarially equivalent coverage. In both cases, access would have to be provided to negotiated prices.

For 2005, A standard coverage would be defined as having a \$250 deductible; 20 percent cost-sharing up to the initial co-payment threshold (\$1,000) 50 percent cost-sharing for costs above the initial co-payment threshold up to the \$2,000 initial coverage limit (the next \$1,000 above the initial co-payment threshold and catastrophic coverage at \$4,500. Once the beneficiary reached the catastrophic (A stop loss at limit, full coverage would be provided. Beginning in 2006, 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 co-payment threshold, that were actuarially consistent with an average expected 20 percent cost-sharing for costs up to the initial co-payment threshold. Similarly, they could substitute cost-sharing requirements, for costs above the initial cost-sharing threshold up to the initial coverage limit, that were actuarially consistent with an average expected 50 percent cost-sharing for costs up to the initial coverage threshold. They could also apply tiered co-payments, provided such co-payments were actuarially consistent with the average 20 percent and 50 percent cost-sharing requirements.

The provision would specify incurred costs that would count toward meeting the deductible, initial coverage limit, and amounts for which benefits are not provided because of application of the initial coverage limits. Costs would be treated as incurred costs only if they were paid by the individual, paid on behalf of a low-income individual under the subsidy provisions, or paid under the Medicaid program.

The provision would permit a PDP or M+C 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 reinsurance 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 M+C organization 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 limit. Insofar as a state elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. The PDP sponsor or M+C organization would be required to disclose to the Administrator the extent to which manufacturer discounts or rebates 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 M+C organization 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) 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) prescription smoking cessation agents otherwise excluded under Medicaid. The definition includes any use of a covered outpatient drug for a medically accepted indication. Drugs that 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 1660C. In addition, a PDP or M+C 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 1860C. Beneficiary Protections for Qualified Prescription Drug Coverage.

The New Section 1860C would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the New Section 1860A and the non-discrimination provisions specified in the new Section 1860F.

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 functions; 3) co-payment and deductible requirements (including any applicable tiered co-payment requirements; and 4) grievance and appeals procedures. In addition, as is the case for M+C, beneficiaries would have the right to obtain more detailed plan information. Plans would be required to have a mechanism for providing

specific information to enrollees on request. The sponsor would be required to make available, through an Internet WEB site and, on request, in writing, information on specific changes in the formulary. Plans would be required to furnish to enrollees, at least monthly, a detailed explanation of benefits when drug benefits were provided.

Plans would be required to secure the participation in its network of a sufficient number of pharmacies that distribute drugs directly to patients to make access to covered benefits convenient for enrollees. **Mail order only pharmacies would not count towards meeting this requirement.** The PDP sponsor would be required to establish an optional point-of-service method of operation under which the plan provides access to any or all pharmacies that are not participating pharmacies in its network. Plans could charge beneficiaries, through adjustments in premiums or co-payments, additional costs associated with the point of service option.

The PDP sponsor would be required to issue (and reissue as appropriate) a card or other technology that may be used by an enrolled beneficiary to assure access to negotiated prices for drugs when coverage is not otherwise provided under the plan.

The provision would specify that if a plan used a formulary, it would have to meet certain requirements. It would be required to establish a pharmaceutical and therapeutics 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, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. 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. 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 PDP sponsor would be required to have, as part of its appeals process, a process for appeals of coverage denials based on application of the formulary.

The PDP sponsor would be required to have an effective cost and drug utilization management program, quality assurance measures including a medication therapy management program and, for years beginning with 2006, an electronic prescription drug program, and a program to control fraud, waste, 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 with chronic diseases or multiple prescriptions, that drugs under the plan were appropriately used to achieve therapeutic goals and 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. It 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. Grants would be authorized under the Public Health Service Act to assist health care professionals in implementing electronic prescription drug programs. Each PDP sponsor would ensure that enrolled beneficiaries were informed 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 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, pharmacists, and technology experts, Department of Veterans Affairs, Department of 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 systems reduce medication errors and can be readily implemented by physicians and hospitals; 3) efforts to develop a common software platform for computerized prescribing; 4) cost of implementing such systems in hospital and physician office settings; and 5) implementation issues as they relate to administrative simplification requirements and current Federal and state prescribing laws and regulations and their impact on implementation and computerized prescribing. The Administrator would be required to establish the task force by April 1, 2003. It would be required to submit recommendations to the Administrator by January 1, 2004. The Administrator would be required to promulgate national standards by January 1, 2005.

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 M+C. 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 was not as effective for the enrollee or had adverse effects for the enrollee.

In general, PDP plan sponsors would be required to meet the requirements for independent review of coverage denials and appeals in the same manner that such requirements apply to M+C plans. 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 M+C plans.

New Section 1860D. Requirements for Prescription Drug Plan (PDP) Sponsors; Contracts; Establishment of Standards

New Section 1860D 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 benefits or health insurance 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 reinsurance payments for high cost enrollees; or 2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish new plans. The entity could obtain reinsurance to cover the risk of providing benefits.

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 Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans. The Administrator would be required to take into account reinsurance subsidy payments and the adjusted community rate for covered benefits in negotiating the terms and conditions regarding premiums.

The new section would incorporate, by reference, many of the contract requirements applicable to M+C 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 percent of the maximum fee permitted for a M+C 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 be given authority to establish by regulation additional standards as deemed appropriate to implement Part D and would be required to publish such regulations by October 1, 2003.

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 1860E. Process for Beneficiaries to Select Qualified Prescription Drug Coverage.

The new Section 1860E would require the Administrator to establish a process for the selection of a PDP plan or a Medicare+Choice 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 M+C. Further, the process would provide for the coordination of elections through filing with a M+C organization or a PDP sponsor in a manner consistent with that provided under M+C.

The section would specify that a Medicare+Choice enrollee in a M+C plan offering qualified prescription drug coverage could only elect to receive such 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 was a PDP) in their area of residence. The requirement would not be satisfied if only one PDP sponsor or M+C organization offered all the qualifying plans in the area. If necessary to ensure such access, the Administrator would be authorized to provide financial incentives, including the 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, nor could the Administrator provide for any assumption of financial risk for a public PDP sponsor offering a nationwide drug plan. Additionally, the Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and M+C organizations. 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 1860F. Submission of Bids

Each PDP sponsor must submit to the Administrator specified information in the same manner as such information is submitted by M+C 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 for the coverage. The PDP sponsor would have to include an actuarial certification of: 1) the actuarial basis for the bid; 2) the portion of the bid attributable to benefits in excess of the standard coverage; 3) the reduction in the bid resulting from reinsurance subsidies; and 4) such other information required by the Administrator. The Administrator would review the submitted information for purposes of conducting negotiations with the plan.

The bid 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 plan sponsor could encourage enrollees to make payment of the premium through an electronic funds transfer mechanism or at the beneficiary's option, withholding from Social Security. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in M+C plans could be used to reduce the premium otherwise applicable. PDP plans would receive payment based on the bid amount

in the same manner applicable for M+C except that payment would be made from the Medicare Prescription Drug Trust Fund.

Under certain conditions, the PDP sponsor of any plan in an area would be required to accept, for an individual eligible for a premium subsidy, the benchmark amount (as defined in new Section 1860g) 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. M+C plans would be required to accept the benchmark amount under the same conditions.

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

The New Section 1860G 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 150 percent of poverty would have a subsidy equal to 100 percent of the value of standard drug coverage provided under the plan.

(Beginning in 2006, these amounts would be increased by the percentage increase in per capita beneficiary drug costs) For individuals between 150 percent and 175 percent of poverty, there would be a sliding scale premium subsidy ranging from 100 percent of such value at 150 percent of poverty to 0 percent of such value at 175 percent 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 non-preferred drug. PDPs cannot charge individuals receiving cost-sharing subsidies more than \$5 per prescription. PDPs could reduce to zero the cost-sharing otherwise applicable for generic drugs.

State Medicaid plans would be required to determine whether an individual was eligible for the subsidy and the amount of the subsidy. The Administrator would make the determination if the state did not operate such a plan (or a state waiver program under Section 1115 of the Social Security Act). 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 bid amount for the qualified prescription drug coverage that the beneficiary selects whether offered by a PDP plan or a M+C plan in the area. The benchmark bid amount for a PDP plan means the bid amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for enrollment in a plan-providing 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 bid as the actuarial value of standard coverage was to the actuarial value of alternative coverage. The benchmark amount for M+C plans would be the portion of the bid attributable to standard drug coverage.

The Administrator would provide a process whereby the Administrator would notify the PDP sponsor or M+C organization that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or organization 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 organization 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 1860H. Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

New Section 1860H would provide for subsidy payments to qualifying entities. The Payments would reduce premiums for all beneficiaries, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies or through reinsurance, and together create an average 65 percent subsidy. 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, M+C plan, or qualified retiree prescription drug plan equal to a percentage, specified by the Administrator of the actuarial value of standard coverage provided under the plan and totaling 35 percent.

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP plan, a M+C plan providing qualified prescription drug coverage, or a qualified retiree drug plan. The Administrator would provide for reinsurance payments to PDP sponsors, M+C plans providing qualified prescription drug coverage, and qualified retiree drug plans. Reinsurance payments would be provided for 30 percent of an individual's allowable drug costs over the initial coverage limit (\$1,000 in 2005) but not over the initial coverage limit (\$2,000 in 2005). Reinsurance, not to exceed 80 percent would also be provided for costs over the out-of-pocket limit (\$4,500 in 2005).

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that are actually paid by the plan, but in no case be 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 subsidy payments that would be made during the year and total benefit payments that would be expected to be made by qualifying entities for standard coverage during the year. The Administrator would proportionately adjust payments such that: 1) total subsidy payments during the year were

equal to 65 percent of total payments made by qualifying plans for standard coverage during the year; and 2) the ratio of total payments for direct subsidies to total reinsurance payments for the year is 35 to 30. 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.

“Qualified retiree prescription drug plans” would be defined as employment-based retiree health coverage meeting certain requirements. The sponsor of the plan would be required to annually attest to the Administrator (and to provide such assurances as required by the Administrator) that the coverage meets requirements for qualified coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless: the individual was covered under the retiree plan, entitled to enroll under a PDP or M+C plan with prescription drug coverage but elected not to. Payments could not be made for persons covered under the Medicare a secondary payer program.

New Section 1860I. Medicare Prescription Drug Trust Fund.

New Section 1860I 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.

New Section 1860J. Definitions; Treatment of References to Provisions in Part C

New section 1860J 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 Administrator to submit a report to Congress by January 1, 2004, that makes recommendations regarding providing benefits under Part D.

Effective Date:

Enactment

6/18/2002 12:28 PM

Section 102. Offering of Qualified Prescription Drug Coverage Under the Medicare+Choice Program

Current Law

Under current law, Medicare+Choice plans may elect to offer prescription drug coverage under Part C. The extent of these benefits varies 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 a M+C plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. No M+C organization would be required to offer such coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a M+C plan offering such coverage.

The organization would be required to meet beneficiary protections outlined in the new Section 1860C, 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.

Effective Date:

Applies to coverage provided on or after January 1, 2005

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 coverage under Medicaid. Persons entitled to 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 percent 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 percent and 135 percent 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 percent and 175 percent 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 percent 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 expenditure beyond that level is 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 203 would add a new Section 1935 to the Social Security Act entitled a 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 may 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 a 10-year period the federal matching rate for these costs would be increased to cover 100 percent 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 \$20 million in 2005 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

6/18/2002 12:28 PM

The provision would prohibit, effective January 1, 2005, 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 percent of the cost-sharing otherwise applicable (except coverage of 100 percent 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 percent, rather than 50 percent, 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 delayed by court action. However, CMS was allowed to proceed with rule-making. On March 6, 2002, CMS issued proposed rule-making.

Explanation of Provision. The provision would require the Secretary to endorse prescription drug discount programs meeting certain requirements and to make available

information on such programs to beneficiaries. 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. 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 M+C plans. The Secretary would provide appropriate oversight to ensure compliance of endorsed programs with the requirements of Section 105, including verification of discounts, and services. 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.

The provision would provide that the Secretary would provide for an appropriate transition and discontinuance of the endorsement program at the time benefits first become available under Part D.

Effective Date:

Enactment

Title II - Medicare+Choice Revitalization and Medicare+Choice Competition Program

Subtitle A- Medicare+Choice Revitalization

Section 201. Medicare+Choice Improvements

Current Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment amount, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of 3 amounts, calculated according to formulas established in statute. 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.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending, the national growth percentage. The third payment amount, the minimum increase, is updated annually by an additional 2 percent over the previous year's amount.

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.

Explanation of Provision

This provision would make changes to the M+C payment amounts for 2003 and 2004. The capitation rate for an M+C payment area would be based on the largest of 4 amounts. If higher than other M+C payment rates, plans would be paid based on 100 percent of fee-for-service (FFS) costs, as calculated by the adjusted average per capita cost (AAPCC) for that year, for a payment area, including costs for only the fee-for-service beneficiaries and not the costs for those enrolled in an M+C plan. The AAPCC would be adjusted to include an estimate of the additional Medicare payments that would have been made if Medicare beneficiaries had not used facilities of the Department of Veterans Affairs (VA) and the Department of Defense (DOD) for Medicare covered benefits.

This provision would make adjustments to the calculation of the blend payment in 2003 and 2004: 1) the national average used in the calculation of the blend would be revised, to reflect only M+C enrollees, rather than all beneficiaries; and 2) the area-specific rate component of the blend would be modified to include an estimate of the additional payments that would have been made if Medicare beneficiaries received Medicare covered benefits from facilities of the Department of Veterans Affairs (VA) and the Department of Defense (DOD). Budget neutrality would be permanently eliminated, so that payment rates would not be reduced to ensure that estimated total M+C payments in a given year would equal the total payments that would be made if payments were based solely on area-specific rates.

For 2003 and 2004, the minimum percentage increase would be 3 percent above the previous year's amount instead of 2 percent under current law.

Within 2 weeks after enactment, the Secretary would be required to determine and announce the new M+C payments rates, as revised by this Section.

MedPAC would be required to conduct a study to assess the method for determining the AAPCC, including information on the appropriate geographic area, variation in cost between different areas, and the accuracy of risk adjustment. This study must be submitted within 9 months of enactment.

Effective Date:

Enactment

Section 202. Making Permanent Change in Medicare+Choice Reporting Deadlines and Annual, Coordinated Election Period

Current Law

Prior to enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), the Centers for Medicare and Medicaid Services (CMS) was required to announce the annual Medicare+Choice (M+C) payment rates, which would be applicable on January 1st of the following year, by no later than March 1 of each year. Each M+C organization was required to submit to the Secretary of HHS, for each of its M+C plans, specific information about the adjusted community rate (ACR), M+C premiums, cost sharing, and additional benefits (if any) no later than July 1 of each year, also for the following year. The Secretary then reviewed this information and approved or disapproved the M+C plan premiums, cost-sharing amounts, and benefits. Medicare beneficiaries could also make or change elections to an M+C plan each November, during the annual coordinated election period.

P.L. 107-188 made a number of temporary changes. First, CMS moved its annual announcement of M+C payment rates from no later than March 1 to no later than the 2nd Monday in May, effective for 2003 and 2004. P.L. 107-188 also temporarily moved the deadline for plans to submit information about ACRs, M+C premiums, cost sharing, and additional benefits (if any) from no later than July 1 to no later than the 2nd Monday in

September in 2002, 2003, and 2004. It also changed the annual coordinated election period from the month of November to November 15th through December 31 in 2002, 2003, and 2004.

Explanation of Provision

This provision would permanently extend the deadline changes that were temporarily changed by P.L. 107-188. CMS would make its annual announcement of payment rates no later than the 2nd Monday in May of each year. The deadline for plans to submit their information would be no later than the 2nd Monday in September. The annual coordinated election period would take place from November 15th through December 31 of each year.

Effective Date:

Enactment

Section 203. Avoiding Duplicative State Regulation

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 clarify that Federal standards would supersede any State law or regulation (other than state licensing laws or state laws relating to plan solvency), with respect to M+C plans offered by M+C organizations.

Effective Date:

Enactment

Section 204. Specialized Medicare+Choice 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 (who function as primary Medicare care givers and case managers). EverCare receives a fixed capitated payment, based on a percentage of the AAPCC, for all nursing home resident Medicare enrollees. There are 6 demonstration sites, for a total enrollment of about 10,000 individuals.

Explanation of Provision

This provision would allow specialized plans for special needs beneficiaries (such as the EverCare demonstration) to become any type of M+C coordinated care plan. Special needs beneficiaries are defined as those M+C eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized M+C plans could be limited to special needs beneficiaries until January 1, 2007. The Medicare Benefits Administrator would be required to report to Congress by December 31, 2005 providing an assessment of the impact of these plans. The Secretary would be required to issue final regulations establishing requirements for special needs beneficiaries within 6 months after enactment of this legislation.

Effective Date:

Enactment

Section 205. Medicare MSAs

Current Law

The Balanced Budget Act authorized a demonstration to test the feasibility of medical savings accounts for the Medicare program. The M+C option is a combination of a health insurance plan with a large deductible and an M+C MSA. Contributions to an M+C MSA may be made annually from the enrollee's capitation rate after the plan's insurance premium has been paid. These contributions, as well as account earnings, are exempt from taxes. Withdrawals used to pay unreimbursed enrollee medical expenses (that are deductible under the Internal Revenue Code) are not taxed. New enrollment is not allowed after 2003 or after the number of enrollees reaches 390,000.

Explanation of Provision

This 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.

Effective Date:

Enactment

Section 206. Extension of Reasonable Cost and SHMO Contracts

Current Law

Reasonable Cost Contracts. Medicare reimburses cost-based plans for the actual cost of furnishing covered services, less the estimated value of beneficiary cost sharing. Following the enactment of the Balanced Budget Act (BBA), the Secretary was

prohibited from entering into new cost reimbursement contracts, except with organizations that had provided only Part B services. Reasonable cost contracts may apply to expand service areas through September 1, 2003. The Secretary cannot extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

SHMOs. The Deficit Reduction Act of 1984 required the Secretary to grant 3-year waivers for demonstrations of social health maintenance organizations (SHMOs) which provide integrated health and long-term care services on a prepaid, capitated payment basis. The waivers have been extended on several occasions since then, and the Omnibus Budget Reconciliation Act of 1990 authorized a second generation of projects. BBA 97 extended waivers for SHMOs through December 31, 2000, and expanded the number of persons who can be served per site from 12,000 to 36,000. BBRA 99 extended the SHMO waivers until 18 months after the Secretary submits a report with a plan for integration and transition of SHMOs into an option under M+C. BIPA extended SHMO waivers until 30 months after the Secretary submits a report with a plan for integration and transition of SHMOs into an option under the M+C program. This 30-month extension supersedes the 18-month extension in BBRA 99.

Explanation of Provision

Reasonable Cost Contracts. This provision would allow a reasonable cost contract to be extended or renewed beyond December 31, 2004 if there were no coordinated care M+C plans in its service area. A cost contract could convert to an M+C plan to serve its previously served area. The cost contract could continue to operate in parts of its service area without M+C coordinated care plans. A cost contract could re-enter a previously served area if all other coordinated care M+C plans in the area terminated their contracts. The Medicare Benefits Administrator shall submit a report to Congress no later than February 1, 2004 on an appropriate transition for cost contract plans.

SHMOs. The provisions would extend the waivers permitting operation of SHMOs through December 31, 2004. Nothing would prevent a SHMO from offering an M+C plan.

Effective Date:

Enactment

Subtitle B- Medicare+Choice Competition Program

Section 211. Medicare+Choice Competition Program

Current Law

See Section 201 explanation of current law.

Explanation of Provision

Beginning in 2005, a new M+C payment system would be established based on competitive bidding for the provision of all items and services. The provision would establish a benchmark amount for each payment area and a procedure for plans to develop a bid amount. Additionally, enrollees would be eligible for rebates, under certain circumstances.

The bid amount would indicate the proportion of the bid attributable to the provision of: 1) statutory non-drug benefits, 2) statutory prescription drug benefits, and 3) non-statutory benefits. Plans would be required to submit this information and the actuarial bases for determining these amounts, as well as other information that the Administrator may require to verify the actuarial bases. The bid amount could not vary by enrollees within a plan.

The Administrator would have authority to negotiate monthly bid amounts (including portions of the bid), and may reject a bid amount, or a portion of it, that is not supported by the actuarial bases provided by the plan.

The fee-for-service area-specific non-drug benchmark (benchmark) amount would be set at the larger of 100 percent of the FFS costs (95 percent for 2008 and thereafter), the minimum update, or the minimum monthly amount (i.e., floor). FFS costs would be set at the AAPCC for that year, for a payment area (including costs for only the fee-for-service beneficiaries and not the costs for those enrolled in an M+C plan) adjusted to include estimated costs for VA and DOD services to Medicare-eligible beneficiaries.

Both the benchmark and the bids would be risk adjusted based on statewide assumptions, or based on a determination by the Administrator.

If the risk adjusted benchmark exceeded the risk adjusted bid (for statutory non-drug benefits), beneficiaries would qualify for rebates of 75 percent of the difference in the form of: 1) a credit towards their M+C monthly supplementary beneficiary premium, or the premium imposed for prescription drug coverage; 2) a direct monthly payment; 3) other means approved by the Secretary; or 4) some combination. The government would retain the remaining 25 percent of the savings. If the monthly bid exceeded the benchmark, enrollees would pay an M+C monthly basic beneficiary premium, equal to the amount by which the monthly bid exceeded the benchmark.

Plans would be paid based on their bid amounts. For plans with bids below the benchmark, their payment would be the bid amount, risk adjusted for demographic and health status factors, plus the rebate amount. The risk adjustment procedure would not be changed from current law. The rebate amount would be distributed to the plan's enrollees by one of the approved methods, as discussed above. For plans with bids at or above the benchmark, their payments would equal the benchmark amount, risk adjusted for demographic and health status factors.

Effective Date:

Effective for payments and premiums for months beginning with January 2005.

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Section 212. Demonstration Program for Competitive-Demonstration Areas

Current Law

See Section 201 explanation of current law.

Explanation of Provision

This provision would establish a demonstration program for competitive-demonstration areas, defined as: 1) metropolitan statistical areas or areas with a substantial number of M+C enrollees; 2) with at least 2 M+C plans offered by different organizations; and 3) with at least 50 percent of M+C eligibles enrolled in an M+C plan. The demonstration program would be limited to a maximum of 4 sites and no area could be designated as a competitive-demonstration area for more than 2 years. The Administrator would have discretion to decide whether or not to designate as a competitive-demonstration area an area that qualifies for such designation.

For each competitive-demonstration area, the Administrator shall annually determine the choice non-drug benchmark amount, defined as the sum of the weighted FFS and M+C components. The weighted FFS component would be calculated by multiplying the national fee-for-service (FFS) market share for the year (defined as the nationwide proportion of M+C eligibles during March of the previous year who were not enrolled in an M+C plan) by the FFS area-specific non-drug bid (set at the AAPCC for that year, for a payment area (including costs for only the fee-for-service beneficiaries and not the costs for those enrolled in an M+C plan) adjusted to include estimated costs for VA and DOD services to Medicare-eligible beneficiaries). The M+C component would be calculated by multiplying 1 minus the national FFS market share for the year by the weighted average of plan bids for the area and year. The weighted average of plan bids would equal the sum of the proportion of each plan's enrollees in the area times the unadjusted monthly non-drug bid amount, as calculated for each plan.

If the choice risk adjusted benchmark exceeded the risk adjusted bid (for statutory non-drug benefits), beneficiaries would qualify for rebates for 75 percent of the difference in the form of: 1) a credit towards their M+C monthly supplementary beneficiary premium, or the premium imposed for prescription drug coverage; 2) a direct monthly payment; 3) other means approved by the Secretary; or 4) some combination. If instead, the monthly bid exceeded the benchmark, enrollees would pay the amount by which the monthly bid exceeded the benchmark.

Plans would be paid based on their bid amounts. For plans with bids below the choice benchmark, their payment would be the bid amount, risk adjusted for demographic and health status factors, plus the rebate amount for beneficiaries. Plans would be responsible for passing rebates through to beneficiaries as outlined above. For plans with bids at or above the choice benchmark, their payments would equal the benchmark amount, risk adjusted for demographic and health status factors.

Effective for payments and premiums for months beginning with January 2005.

No later than 6 months after the designation of the 4th competitive-demonstration area, the Medicare Benefits Administrator would be required to submit a report to Congress on the impact of this demonstration program on Medicare beneficiaries, savings to the Medicare program, and adverse selection issues.

Effective Date:

Effective January 1, 2005.

Section 213. Conforming Amendments

Current Law

National Coverage Determinations. If National Coverage Determinations (NCDs) occur during a contract year, such changes shall not apply to the M+C plan until the following contract year. If the NCD provides for coverage of additional benefits or coverage under additional circumstances, the M+C payment rate shall not apply to payment for such benefits until the following contract year.

Explanation of Provision

National Coverage Determinations. The provision would allow the Secretary to implement a national coverage determination that will result in a significant change in the cost to an M+C organization only in a prospective manner.

Consolidation of M+C Payment Areas. The chief executive officer of a State may request that the Medicare Benefit Administrator make a geographic adjustment to an M+C payment area, changing the payment area from a county-based system to a single statewide M+C payment area, or a metropolitan-based system. Any adjustment to the geographic payment area must ensure that aggregate payments after geographic adjustment would equal payments that would have been made without the geographic adjustment.

Effective Date:

Enactment

TITLE III - Rural Health Care Improvements

Section 301. Reference to Full Market Basket Increase for Sole Community Hospitals and Hospitals Located in Rural or Small Urban Areas

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 increase in the hospital market basket index (MBI). Sole community hospitals (SCH) receive special treatment under the inpatient hospital prospective payment system (PPS). A SCH can elect to be paid on the basis of its updated hospital-specific amount if that results in greater Medicare reimbursement than payment based on the federal amount. Currently, the update factor is set at MBI-0.55 percentage points for FY2002 and FY2003 and at the MBI for subsequent years.

Explanation of Provision

The provision would eliminate the reduction from the MBI updated specified in Section 401(a) for SCHs for FY2003.

Effective Date

Upon enactment

Section 302. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural 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 specified by BIPA, all hospitals are eligible to receive disproportionate share hospital (DSH) payments when their DSH percentage or threshold amount exceeds 15 percent starting with discharges occurring on or after April 1, 2001. BIPA modified the payment formulas to create the same eligibility threshold for across all hospitals. Still, different formulas are used to establish a hospital's DSH payment, depending upon the hospital's location, number of beds and status as a rural referral center or sole community hospital. BIPA also increased the DSH payment but a small urban or rural hospital receives 5.25 percent while large (100 beds and more) urban hospitals and large rural hospitals (500 beds and more) receive a higher adjustment, the amount of which depends upon its DSH percentage that can be significantly greater.

Explanation of Provision

Starting for discharges on or after October 1, 2002, the DSH adjustment that hospitals (other than urban hospitals with a 100 or more beds or certain public hospitals)

would receive would be based on a blend of their current DSH adjustment and the current DSH adjustment for large urban hospitals. However, the new DSH adjustment would not exceed 10 percent for any hospital that was not classified as a RRC. A hospital's new DSH adjustment would be calculated using 80 percent of the existing DSH adjustment in FY2003; 60 percent in FY2004; 40 percent in FY2005; 20 percent in FY2006; and 0 percent in FY2007 and subsequently.

Effective Date

The amendment would apply to discharges occurring on or after October 1, 2002.

Section 303. 2-Year Phased-in Increase of Small Urban Standardized Amount to Achieve a Single, Uniform Standardized Amount

Current Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount (or base rate) that is 1.6 percent larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas).

Explanation of Provision

For discharges occurring in FY2003, the average standardized amount for hospitals in other areas would be increased by half the difference between the current amount and the larger standardized amount paid to hospitals in large urban areas. For discharges occurring in FY2004, the Secretary would compute one standardized amount for all hospitals, increase this amount by the applicable update, and use this amount to pay all hospitals.

Effective Date

Upon enactment.

Section 304. 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 MBI. The market basket index 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) periodically revises the cost category weights, reevaluates the price proxies for such categories, and rebases (or changes the base period) for the MBI. The MBI used through FY2002 was last rebased in 1997 for FY1998 and reflected data from FY1992. As discussed in its May, 2002 proposed regulation, CMS has developed

a revised and rebased MBI using 1997 data for use in the FY2003 Medicare hospital payment rates.

Explanation of Provision

The provision would direct the Secretary to revise the MBI cost weights 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 305. Improvement to the Critical Access Hospital Program

(a) 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.

Explanation of Provision

Starting with payments made on or after January 1, 2003, eligible critical access hospitals (CAHs) would be able to receive payments made on a PIP basis for inpatient services.

Effective Date

As established in subsection (e), this provision would be effective starting with payments made on or after January 1, 2003.

(b) Condition for Application of Special Physician Payment Adjustment

Current Law

For cost reporting periods starting on or after October 1, 2000, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115 percent of the fee schedule for professional services otherwise included in within its outpatient critical access hospital services.

Explanation of Provision

The provision would preclude the Secretary from requiring 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 percent of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115 percent of the fee schedule for any individual physician who did not assign billing rights to the CAH.

Effective Date

As established in subsection (e), this provision would be effective as if included in BBRA.

(c) Flexibility in Bed Limitation For Hospitals with Strong Seasonal Census Fluctuations

Current Law

CAHs are limited-service hospitals that provide 24-hour emergency care services with no more than 15 acute care beds or up to 25 beds, including 10 swing beds, in limited cases. CAHs may not have patient stays that are, on average, more than 96-hours long.

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 inpatient acute beds it can maintain (and still retain its classification as a CAH).

Effective Date

As established in subsection (e), this provision would apply to designations made on or after January 1, 2006, but would not apply to CAHs that were designated by enactment.

(d) 5-Year Extension of the Authorization for Appropriations for Grant Program

Current Law

The Rural Hospital Flexibility Grant Program that awards grants to (1) states for rural health care planning and implementation activities, rural network development, and CAH designations and to (2) hospitals that have applied to be CAHs to implement data systems required under BBA 97 expires in FY2002.

Explanation of Provision

The provision would extend the grant program which permits annual appropriations from the Medicare's Federal Hospital Insurance Trust Fund of \$25 million through FY2007.

Effective Date

Upon enactment

(e) Effective Dates

Current Law

No provision

Explanation of Provision

Subsection (a) concerning PIP payments would be effective starting with payments made on or after January 1, 2003; subsection (b) concerning physician payment would be effective as if included in BBRA.; and subsection (c) concerning the CAH bed limit would apply to designations made on or after January 1, 2003.

Sec. 306. Extension of Temporary Increase for Home Health Services Furnished in a Rural Area

Current Law

The Medicare home health PPS was implemented on October 1, 2000. It provides a standardized payment for a 60-day episode of care furnished to a Medicare beneficiary, with the payment adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA 2000 increased PPS payments by 10 percent for home health services furnished in the home of beneficiaries living in rural areas. The increased payments are effective during the 2-year period beginning April 1, 2001, through March 31, 2003, without regard to budget neutrality for the overall 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 through December 31, 2004, the 10 percent additional payment for home health care furnished to beneficiaries residing in rural areas.

Effective Date:

Enactment

Sec. 307. Reference to 10 Percent Increase in Payment for Hospice Care Furnished in a Frontier Area

The provision would provide a cross reference to Section 422 of the bill.

Section 308. Reference to Priority for Hospitals Located in Rural or Small Urban Areas in Redistribution of Unused Graduate Medical Education Residencies.

Current Law

With certain exceptions, Medicare limits the total number of paid residency positions in a hospital's approved teaching programs that are reimbursed based on the number that were reported by the hospital for the cost reporting period ending in calendar year 1996. For example, hospitals that established new training programs before August 5, 1997 are partially exempt from the payment cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and urban hospitals operating training programs in rural areas) can be reimbursed for 130 percent of the number of residents allowed by their cap. The cap is calculated as a 3-year rolling average, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years.

Explanation of Provision

Section 612 of this legislation would establish that hospitals located in rural or small urban areas would have priority for redistribution of unused graduate medical education residency payments.

Effective Date

Upon enactment

Section 309. GAO Study of Geographic Differences in Payments for Physician 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; (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 data and use of price proxies, would be due to Congress within 1 year of enactment.

Effective Date

Upon enactment

Section 310. 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 to induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

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 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. 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 30-day opportunity for public comment.

Effective Date

Upon enactment

Title IV - Provisions Relating to Part A

Subtitle A - Inpatient Hospital Services

Section 401. Revision of Acute Care 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 increase in the hospital market basket index (MBI). Sole community hospitals (SCH) receive special treatment under the inpatient hospital prospective payment system (PPS). A SCH can elect to be paid on the basis of its updated hospital-specific amount if that results in greater Medicare reimbursement than payment based on the federal amount. Currently, the update factor is set at MBI-0.55 percentage points for FY2002 and FY2003 and at the MBI for subsequent years.

Explanation of Provision

For FY2003, the hospital update factor would be MBI-0.25 for all hospitals except SCHs which would receive an update factor of the full MBI.

Effective Date

Upon enactment

Section 402. 2-Year Increase in Level of Adjustment for Indirect Costs of Medical Education (IME)

Current Law

Medicare makes additional payments to teaching hospitals for indirect medical education (IME), which is supposed to recognize extra clinical and diagnostic costs for residents providing care. The Balanced Budget Act of 1997 (BBA 97) reduced the IME adjustment from the existing 7.7 percent increase (for each 10 percent increase in a hospital's ratio of interns and residents to beds) in FY1997 to 7.0 percent in FY1998; to 6.5 percent in FY1999; to 6.0 percent in FY2000; and to 5.5 percent in FY2001 and subsequent years. These percentage IME adjustments were subsequently modified by the Balanced Budget Refinement Act of 1999 (BBRA) and the Benefits Improvement and Protection Act of 2000 (BIPA). Currently the IME adjustment is set at 6.5 percent in FY2002 and 5.5 percent for FY20003 and subsequently.

Explanation of Provision

This provision would set the IME adjustment to 6 percent in FY2003, 5.9 percent in FY2004 and 5.5 percent for FY2005.

Effective Date

Upon enactment

Section 403. 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. CMS published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes. (ICD-9-CM codes). The regulation also established that technology that provided a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis related group (DRG) payment was inadequate; this threshold, which was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50 percent of the costs of the new technology or (b) 50 percent 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 percent of the total operating inpatient payments, the add-on payments are reduced prospectively.

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 following fiscal year. 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 50 percent of the national standardized amount for all hospitals and all DRGS or one standard deviation for the DRG involved. The Secretary would be required to provide additional clarification in regulation on the criteria used to determine whether a new service represents a substantial improvement on existing treatment. The Secretary would be required to deem that a technology provides substantial improvement on an existing treatment if the technology in question is a drug or biological that is designated under section 506 (fast track product) or 526 (drugs for rare diseases and conditions) 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, for which priority or expedited review has been provided under section 515(d)(5) (breakthrough technology) or is a substantially equivalent device for which expedited review is provided for under 513(f) of such Act. 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 determine if one or more DRGs can be identified 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 calculate add-on payments based on the marginal rate associated with inpatient outlier cases.

Effective Date

These provisions would be effective for classifications beginning in FY2004. 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.

Section 404. 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 percent of the federal national amount and 75 percent 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 through 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 55 percent national and 45 percent local; changing to 60 percent national and 40 percent local during FY2005; 65 percent national and

35 percent local during FY2006; 70 percent national and 30 percent local during FY2007 and 75 percent national and 25 percent local for FY2007 and subsequently.

Effective Date

Upon enactment

Section 405. Reference to Provision Relating to Enhanced Disproportionate Share Hospital (DSH) Payments for Rural Hospitals and Urban Hospitals With Fewer than 100 Beds

Current Law

As explained in Section 302, Medicare makes additional payments to certain acute hospitals that serve a disproportionate share of low-income Medicare and Medicaid patients.

Explanation of Provision

The provision that would increase the adjustment for rural hospitals and under 100 bed urban hospitals that serve a disproportionate share of low-income Medicare and Medicaid patients is included in Section 302.

Effective Date

Upon enactment

Section 406. Reference to Provision Relating to 2-Year Phased-in Increase in the Standardized Amount in Rural and Small Urban Areas to Achieve a Single, Uniform Standardized Amount

Current Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6 percent larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas).

Explanation of Provision

The provision that would increase the standardized amount for other areas to the standardized amount paid to hospitals in large urban areas over a 2-year period is included in Section 303.

Effective Date

Upon enactment

Section 407. Reference to Provision for More Frequent Updates in the Weights Used in the Hospital Market Basket

Current Law

As discussed in Section 304, 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 index (MBI).

Explanation of Provision

The provision that would require more frequent updates in the hospital market basket is included in Section 304.

Effective Date

Upon enactment

Subtitle B- Skilled Nursing facility Services

Sec. 411. Payments for Covered Skilled Nursing Facility Services

Current Law

Medicare uses a system of daily rates to pay for care in a SNF. There are 44 daily rate categories, known as resource utilization groups (RUGS), and each group reflects a different mix and intensity of services, such as skilled nursing care and/or various therapy and other services. BIPA 2000 increased the skilled nursing care component of each RUG by 16.66 percent over and above the RUG rates for SNF care as specified in Tables 3 and 4 of the final rule published in the Federal Register on July 31, 2000, and as subsequently updated. The increase applies to SNF services furnished after April 1, 2001, and before October 1, 2002.

Explanation of Provision

The provision would retain the increase in the nursing component of each RUG at 8 percent. The 8 percent increase is over and above the rates for SNF care as specified in Tables 3 and 4 of the final rule published in the Federal Register on July 31, 2000, and as subsequently updated under section 1888(e)(4)(E)(ii) of the Act. The increase would apply to SNF services furnished on or after October 1, 2002, and before October 1, 2005.

The provision would increase by 128 percent the RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS). The 128 percent increase shall

not apply on or after such date as the Secretary certifies that there is an appropriate change to the SNF case mix adjustment to compensate for increased costs associated with caring for residents with AIDS. The provision would be effective October 1, 2002.

Effective date:

Applies to services furnished on or after October 1, 2003.

Subtitle C- Hospice

Section 421. Coverage of Hospice Consultation Services

Current Law

Current law authorizes coverage of hospice services, in lieu of certain other Medicare benefits, for individuals who elect such coverage.

Explanation of Provision

The provision would authorize coverage of certain physicians' services for certain terminally ill individuals. Persons entitled to these services would be individuals who had not elected the hospice benefit and had 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 a similar service of moderate complexity under the physician fee schedule, excluding the practice expense component.

Effective Date:

Applies to consultation services provided by a hospice program on or after January 1, 2004.

Sec. 422. 10 Percent Increase in Payment for Hospice Care Furnished in a Frontier Area

Current Law

Medicare pays for hospice care for terminally ill beneficiaries at daily rates that differ depending on the level of care, i.e., routine home care, continuous home care, inpatient respite care, and general inpatient care. The labor components of the rates are adjusted by the hospital wage index to reflect differences in area wage levels. BBRA 1999 temporarily increased payment rates for FY 2001 and FY 2002 by 0.5 percent and 0.75 percent respectively. BIPA 2000 increased Medicare daily payment rates for hospice care

furnished on or after April 1, 2001, and during FY 2001 by 5 percent over the rates in effect in FY 2000.

Explanation of Provision

The provision would increase by 10 percent the Medicare daily payment rate for hospice care furnished in a frontier area on or after January 1, 2003, and before January 1, 2008. A frontier area would be defined as a county in which the population density is less than 7 persons per square mile. The GAO would be required to submit a report to Congress, not later than January 1, 2007, on the costs of furnishing hospice care in frontier areas. The report would include recommendations regarding the appropriateness of extending, and modifying, the payment increase provided under this section.

Effective Date:

Enactment

Section 423. Rural Hospice Demonstration Project

Current Law

No provision

Explanation of Provision

The provision would require the Secretary to conduct a demonstration project for the delivery of hospice care for beneficiaries in rural areas. Under the project, beneficiaries who were unable to receive hospice care in the home for lack of an appropriate caregiver would be provided such care in a facility of 20 or fewer beds which offered, within its walls, the full range of covered Medicare hospice benefits. The project could cover no more than three hospice programs over a period of 3 years each. In general, the program would comply with requirements otherwise applicable for hospices except that it would not be required to offer services outside the home nor be subject to the limitation on inpatient days. Payments would be made at the rates otherwise applicable. The Secretary would be required, upon completion of the project, to submit a report to the Congress. The report would include recommendations regarding extension of such project to programs serving rural areas.

Effective Date:

Enactment

Subtitle D -Other Provisions

Section 431. 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 which would examine the use of recovery audit contractors under the Medicare Integrity Program where (1) the contractor could receive payment on a contingent basis; (2) the Secretary could retain a percentage of the amount recovered for the CMS program management account; and (3) the Secretary would examine the efficacy of such use with respect to duplicate payments and coding accuracy as well as other payment policies where inaccurate payments may arise.

The project would cover at least 2 states and 3 contractors for no longer than 3 years. The Secretary would be able to waive Medicare statutory provisions to pay for the contractors' services. The Secretary would not be able to enter into a recovery audit contract with an entity that is a fiscal intermediary, carrier, or Medicare Administrative Contractor. The Secretary would be required to show preference to contracting with entities that have employees with demonstrated proficiency in recovery audits with private insurers or Medicaid programs and have knowledge of Medicare's laws and regulations. Within 6 months of completion, the Secretary would be required to submit a report to Congress on the project's cost savings and include any recommendations on the cost-effectiveness of extending or expanding the project.

Effective Date

Upon enactment

Title V - Provisions Relating to Medicare Part B

Subtitle A - Provisions Relating to Physicians' Services

Section 501. Revisions 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 conversion factor for 2001 was \$38.2581. The conversion factor for 2002 dropped 5.4 percent to \$36.1992.

The law provides a specific formula for calculating the annual update to the conversion factor. Several factors enter into the calculation of the formula. These include: 1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services; 2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services; and 3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced. If expenditures fall short of the target, the update for a future year is increased.

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 percent or more than plus 3 percent.

The update adjustment factor is the sum of: 1) the *prior year adjustment component*, and 2) the *cumulative adjustment component*. The prior year adjustment component is determined by: 1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year; 2) dividing this amount by the actual expenditures for that year; and 3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: 1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period; 2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined; and 3) multiplying that

amount by 0.33. Use of both the prior year adjustment component and the cumulative adjustment component allows any deviation between cumulative actual expenditures and cumulative allowed expenditures to be corrected over several years rather than a single year.

The law also specifies a formula for calculating the SGR. It is based on changes in four factors: 1) estimated changes in input prices for physician services; 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. By November 1 of each year, (using the best data available as of September 1), CMS is required to publish the SGRs for three time periods in the *Federal Register*. These periods are the upcoming year, the current year, and the preceding year. For example, by November 1, 2002, CMS is to publish an estimate of the SGR for CY2003, a revision of the CY2002 SGR estimated in 2001 and a revision of the CY2001 SGR first estimated 2 years earlier and revised 1 year earlier.

The negative update adjustment factor for 2002 reflected the application of the SGR system. Four items had particular importance for the 2002 calculation. First, allowed expenditures under the SGR system declined from earlier estimates, in part because GDP growth was lower than anticipated. Second, claims data for physicians services in the first half of 2001 showed higher than expected spending over the period and raised estimates for all of 2001. Third, certain technical errors in the calculations for previous years (which raised the updates in those years) further reduced the 2002 update. Fourth, underestimates of both the number of fee-for-service beneficiaries, by over one million, and the growth in GDP in 1998 and 1999 resulted in a reduction in cumulative SGR targets. CMS estimates that under current law, the updates for 2003 to 2006 would also be negative, at -5.7 percent in 2003, -5.7 percent in 2004, -2.8 percent in 2005, and -0.1 percent in 2006.

If CMS were to revise the SGR targets to reflect accurate data for the number of fee-for-service beneficiaries and GDP in 1998 and 1999, CMS projects that the updates would be positive from 2003 to 2012. The updates would be 1.0 percent in 2003, 1.4 percent in 2004, 2.3 percent in 2005, and positive, but less than 1.0 percent from 2006 through 2012. CMS claims that it lacks authority to make changes to the 1998 and 1999 SGR targets administratively, despite the fact that these changes would replace the erroneous data currently used in the calculations.

Explanation of Provision

The provision would modify the calculation of the updates for 2003 - 2005. For 2003, the update to the conversion factor would be set at 2 percent.

The calculation for 2004 and 2005 would be modified. When calculating the update adjustment factor for 2004 and 2005, actual 2002 spending would be used as the measure of allowable costs for 2002. In addition, January 1, 2002, rather than April 1, 1996 would be used as the beginning date for calculating the cumulative adjustment component.

The provision would also modify the formula for calculating the sustainable growth rate. For 2003, 2004, and 2005, one-percentage point would be added to the

GDP factor. The provision would also make a permanent change in the computation of the GDP factor, beginning for 2002. It would replace the current factor that measures the one-year change from the preceding year with the annual average change over the preceding 10 years. For 2003 - 2005, the 10-year rolling average GDP would be calculated, and then increased by one percentage point.

The provision would also eliminate the budget neutrality adjustment for 2003 - 2005.

Effective Date:

Enactment

Section 502. 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 are not available for a subsequent period; however, several surveys have shown a decline in the percentage of physicians accepting new Medicare patients.

Explanation of Provision

The provision would require the GAO 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 patients. Within one year of enactment, GAO would be required to submit a report to Congress on this study. 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 provision would require the Secretary 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 a report to Congress, within two years of enactment, on the results of the study.

Effective Date:

Enactment

Section 503. 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

The provision would require MedPAC 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 physicians' services by Medicare beneficiaries; and 5) effect of such refinements on physician participation under the Medicare program. The report would be due within one year of enactment.

Effective Date:

Enactment

Section 511. Competitive Acquisition of Certain Items and Services.

Current Law.

BBA 97 authorized the Secretary to conduct up to 5 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 3 competitive acquisition areas for this purpose. Medicare implemented the first competitive bidding demonstration for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in Polk County, Florida. Multiple suppliers were selected through a competitive bidding process in the Spring of 1999 in five product categories: oxygen equipment and supplies, hospital beds and accessories, enteral nutrition products and supplies, urological supplies, and surgical dressings. Payments under this demonstration began on October 1, 1999, and demonstration prices remained in effect through September 30, 2001.

Medicare implemented a second DMEPOS competitive bidding demonstration in the San Antonio, Texas area (Bexar, Comal, and Guadalupe counties) on February 1, 2001. Multiple suppliers were selected through a competitive bidding process to provide the following product categories: oxygen equipment and supplies, hospital beds and accessories, manual wheelchairs and accessories, general orthotic devices, and nebulizer inhalation drugs. The demonstration prices in the San Antonio, Texas area will remain in effect until December 31, 2002.

Another round of competitive bidding was implemented in Polk County in October 2001. Multiple suppliers were selected through a competitive bidding process to provide the following product categories: oxygen equipment and supplies, hospital beds and accessories, urological supplies, and surgical dressings. Demonstration prices are to remain in effect through September 30, 2002.

Explanation of Provision

The provision would replace the current demonstration authority. It would require the Secretary to establish and implement programs under which competitive acquisition areas were established throughout the United States. The areas could differ for different items and services. The programs would be phased-in over a period of not longer than 3 years with competition under the programs occurring in at least 1/3 of the areas in 2004 and at least 2/3 of the areas in 2005. In carrying out the programs, the Secretary would be permitted to waive provisions of the Federal Acquisition Regulation as are necessary for efficient implementation, other than provisions relating to confidentiality of information or other provisions the Secretary determines are appropriate.

The provision would specify the items and services covered under the competitive acquisition programs as: 1) durable medical equipment paid for by Medicare, except for products used in infusion; and 2) orthotics paid for by Medicare which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit the patient.

The Secretary would be permitted to exempt areas that were not competitive due to low population density. The Secretary would also be able to exempt items and services for which the application of competitive acquisition was not likely to result in significant savings.

The provision would establish program requirements. The Secretary would be required to conduct a competition among entities supplying covered items and services for each competitive acquisition area in which the program was implemented for such items and services. The Secretary could not award a contract to an entity unless the Secretary made the following findings: 1) the entity met quality and financial standards specified by the Secretary or developed by accreditation entities or organizations recognized by the Secretary; 2) total amounts to be paid under the contract (including administrative costs) were expected to be less than what would otherwise be paid; 3) beneficiary access to a choice of multiple providers was maintained; and 4) beneficiary liability was limited to the applicable percentage of the contract award price. The specified quality standards could not

be less than those that would otherwise apply and would include consumer services standards. The Secretary would be required to consult with an expert outside advisory panel composed of an appropriate selection of physicians, practitioners, and suppliers. The panel would review and advise the Secretary concerning quality standards.

The provision would provide that the Secretary would specify the terms and conditions of the contract. The Secretary would be required to rebid contracts at least once every 3 years. The Secretary could limit the number of contractors in an area to the number needed to meet projected demand for the items and services covered under the contract. The Secretary would be required to take into account the ability of bidding entities to furnish the items and services in sufficient quantities to meet anticipated beneficiary needs in the geographic area covered by the contract on a timely basis. The Secretary would award contracts to more than one entity submitting a bid in each area for an item or service. Payments could not be made for services provided by a contractor in a competition area unless the contractor had submitted a bid and the Secretary had awarded a contract to the entity. The Secretary would be authorized to award a contract to an appropriate entity for education, outreach, and complaint services.

The Secretary would be required to submit an annual management report to the Congress which would include information on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction.

The provision would require the Secretary to conduct a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests (including colorectal cancer screening tests) that are furnished without a face-to-face encounter between the individual and the hospital or physician ordering the test. The project would be under the same terms and conditions applicable to durable medical equipment and off the shelf orthotics. The Secretary would be required to submit to the Congress an initial report on the project not later than December 31, 2004. The Secretary would also submit progress and final reports as deemed appropriate.

The provision would specify that any competitive acquisition demonstration project in effect on the day before enactment could continue under the same terms and conditions that were applicable to that project on that date.

The provision would require the GAO to submit a report to Congress that analyses differences in reimbursement between public and private payors for clinical diagnostic laboratory services. The report would be due within 18 months of enactment.

Effective Date:

Enactment

Section 512. Payment for Ambulance Services

Current Law.

Payments for ambulance services under Medicare have traditionally been based on reasonable charges for independent suppliers and reasonable costs for provider-based services. The BBA 97 provided for the replacement of these payment methodologies with a national fee schedule. The Secretary was required to phase-in the fee schedule in an efficient and fair manner. The fee schedule became effective April 1, 2002. By regulation, it is to be phased-in over the April 2002 - January 2006 period. Under the phase-in schedule, a gradually decreasing portion of the payment is to be based on the previously existing payment (reasonable charges or reasonable costs) received by each ambulance and a gradually increasing percentage is to be based on the national fee schedule. In 2002, the blend is 80 percent of ambulance specific payments and 20 percent of the fee schedule. In 2003, the blend is 60 percent of ambulance specific payments and 40 percent of the fee schedule. In 2004, the blend is 40 percent of ambulance specific payments and 20 percent of the fee schedule. In 2005, the blend is 20 percent of ambulance specific payments and 80 percent of the fee schedule. Beginning in 2006, the payment is to be based entirely on the fee schedule.

The fee schedule payment amount equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage greater than 17 miles and up to 50 miles by at least one-half of the additional payment per mile established under the fee schedule for the first 17 miles of transport for services provided before January 1, 2004.

Explanation of Provision

The provision would substitute a new phase-in methodology for the national part of the phase-in and lengthen the phase-in schedule. Under the provision, the national part phase-in calculation would be based on a blend of the national fee schedule and a regional fee schedule or, if higher, the national only phase-in is retained. The regional fee schedule would be established by the Secretary for each of the 9 Census regions using the methodology used for calculating the regional conversion factor and regional mileage rate used for the national fee schedule. It would also use the same payment adjustments and the same relative value units as used for the national fee schedule.

In effect, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. Essentially these fee schedules represent the national fee schedule broken out into 9 separate fee schedules. For example, to construct the national fee schedule, CMS used 1998 data and created a national conversion factor. To construct the regional fee schedules, CMS will use the 1998 data used to create the national fee schedule but will break it out region by region. Using the 1998 data for each region, CMS will create a conversion factor for each region. Some of the conversion factors will be lower than the national conversion factor and some will be higher. CMS will also use the 1998 data for each region to create a loaded mileage base rate for each region.

Under the provision, the regional conversion factor for each region would be adjusted in the same way the national conversion factor is adjusted - the relative value units will be used with each regional conversion factor to create a regional base payment rate for

each level of service. The payment for a given service under the national fee schedule would be compared with the payment under the appropriate regional fee schedule.

In 2003, the blended rate would be based on 20 percent of the national fee schedule and 80 percent of the regional fee schedule. In 2004, the blended rate would be based on 40 percent of the national fee schedule and 60 percent of the regional fee schedule. In 2005, the blended rate would be based on 60 percent of the national fee schedule and 40 percent of the regional fee schedule. In 2006, the blended rate would be based on 80 percent of the national fee schedule and 20 percent of the regional fee schedule. Beginning in 2007, the payment would be based entirely on the national fee schedule. The ambulance specific part of the phase-in remains the same.

The provision would increase mileage payments for certain ground ambulance trips furnished on or after January 1, 2003, and before **January 1, 2008**. Payments for trips above 50 miles would be increased by at least one-quarter of the amount otherwise established under the fee schedule. This increase would apply regardless of where the transportation originated.

Effective Date:

Applies to ambulance services furnished on or after January 1, 2003.

Section 513. 1-Year Extension of Moratorium on Therapy Caps; Provisions Relating to Reports

Current Law

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. The limits did not apply to outpatient therapy services provided by hospitals.

There were two per beneficiary limits. The first was a \$1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second was 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.

BBRA 99 suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. The limits are scheduled to go into effect in 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. The BBRA 99 revised requirements for the BBA 97 report to include recommendations, and required a new study on utilization of therapy services. BBRA 99 required the Secretary to report to Congress on utilization of therapy services by June 30, 2001.

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.

Explanation of Provision

The provision extends the moratorium on application of the therapy caps for an additional year through 2003. It would also require the Secretary to submit the reports required by BBA 97 and BIPA by December 31, 2002.

The provision would require the Secretary 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, 2003, and a final report by September 1, 2003.

The provision would require the GAO 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. The GAO would be required to submit a report to Congress on the study within one year of enactment.

Effective Date:

Enactment

Section 514. Accelerated Implementation of 20 Percent Coinsurance for Hospital Outpatient Department (OPD) Services; Other OPD Provisions

Current Law

BBA 97 provided for the implementation of a prospective payment system (PPS) for hospital outpatient department (OPD) services. This system was implemented August 2000. Under the system, services that are similar clinically and in terms of resource utilization are arranged into groups according to ambulatory payment classifications (APCs). A payment amount is established for each group and is the same for each service in the

group. The payments cover hospital facility and nonphysician personnel costs with adjustments for geographic location of the facility and area wages.

Before implementation of the PPS, beneficiary coinsurance was generally based on 20 percent of the hospital's charges, while the Medicare program based its payments on the hospital's costs. Over time, hospitals' charges grew more quickly than costs; as a result the share paid by beneficiaries grew to about 50 percent. BBA 97 provided for a gradual decrease in the portion paid by beneficiaries. Under the new payment system, coinsurance is set at 20 percent of historical national median charges for all services in the group. For all APC groups with coinsurance rates above 20 percent, the dollar amounts are frozen until the coinsurance represents 20 percent of total payments. MedPAC estimated this process could take multiple decades for certain services.

BBRA 99 limited the coinsurance by placing a dollar cap on the coinsurance for a given service equal to the inpatient hospital deductible. BIPA established an additional coinsurance reduction policy. A cap was placed on coinsurance liability for a single service. Starting April 1, 2001, the cap was 57 percent of the total payment amount for the service. This cap is 55 percent in 2002 and 2003. It is then reduced by 5 percentage points each year over the 2004-2006 period until the limit is 40 percent for each service. During this period, the BBA 97 provision decreasing coinsurance continues to apply as the underlying process.

The law provides for transitional pass-through payments for additional costs of innovative medical devices, drugs, and biologicals.

Explanation of Provision

The provision would modify the BIPA provision to accelerate the reductions in coinsurance. The per service coinsurance cap would be 45 percent in 2004, 40 percent in 2005, 35 percent in 2006 - 2009, 30 percent in 2010, 25 percent in 2011, and 20/ percent in 2012 and thereafter. Thus, by 2012, the coinsurance would be 20 percent for all services.

The provision would remove temperature-monitored cryoablation from the list of cancer therapy drugs and biologicals entitled to pass-through payments.

Effective Date:

Enactment, except provision dealing with temperature-monitored cryoablation applies to payments for services furnished on or after January 1, 2003.

Section 515. Coverage of An Initial Preventive Physical Examination

Current Law

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

Explanation of Provision

The provision would authorize coverage of an initial preventive physical examination. 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 specified by the Secretary in regulations. A covered initial preventive physical examination would be one performed not later than six 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.

Effective Date:

Applies to services furnished on or after January 1, 2004 for individuals whose coverage begins on or after such date.

Section 516. Renal Dialysis Services

Current Law

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospective payment amount for each dialysis treatment. BBRA 99 updated the composite rate by 1.2 percent for dialysis services furnished in 2000 and 1.2 percent for services furnished in 2001. BIPA provided for a 2.4 percent increase in 2001, in lieu of the 1.2 percent provided under BBRA. BIPA specified that the increase would be implemented through the application of two composite rates in 2001, in order to avoid retroactive processing of claims caused by the January 1, 2001 effective date. For services furnished from January - March 2001, the 1.2 percent increase specified under BBRA applied; for the remainder of the year a 2.79 percent transition increase applied. Effective January 1, 2002, the composite rates reverted to the December 31, 2000 rate, increased by 2.4 percent.

BIPA prohibited exceptions to the composite rates, except in the case of facilities that had exceptions for their 2000 rates or who applied for exceptions during the first 6 months of 2001.

A small proportion of ESRD patients uses home dialysis. Currently, the payment system does not vary rates by different methods of treatment.

Explanation of Provision

The provision would increase the composite rate 1.2 percent for services furnished in 2004. The provision would specify that the prohibition on exceptions to the composite rate would not apply to pediatric facilities, as of October 1, 2002, that did not have an exception rate as of that date. Pediatric facilities would be defined as a renal facility at least 50 percent of whose patients were under age 18.

The provision would require the General Accounting Office of the Department of Health and Human Services to submit a report to Congress within one year of enactment. The report would be required to contain: 1) an analysis of the differences in costs of providing renal dialysis services in home settings and facility settings; 2) an assessment of the percentage of overhead costs in home settings and facility settings; and 3) an evaluation of whether the charges for home dialysis equipment and supplies were reasonable and necessary.

Effective Date: Enactment

Title VI - Provisions Relating to Parts A and B

Subtitle A - Home Health Services

Sec. 601. Elimination of 15 Percent Reduction in Payment Rates Under the Prospective Payment System

Current Law

In the first year of the home health PPS (FY 2001), payments to home health agencies were to be calculated so that, in that year, Medicare total spending for home health care would be the same as it would have been had the previous payment system remained in effect, but with the cost of the previous system calculated to include a 15 percent cut to limits on payments per visit and per beneficiary. However, Congress postponed the adjustment to PPS rates based on the 15 percent cut to October 1, 2002, 2 years after the previous payment system had ended.

Explanation of Provision

The provision would eliminate the adjustment to PPS rates based on the 15 percent reduction in the per visit and per beneficiary limits, effective for episodes of home health care concluding on or after October 1, 2001. In addition, the provision would continue to specify that the Secretary could include in the PPS recognition of regional differences or differences based on whether or not home health care services were furnished in an urbanized area or the home health agency was located in an urbanized area.

Effective Date:

Takes effect as if included in amendments made by BIPA.

Sec. 602. Establishment of Reduced Co-payment for a Home Health Service Episode of Care for Certain Beneficiaries

Current Law

Current law does not require beneficiaries to pay any cost-sharing charges, such as a deductible or coinsurance, when they use home health services.

Explanation of Provision

The provision would establish, beginning with 2003, a beneficiary co-payment for each 60-day episode of care. The co-payment would be 1.5 percent of the national average payment per episode in a calendar year as projected by the Secretary before the beginning of the year. (Administrative and judicial review of the average amounts would be prohibited.) The co-payment would be rounded to the nearest multiple of \$5. Unless the Secretary determines otherwise on a timely basis, the co-payment in 2003 would be \$40. Qualified Medicare beneficiaries (low income beneficiaries for whom Medicaid pays the

Medicare premiums, deductibles, and coinsurance), persons dually eligible for both Medicare and Medicaid, and beneficiaries receiving 4 or fewer home health visits in an episode of care would be excluded from the co-payment requirement.

Effective Date:

Enactment

Sec. 603. Update in Home Health Services

Current Law

Under current law, home health PPS amounts are updated annually by the increase in the home health market basket index minus 1.1 percentage points in FY 2002 and FY 2003 and by the full increase in the market basket index in subsequent years.

Current law also provides payments to home health agencies for a outlier of home health patients (those for whom care is unusually costly) over and above the PPS amount, but the total amount of the additional payment or payment adjustments in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made in such year.

Explanation of Provision

The provision would change the implementation updates to the home health PPS amounts from the start of a fiscal year to the start of a calendar year. It would increase payments by 2.0 percentage points at the start of 2003; by 1.0 percentage point for 2004; and by the increase in the home health market basket index minus 0.8 percentage point for 2005.

The provision would limit the total amount of outlier payments or payment adjustments for home health care in a fiscal year to no more than 3 percent of total projected payments, beginning in 2003.

Effective Date:

Applies to years beginning with 2003.

Section 604. OASIS Task Force; Suspension of Certain Oasis Data Collection Requirements Pending Task Force Submittal of Report

Current Law

BBA 97 authorized the Secretary to require all home health agencies to submit additional information that the Secretary considered necessary for development of a reliable case mix system. The Secretary has implemented an Outcome and Assessment

Information Set (OASIS). Home health agencies are required to collect OASIS data and report information to their State survey agency.

Explanation of Provision

The provision would require the secretary to establish and appoint a task force, known as the OASIS Task Force. The task force would be required to examine the data collection and reporting requirements under OASIS. It would be composed of staff from the Centers for Medicare and Medicaid Services with expertise in post-acute care; representatives of home health agencies, health care professionals and research and health quality experts outside the Federal government with experience in post-acute care, and advocates for individuals requiring home health services.

The task force would review and make recommendations to the Secretary regarding changes in OASIS to improve and simplify data collection for the purposes of assessing the quality of home health services and providing consistency in payment for such services under the prospective payment system. The task force would report its findings and recommendations to the Secretary within 18 months of enactment and would terminate 60 days after submission of the report. The task force would not be subject to the provisions of the Federal Advisory Committee Act.

The provision would prohibit the Secretary from requiring home health agencies to gather or submit information on persons not eligible for Medicare or Medicaid benefits for the period beginning January 1, 2003 and ending on the last day of the second month following submission of the task force report.

Effective date:

Enactment

Section 605. MedPAC Study on Medicare Margins of Home Health Agencies

Current Law

No provision

Explanation of Provision

The provision would require MedPAC to conduct a study of payment margins of home health agencies under the prospective payment system. The study would examine whether systematic differences in payment margins are related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report on the study to Congress, within two years of enactment.

Effective Date:

Enactment

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Subtitle B - Direct Graduate Medical Education

Section 611. 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 hospital's number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70 percent of a geographically adjusted national average amount. Hospitals with per resident amounts above 140 percent 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. Hospitals with per resident amounts between 70 percent and 140 percent 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

Hospitals with per resident amounts about 140 percent of the geographically adjusted national average amount in FY2001 or FY2002 would receive that payment amount through FY2012.

Effective Date

Upon enactment

Section 612. Redistribution of Unused Resident Positions

Current Law

Medicare's graduate medical education payment to teaching hospital is based on its updated cost per resident, the 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.

Medicare limits the total number of residents in a hospital's approved teaching programs that are reimbursed based on the number that were reported by the hospital for the cost reporting period ending in calendar year 1996. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply

to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130 percent of the number of residents allowed by their cap. The cap is calculated as a 3-year rolling average, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years.

Explanation of Provision

The Secretary will determine if a teaching hospital's current number of residents (reference level) is less than applicable resident limit. If so, 25 percent of the unused residency payments would be retained by the hospital and 75 percent redistributed. 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, 2001. 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, 2002.

The Secretary would be authorized to increase the applicable resident limits for other hospitals. 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, 2004. 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 hospitals. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. A hospital's indirect medical education (IME) limit would be treated in the same way as changes to the aggregate limit except any resulting increase in resident counts would not affect a hospital's IME payments.

These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs.

The Secretary would be required to submit a report to Congress no later than July 1, 2004 that recommends whether to extend the application deadline for increases in resident limits.

Effective Date

Upon enactment

Subtitle C - Other Provisions

Section 621. Modifications to Medicare Payment Advisory Commission (MedPAC)

Current Law

The Medicare Payment Advisory Commission (MedPAC) is required to review Medicare payment policies, make recommendations, and issue annual reports with respect to the Medicare +Choice program, Medicare's fee-for-service, and the interaction of these policies with the overall health care delivery system. MedPAC is composed of 17 members appointed by the Comptroller General to include individuals who are nationally recognized for their expertise in health finance and economics, actuarial science, health facility management, health plans and other related fields and who will provide a mix of broad geographic representation and a balance between rural and urban interests. Commission members include but are not limited to physicians, health professionals, employers, and other individuals skilled in health services and health economics research. Representatives of the elderly and consumers are also included in MedPAC. Individuals who are directly involved in the provision or management of the delivery of Medicare covered items or services are not to constitute a majority of the Commission.

Explanation of Provision

MedPAC would be required to examine the budget consequences of its recommendations prior to issuing such recommendations, either directly or by consulting appropriate expert entities. MedPAC would be required to submit a 2 reports to Congress no later than June 1, 2003 on: (1) the need and availability of data to determine the financial circumstances, including solvency, of hospitals and other Medicare providers; and (2) the investments and capital financing of participating hospitals and related foundations which would be based on data from Form 990 of the Internal Revenue Service.

Effective Date

Upon enactment

Section 622. Demonstration Project for Disease Management for Certain Medicare Beneficiaries with Diabetes

Current Law

BIPA required the Secretary to conduct a demonstration project targeting certain Medicare fee-for-service beneficiaries with diagnosed, advanced stage congestive heart failure, diabetes, or coronary heart disease to examine the impact on costs and health outcomes of applying disease management services, supplemented with prescription drug coverage. No more than 30,000 beneficiaries may participate at any time and the project must result in a net reduction in aggregate Medicare expenditures. CMS published a notice requesting proposals for this project on February 22, 2002.

Explanation of Provision

6/18/2002 12:28 PM

The Secretary would be required to conduct a demonstration project, for up to 3 years, to examine the impact on costs and health outcomes of applying disease management to Hispanic Medicare beneficiaries who are diagnosed with diabetes. No more than 30,000 beneficiaries would be able to participate at any time. The beneficiaries would meet specified medical criteria, would have their physicians approve of their participation in the project and would not be enrolled in a Medicare+Choice plan. These participants would be eligible for disease management services related to their diabetes and, except for modest cost sharing provided for by the project, would have all their prescription drug costs covered without regard to whether the drugs relate to the diabetes. The Secretary would carry out the project through contracts with up to 3 disease management organizations that have demonstrated improved health outcomes and reduced aggregate expenditures with such programs. Under the contracts, the organizations would be required to provide prescription drug coverage, would be paid a fee negotiated by the Secretary so that Medicare expenditures would not increase but rather, to the extent practicable, would decrease. The organization would be required to guarantee that Medicare expenditures would not increase through an appropriate arrangement with a reinsurance company. Payments to these organizations would be made in appropriate proportion from the Medicare trust funds.

The Secretary would be required to establish a working group of employees of the Department of Health and Human Services to become the focal point of all disease management programs in the agency. Specifically, the working group would: (1) oversee the new diabetes disease management project; (2) establish policy and criteria for Medicare disease management programs; (3) identify targeted medical conditions and individuals; (4) select areas for disease management programs; (5) monitor health outcomes under the programs; (6) measure the effectiveness of such programs with respect to budget neutrality requirements; and (7) serve as a focal point for dissemination of information on all CMS run disease management programs. Participants would be offered certain protections for the period of the demonstration project that are afforded to Medicare beneficiaries enrolled in Medicare+Choice plans with respect to their existing Medicare supplemental insurance policies. The Secretary would be required to waive Medicare provisions as necessary to provide for payment for the disease management program.

The Secretary would be required to submit an interim report to Congress on the project no later than 2 years after the date it is first implemented; a final report would be due 6 months after its completion. These reports would include information on the impact of the project on costs and health outcomes as well as recommendations on the cost-effectiveness of extending or expanding the project.

GAO would be required to submit a report to Congress that compares Medicare's disease management programs with those conducted in the private sectors and identifies the cost effectiveness of such programs. The report would be due no later than 18 months from the date of enactment.

Effective Date

Upon enactment

Section 623. Demonstration Project for Medical Adult Day Care

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 percent 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

Title VII - Medicare Benefits Administration

Section 701. Establishment of Medicare Benefits Administration

Current Law

The Medicare statute requires that the Administrator of the Health Care Financing Administration (HCFA, now known as CMS) be appointed by the President with the advice and consent of the Senate. The HCFA Administrator is paid at level III 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. To be appointed as actuary, an individual must possess demonstrated experience and superior expertise in actuarial sciences, exercise duties that are appropriate to the office, and act in accordance with professional standards of actuarial independence. The Medicare statute specifies certain responsibilities for this position with respect to the Medicare+Choice program. Specifically, annual Medicare+Choice capitation rates are computed and published by the Secretary, through the Chief Actuary of HCFA; adjustments to the Medicare+Choice payment rates that reflect changes in coverage are based on a cost analysis by the CMS' Chief Actuary; and the assumptions and data in the adjusted community rating submitted by Medicare+Choice plans are reviewed and assessed by CMS' Chief Actuary. The Chief Actuary may be removed only for cause.

Explanation of Provision

The Medicare Benefits Administration (MBA) would be an agency established within HHS that would be headed by an Administrator appointed by the President with the advice and consent of the Senate for a 5-year term. If a successor is not appointed immediately, the existing Administrator would continue in office. When the subsequent administrator was appointed, that person would serve as Administrator only for the remainder of the term. The Administrator who would be paid at level III of the Executive Schedule would report directly to the Secretary. The Secretary would ensure appropriate coordination between the Administrators of MBA and CMS.

The Administrator would be (1) responsible for all the duties of the MBA; (2) would have control over all related personnel and activities; (3) able to establish, alter, consolidate or discontinue organizational units except as further specified; (4) able to assign duties and delegate the authority to act to such officers and employees of MBA (these actions, within the limitation of such delegations, shall have the same force as if performed by the Administrator); and (5) able to prescribe necessary rules and regulations to carry out the functions of the MBA (subject to the rulemaking procedures of the section 553 of Title 5 of the United States Code, the Administrative Procedure Act).

The Deputy Administrator of MBA who would be paid at level IV of the Executive Schedule would be appointed by the President with the advice and consent of the Senate for a 5-year term. If a successor is not appointed immediately, the existing Deputy Administrator would continue in office. The subsequent deputy administrator would serve in

that capacity only for the remainder of the term. The Deputy would perform duties as assigned by the Administrator and would act as Acting Administrator during any absence or disability, unless the President designates another officer of the Government as Acting Administrator in the event of a vacancy in that office.

The MBA Administrator would 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. To be appointed as Chief Actuary, an individual must possess demonstrated experience and superior expertise in actuarial sciences, exercise duties that are appropriate to the office, and act in accordance with professional standards of actuarial independence. The Chief Actuary would be able to be removed only for cause.

The MBA Administrator would be responsible for carrying out the duties associated with Parts C and D of Medicare including (1) negotiating, entering into, and enforcing Medicare+Choice contracts, including prescription drug coverage; (2) negotiating, entering into, and enforcing contracts with PDP sponsors for prescription drug coverage; (3) other duties provided for under Parts C or D, including certain demonstration projects; and (4) other duties relating to the Medicare prescription drug discount card endorsement program. In carrying out the duties with respect to prescription drug coverage, the Administrator may not (1) require a particular formulary or institute a price structure for reimbursement of covered outpatient drugs; (2) interfere with negotiations between PDP sponsors and Medicare +Choice organizations, drug manufacturers, wholesalers, or other suppliers of outpatient drugs; and (3) interfere with the competitive nature of providing coverage through such sponsors and organizations. The Administrator would be required to submit to Congress a report on the administration of Parts C and D by March 31st of each year.

The MBA Administrator would be able to hire employees and officers with the necessary expertise to negotiate private sector contracts without regard to chapter 31 of Title 5 (other than 3110 and 3112) of the United States Code (relating to hiring of federal personnel and other employment matters) with the approval of the Secretary. The MBA staff would be paid without regard to the provisions of chapters 51 (other than 5101) and 53 (other than 5301) of Title 5 of the United States Code (relating to classification and pay schedules), but in no case would these employees receive more than the basic pay for level IV of the Executive Schedule. The MBA Administrator would not be able to employ more FTE's to perform a specific function than were previously used by CMS on the date of enactment to perform that function.

The Secretary and the Administrators of CMS and MBA would establish an appropriate transition of responsibility to redelegate the administration of Medicare Part C from CMS to MBA. The Secretary would ensure that the CMS Administrator transfer necessary data and information to the MBA Administrator. To the extent that a responsibility is transferred from the Secretary or from CMS to the MBA Administrator, any statutory reference with respect to such a responsibility is deemed to be a reference to the MBA Administrator.

The Secretary would be required to establish an Office of Beneficiary Assistance as a separate operating division within the MBA to (1) make Medicare eligibility

determinations, and (2) enroll Medicare beneficiaries. The Office of Beneficiary Assistance would disseminate information on benefits and payment limitations (including cost-sharing requirements, stop-loss provisions, and formulary restrictions) under Parts C and D as well as benefits and payment limitations (including information on Medicare supplemental plans) under Parts A and B. The information would be disseminated by mail, through an internet site, and through a toll free telephone number in a way so that beneficiaries would be able to compare benefits under Parts A, B, D and supplemental insurance with benefits offered by Medicare +Choice plans. Information on the grievance and appeals procedures for all parts of Medicare would be disseminated as well.

A Medicare Policy Advisory Board would be established within the MBA to advise, consult with, and make recommendations to the MBA Administrator with respect to Parts C and D. The Board would consist of 7 members who serve a 3-year term and who are appointed as follows: 3 members would be appointed by the President; 2 members would be appointed by the Speaker of the House with the advice of the chairmen and ranking minority members of the committees of jurisdiction and 2 members would be appointed by the President pro tempore of the Senate with the advice of chairman and ranking minority member of the committee of jurisdiction. The members would be chosen on the basis of their integrity, objectivity, and judgement as well as their experience with healthcare benefits management. No officer or employee of the United States would be able to serve on the Board. Board members would be compensated for each day of work (including time spent traveling) at a rates equal to level IV of the Executive Schedule.

The terms of the initial appointees would be established on a staggered basis. As designated by the President at time of appointment, 1 member would have a 1-year term; 3 members would have a 2-year term; and 3 members would have a 3-year term. No individual would be able to serve³ on the Board for more than 8 years. Any individual appointed to fill a vacancy on the Board would serve for the remainder of the term. A Board member would be able to serve after the expiration of that member's term until a successor is appointed. A vacancy in the Board would be filled in the manner in which the original appointment was made.

The Chair of the Board would be elected by the members to serve 3 years. The Board would meet at least 3 times during each fiscal year at the call of the chair. The Board would have a Director who would be appointed by the Chair. The Director would be able to appoint personnel, without regard to chapter 31 of Title 5 USC, but with the Board's approval. The staff would be paid without regard to the provisions of chapters 51 and 53 of Title 5 USC (relating to classification and pay schedules), but in no case would these employees receive more than the basic pay for level IV of the Executive Schedule.

The Board would submit reports to Congress and the MBA Administrator that would contain recommendations for legislative or administrative changes to improve administration in such areas as fostering competition, beneficiary education, risk-adjustment methods, disease management programs, and access in rural areas. The Board would submit these reports directly to Congress without prior review and approval to any federal officer or agency. No later than 90 days after a report is submitted, the MBA Administrator would be required to submit an analysis of the Board's recommendations to Congress and the President. This analysis would also be published in the *Federal Register*.

The MBA Administrator would be required to make necessary information available to the Board. The Board would be able to contract with and compensate government and private agencies without regard to sections 3709 of the Revised Statutes (41 USC 5). Necessary sums would be authorized to be appropriated from the Medicare trust funds, including the Medicare Prescription Drug Account.

The MBA Administrator would become an ex-officio member of the Board of Trustees of the Medicare Trust Funds. The Administrator of CMS would be paid at level III of the Executive Schedule.

Effective Dates

The Administrator and Deputy Administrator would be appointed on or after March 1, 2003. The MBA Administrator would be responsible for Medicare enrollment and eligibility determinations beginning on or after January 1, 2005. Before the MBA Administrator would be appointed, the Secretary would provide for the conduct of any of the Administrator's responsibilities that are otherwise provided for under law. On January 1, 2003, the MBA Administrator would become an ex-officio member of the Board of Trustees of the Medicare Trust Funds. The Administrator of CMS would be paid at level III of the Executive Schedule, effective on January 1, 2003.

TITLE VIII—REGULATORY REDUCTION AND CONTRACTING REFORM

Section 801. Construction; Definition of Supplier.

Current Law. No provision.

Explanation of Provisions. None of the provisions shall be construed to (1) compromise the existing legal remedies for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent the Department of Health and Human Services (HHS) from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare’s administrative contracting functions (as provided for in this bill) would not consolidate the Federal Hospital Insurance Trust Fund, which pays for Part A, services and the Federal Supplementary Medical Insurance Trust fund, which pays for Part B services. The bill notes that this administrative consolidation does not reflect any position on that issue.

The term “supplier” refers to a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under title XVIII of the Social Security Act.

Effective Date. Upon enactment.

Reason for Change. The Committees are committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

SUBTITLE A—REGULATORY REFORM

Section 802. Issuance of Regulations.

(a) Consolidation of Promulgation to Once a Month.

Current Law. The Secretary is required to prescribe regulations that are necessary to administer Parts A and B of the Medicare program. No rule, requirement or policy statement (other than a national coverage determination) that establishes or changes a substantive legal standard that determines Medicare’s scope of benefits, level of payment, or eligibility of individuals, entities or organizations to receive benefits or furnish services can take effect unless it is promulgated by regulation. The Secretary must publish a proposed regulation in the *Federal Register*, with at least 60 days to solicit public comment, before issuing the final regulation with the following exceptions: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementation of a provision is less than 150

days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of Title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest. The Secretary must publish in the *Federal Register* no less frequently than every three months a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provisions. The Secretary would be required to issue proposed or final regulations (including interim final regulations) on one business day of every month, unless the Secretary finds that publication on other dates is required to comply with Medicare law or that this restriction is contrary to the public interest. In such instances, the Secretary would be required to include an explanation of such a finding when the regulations are issued. The Secretary would be required to coordinate the issuance of new regulations relating to a category of provider or supplier based on an analysis of the collective impact of the regulatory changes on such category. No later than three years after enactment, the Comptroller General of the US General Accounting Office would be required to report to Congress on the feasibility of issuing regulations only on one day in each calendar quarter.

Effective Date. The provisions would apply to regulations issued 30 days after enactment.

Reason for Change. The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring regulations to be released on a certain date, providers and suppliers will be better able to keep informed of program changes. The Secretary may stagger the notice and comment periods of regulations issued on the same day, so that the comment deadlines for these regulations do not occur simultaneously, in order to ensure that interested parties have the opportunity to comment on multiple regulations.

The collective impact provision ensures that the Department will consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

(b) Regular Timeline for Publication of Final Rules.

Current Law. See above. The Secretary must publish in the *Federal Register* no less frequently than every three months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines which are promulgated to carry out Medicare's law.

Explanation of Provisions. The Secretary, in consultation with the Director of the Office of Management and Budget, would establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The timeline may vary by regulation due to complexity, number and scope of comments received and other factors, but would not be longer than three years unless there are exceptional circumstances. If the Secretary intends to vary a regulation's timeline, a notice of the different timeline would be required to be published in the *Federal Register*. This notice would include a brief explanation of the justification for such variation. If the timeline established for an interim final regulation expires without promulgation of a final regulation (including the public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that includes an explanation for not complying with the deadlines. This provision applies to the regular timelines and any subsequent 1-year extension to the timeline. If a notice of continuation is published, the regular timeline or the timeline as previously extended would be extended for 1 additional year. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable timeline.

Effective Date. Upon enactment. The Secretary would be required to provide for a transition period for previously published interim final regulations.

Reason for Change. Numerous regulations have been issued by CMS as interim final regulations and never finalized. This injects an element of uncertainty into the regulation in question, and it precludes the ability of CMS to incorporate changes based on comments received by interested parties into a final regulation. The provision ensures that proposed regulations will move through the process of finalization in a predictable and timely manner with input from affected parties.

(c) Limitation on New Matter in Final Regulations.

Current Law. No provision.

Explanation of Provisions. A provision in a final regulation that is not a logical outgrowth of the proposed regulation (including an interim final regulation) would be treated as a proposed regulation and would not take effect without a separate public comment period followed by its publication as a final regulation.

Effective Date. Final regulations published on or after enactment.

Reason for Change. The provision ensures that interested parties will be given an opportunity to comment on issues addressed in regulations before they take effect. The Committees recognize that proposed regulations for annual payment updates for providers and suppliers include proposed overall payment updates, and that specific payment amounts for specific codes or specific payment areas are not typically included until final rules. The Committees do not intend to change past custom to recognize such details in final rules as a “logical outgrowth” of proposed rules. It is the Committees’ intent that if the Secretary publishes a final rulemaking document which includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking, such provision will not take effect until there is further opportunity for public comment and a publication of the provision again as a final regulation.

Section 803. Compliance with Changes in Regulations and Policies.

(a) No Retroactive Application of Substantive Changes.

Current Law. No provision.

Explanation of Provisions. A substantive change in a regulatory or a subregulatory issuance would not be applied retroactively to items or services, unless the Secretary determines that retroactive application (1) would be necessary to comply with statutory requirements; or (2) would be beneficial to the public interest.

Effective Date. For substantive changes issued on or after enactment.

Reason for Change. This provision will ensure that Medicare’s rules are not generally applied retroactively.

(b) Timeline for Compliance with Substantive Changes after Notice.

Current Law. No provision.

Explanation of Provisions. A substantive change would not become effective before 30 days after the date the change is issued or published. The Secretary would be able to waive the 30-day period to comply with statutory requirements or if such waiver is in the public interest. If an earlier date is established, the Secretary would be required to include a brief explanation of such finding in the issuance or publication of the substantive change. No compliance action would be permitted against a provider or supplier for goods and services furnished before the effective date of the substantive change.

Effective Date. For compliance actions undertaken on or after enactment.

Reason for Change. This provision will ensure providers and suppliers have sufficient **time to make any changes to systems needed to comply with changes in regulations.**

(c) Reliance on Guidance.

Current Law. No provision.

Explanation of Provisions. (1) The provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor. (3) the guidance is inaccurate. A provider or supplier who reasonably relied on erroneous guidance would not be subject to any sanction or penalties, including repayment. This provision would not prevent recoupment or repayment (without additional penalty) if the overpayment was solely the result of a clerical or technical operational error.

Effective Date. Upon enactment, but would not apply to sanctions where notice was provided on or before enactment.

Reason for Change. This provision will ensure that providers and suppliers who, in good faith based, on the information received from contractors, will not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided by their Medicare contractors.

Section 804. Reports and Studies Relating to Regulatory Reform.

Current Law. No provision.

Explanation of Provisions. The legislation has two studies in this area. First, the Comptroller General of the United States (GAO) would be required to conduct a study to determine the appropriateness and feasibility of providing the authority to the Secretary to issue legally binding advisory opinions on the interpretation and application of Medicare regulations. The study would examine the appropriate time frame for issuing the decisions as well as the need for additional staff and funding. GAO would submit the study to Congress by January 1, 2004.

Second, the Secretary would be required to report to Congress on the administration of the Medicare program and inconsistencies among existing Medicare statutory or regulatory provisions. The report would include (1) information from beneficiaries, providers, suppliers, Medicare Beneficiary and Provider Ombudsmen (established in this legislation), and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and (3) recommendations from the Secretary for appropriate legislation or administrative actions. The report would be due no later than two years after enactment and every two thereafter.

Effective Date. Upon enactment.

Reason for Change. The Committees are interested in receiving additional information regarding both advisory opinions and inconsistencies in Medicare regulations.

SUBTITLE B—CONTRACTING REFORM

Section 811. Increased Flexibility in Medicare Administration.

(a) Consolidation and Flexibility in Medicare Administration.

Current Law. Section 1816 of the Social Security Act authorizes the Secretary to establish agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. Section 1842 of the Act authorizes the Secretary to enter into contracts 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. Section 1893 authorizes the Secretary to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established. Specifically, the contracts are awarded without full and open competition; generally must cover the range of claims processing and related activities; cannot be terminated without cause and without the opportunity for a public hearing; and incorporate cost-based, not performance-based, reimbursement methods with no incentive bonuses.

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 Provisions. The legislation would add Section 1874A to the Social Security Act to permit the Secretary to enter into contracts with any entity to serve as a Medicare administrative contractor. These contractors would perform or secure the performance (through subcontracting) of some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; provide consultative services; communicate with providers and suppliers; educate and offer technical assistance to providers; and perform additional functions as necessary. An entity eligible to enter into a contract with respect to the performance of a particular function as an entity would (1) have demonstrated capability to carry out such function; (2) comply with conflict of interest standards that are generally applicable under Federal acquisition and procurement; (3) have sufficient assets to financially support the performance of such functions and (4) meet other requirements imposed by the Secretary. The claims processing jurisdiction of Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function is the entity that has the contract to perform that function for any given beneficiary, any given provider or supplier, or class of same.

The Federal Acquisition Rules (FAR) would apply to Medicare administration contracts except to the extent it is inconsistent with a specific Medicare requirement. The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract and would take into account performance quality, price, and other factors. The Secretary would be able to renew a contract for up to five years without regard to statutory requirements concerning competitive contracting if the entity has met or exceeded specified performance standards. The Secretary would be able to transfer functions among contractors consistent with these provisions. The Secretary would be required to (1) ensure that performance quality is considered in such transfers and (2) provide notice of such transfer (in the *Federal Register* or otherwise) that describes the transferred functions, the affected providers and suppliers, and includes contractor contact information.

The Secretary would be required to (1) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and (2) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. In developing the performance standards, the Secretary would be able to consult with providers and suppliers, organizations representing Medicare beneficiaries, and Medicare contractors. In developing the performance requirements for Medicare administrative contractors,

the Secretary may include satisfaction of beneficiaries as a standard for measuring performance. The Secretary would be required to contract only with those entities that will (1) perform efficiently and effectively; (2) meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) agree to furnish timely and necessary data; and (4) maintain and provide access to necessary records and data.

The performance requirements would be (1) set forth in the contract between the Secretary and the appropriate Medicare contractor; (2) used to evaluate contractor performance; and (3) consistent with the contract's written statement of work. The statement of work and contract are public documents. A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the inclusion of the existing standards in effect for timeliness of reviews, reconsiderations and exemption decisions.

The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of the identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of durable medical equipment. An entity with a MIP contract would not be treated as a Medicare administrative contractor, simply because it has a MIP contract.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to provide a surety bond to the United States in an amount established by the Secretary. It is the intent of Congress that the definition of a surety bond in this instance includes fidelity bonds and the Secretary has the authority to request fidelity bonds. The contractor's employee who disburses payments is not liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon an authorization from the certifying employee and the authorization meets the internal control standards established by GAO. The contractor is not liable for payments made by its certifying or disbursing officers unless in connection with such payments or in the supervision or selection of such officers the contractor acted with gross negligence.

The Secretary would be able to indemnify a Medicare administrative contractor, subcontractor, or employee who is made a party to any judicial or administrative proceeding arising from the claims administration process to an appropriate extent as determined by the Secretary and specified in the contract. Indemnification in this case may include payment of judgments, certain settlements, awards and costs (including reasonable legal expenses). Settlement proposals would not be negotiated or compromised without prior written approval by the Secretary. The Secretary would not be able to provide any indemnification if the liability arises directly from conduct that is

determined in the proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided before such determination is made and the contractor's conduct is found to be, the contractor would reimburse the Secretary for these costs. The provisions would not change common law immunity available to the Medicare contractor or other party, or permit the payment of costs not otherwise allowable, reasonable or allocable under the Federal Acquisition Regulation.

Effective Date. See subsection (d).

Reason for Change. Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

Medicare contracting is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare contracting is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare contracting is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers.

(b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries).

Current Law. Section 1816 of the Social Security Act establishes the provider nomination process, the contracting specifications, and performance standards for fiscal intermediaries that currently contract with Medicare to process claims and perform other related administrative activities for institutional providers.

Explanation of Provisions. The provisions establish that the activities of fiscal intermediaries in administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Effective Date. See subsection (d).

Reason for Change. These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which hospitals have rarely been allowed to exercise in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

(c) Conforming Amendments to Section 1842 (Relating to Carriers).

Current Law. Section 1842 of the Social Security Act establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities.

Explanation of Provisions. The provisions would establish that the activities of carriers administering Medicare would be conducted through contracts with Medicare administrative contractors as set forth in subsection (a). Certain instructions including those pertaining to nursing facilities payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both a cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. Since the Carrier fair hearing requirement were eliminated in BIPA, the requirements for the hearing are eliminated to conform with existing law. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

The Committee directs the Secretary's attention to the provision of the Balanced Budget Act of 1997 requiring CMS to designate no more than five regional carriers to process laboratory claims.

This provision was passed in order to streamline the processing of laboratory claims and was to be implemented by July 1, 1999, but CMS has taken no action to date. In consultation with the clinical laboratory industry, CMS may consider other potential solutions, including the designation of a single contractor to process all claims of laboratory entities operating in more than one state. CMS is directed to report back to the Committee on Ways and Means and the Committee on Energy and Commerce within three months detailing the action it has taken to implement this directive.

Effective Date. See subsection (d).

Reason for Change. The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers, which is intended to reduce administrative costs and improve quality. Since the carrier fair hearing requirement was eliminated in previous legislation, the requirements for the hearing are eliminated in order to conform with existing law.

(d) Effective Date; Transition Rule.

Current Law. No provision.

Explanation of Provisions. Except as otherwise provided in this subsection, the provisions in this section would be effective October 1, 2004. The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis to transition from the contracts established under sections 1816 and 1842 of the Social Security Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2009. The requirement that MIP contracts be awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. The MIP contracting exception that allows agreements according to current law would be deemed to be a contract established under the new authority of 1874A and would continue existing activities. The Secretary has the authority to recognize the appropriate termination costs of the current contractors during the transition from cost contracts to competitively bid contracts.

(e) References.

Current Law. No provision.

Explanation of Provisions. After this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

(f) Reports on Implementation.

Current Law. No provision.

Explanation of Provisions. The Secretary would submit an implementation plan to Congress and GAO no later than October 1, 2003. GAO would evaluate the plan and include appropriate recommendations no later than six months after the plan is received. No later than October 1, 2007, the Secretary would be required to submit a status report to Congress including (1) the number of contracts that have been competitively bid; (2) the distribution of functions among contracts and contractors; (3) a timeline for complete transition to full competition; and (4) a detailed description of changes to contractor oversight and management.

Effective Dates. Upon enactment.

Section 812. Requirements for Information Security.

Current Law. No provision.

Explanation of Provisions. Medicare administrative contractors that determine and make payments would be required to implement a contractor-wide information security program that meets the requirements imposed on Federal agencies to ensure the security, integrity, confidentiality, authenticity, and availability of operational data and systems supporting operations. An annual audit of the information security at each Medicare administrative contractor: (1) would be performed by an independent entity that meets the independence requirements specified by the Inspector General (OIG) in HHS; and (2) would test the effectiveness of the information security techniques for an appropriate subset of the contractor's systems. An audit of new contractors (those that have not been fiscal intermediaries or carriers) would be required prior to the start of their performing Medicare payment functions. An audit of existing contractors (those that are now fiscal intermediaries and carriers) would be required to be completed within one year from enactment. The results of the audits would be reported promptly to the OIG, which will submit a report annually to Congress. These provisions would be equally applicable to fiscal intermediaries and carriers as to Medicare administrative contractors.

Effective Date. Upon enactment.

Reason for Change. The increased reliance by the Federal government on the Internet and related telecommunications technologies has resulted in enhanced inter-connectivity and interdependencies associated with Federal computer systems and between federal and private computer systems. Over the past several years, this inter-connectivity or Anetworking@ has resulted in increased security vulnerabilities that have put at greater risk computer systems and data that are critical to ensuring national and economic security and public health and welfare, including sensitive, non-public information that is collected and maintained by CMS and its business partners.

On May 23, 2001, the Committee on Energy and Commerce held a hearing to investigate the extent to which sensitive, non-public information related to collecting and processing Medicare claims was adequately secure on the computer networks operated by CMS and its business partners, including Medicare contractors. That investigation revealed significant weaknesses, which the agency has been working to address. Some of the computer security concerns identified include weak password management, inadequate access controls, excessive user privileges, improper network configurations, and inadequate testing of critical systems. In addition, the OIG conducted assessments of financial controls - including electronic data processing controls - at CMS and its major Medicare contractors, and, in every year since 1997, the OIG has identified computer security controls to be a material weakness at both CMS and the Medicare contractors reviewed.

Section 812 is intended to assist CMS in identifying and working with contractors to address potential security deficiencies in order to ensure that sensitive, non-public information related to the processing of Medicare claims is adequately secure from unauthorized access, misuse, or destruction.

SUBTITLE C—EDUCATION AND OUTREACH

Section 821. Provider Education and Technical Assistance.

(a) Coordination of Education Funding.

Current Law. Medicare's provider education activities are funded through the program management appropriation and through the 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 (1) coordinate the educational activities provided through the Medicare administrative and MIP contractors and (2) to submit an evaluation to Congress, no later than October 1, 2003, on actions taken to coordinate the funding of provider education.

Effective Date. Upon enactment.

Reason for Change. This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion of Medicare Integrity Program funds spent on provider education.

(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 develop and implement a methodology to measure the specific claims payment error rates at each Medicare administrative contractor. This methodology would apply to existing fiscal intermediaries and carriers in the same manner as it applies to Medicare administrative contractors. No later than October 1, 2003, GAO would submit to Congress and to the Secretary a report on the adequacy of the methodology, including recommendations as appropriate. No later than October 1, 2003, the Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs and (2) whether methodology should be used as a basis of contractors' performance bonuses.

Effective Date. As specified.

Reason for Change. This provision would ensure that the Department monitors contractor performance for claims payment error rates, and it would identify best practices for provider education - all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements. It is the Committees' intent that, in consultation with representatives of providers and suppliers, the Secretary shall identify and encourage best practices developed by contractors for educating providers and suppliers.

(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 communication strategy with beneficiaries, providers and suppliers. Each Medicare administrative contractor would be required to (1) provide general written responses (which may be through electronic transmission) in a clear, concise and accurate manner to written inquiries from beneficiaries, providers and suppliers within 45 business days; (2) provide a toll-free telephone number where these interested parties may obtain billing, coding, claims, coverage and other appropriate Medicare information; (3) maintain a system for identifying which employee provided both the written and oral information; and (4) monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public the standards used to monitor the accuracy, consistency, and timeliness of information provided in response to written and telephone inquiries. The standards would be developed in consultation with provider, supplier, and beneficiary organizations and would be consistent with the contractors' performance requirements. The Secretary would be able to directly monitor the quality of the information so provided. These provisions would also apply to existing fiscal intermediaries and carriers.

Effective Date. By October 1, 2003.

Reason for Change. This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training.

Current Law. In FY2000, \$54.8 million was spent on provider education and training activities: about \$43 million came from the program management appropriation and about \$12 million came from the Provider Education and Training component of MIP. In FY2001, about \$57.3 million was budgeted for these activities.

Explanation of Provisions. The provisions would authorize \$25 million in Medicare appropriations in FY2004 and FY2005 and such funds as necessary in subsequent years to increase provider education and training and to improve the accuracy and quality of contractor responses. The Committees intend for this amount to be provided in addition to current funding levels. Starting on October 1, 2003, the contractors' training activities would accommodate the special needs of small providers and suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a non-facility based provider or supplier with fewer than 10 FTEs.

Effective Date. Upon enactment and as specified.

Reason for Change. This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement to Maintain Internet Sites.

Current Law. No provision.

Explanation of Provisions. The Secretary and each contractor would be required to maintain an Internet site that provides answers to frequently asked questions in an easily accessible format as well as other materials published by the contractor.

Effective Date. By October 1, 2003.

Reason for Change. This provision will facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions.

Current Law. No provision.

Explanation of Provisions. A Medicare contractor would not be able to use attendance records at educational programs or information gathered during these programs to select or track candidates for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

Effective date. Upon enactment.

Reason for Change. This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at education activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the

disclosure by a Medicare contractor of the claims processing screens or computer edits used for identifying claims that will be subject to review.

Section 822. Small Provider Technical Assistance Demonstration Program.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a demonstration program and contract with qualified entities to offer technical assistance, when requested and on a voluntary basis, to small providers or suppliers. Small providers and suppliers would be those institutional providers with less than 25 full-time equivalents (FTEs) or suppliers with less than 10 FTEs. Technical assistance would include direct, in-person examination of billing systems and internal controls by qualified entities such as peer review organizations or other entities. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the Office of the Inspector General (OIG) in HHS or the GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25 percent of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. However, this protection would only apply to claims filed as part of the demonstration project, would last only for the duration of the project and only as long as the provider or supplier was participating in the project. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than two years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The provision would authorize \$1 million in FY2004 and \$6 million in FY2005 of appropriations from the Medicare Trust Funds to carry out demonstration project.

Effective Date. Upon enactment.

Reason for Change. Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers - but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration will also test whether encouraging technical assistance on the front end to help providers and suppliers play by the rules can save the program money in the long term by promoting greater program compliance.

Section 303. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

(a) Medicare Provider Ombudsman.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to appoint a Medicare Provider Ombudsman within HHS to (1) to resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program including peer review and administrative requirements; and (2) recommend changes to improve program administration. The Ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

Effective Date. One year after enactment.

Reason for Change. Providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The new ombudsman will help providers navigate Medicare's complicated rules and regulations.

The Medicare Provider Ombudsman shall make recommendations to the Secretary concerning how to respond to recurring patterns of confusion in the Medicare program. Such a recommendation may include calling for the suspension of the imposition of provider sanctions (except those sanctions relating to the quality of care) where there is widespread confusion in program administration. Nothing in this section shall be construed as allowing for the suspension of provider sanctions relating to the quality of care, regardless of whether widespread confusion in the Medicare program exists.

(b) Medicare Beneficiary Ombudsman.

Current Law. No provision.

Explanation of Provisions. The Secretary would be required to appoint a Medicare Beneficiary Ombudsman within HHS from individuals with health care expertise, advocacy, and education of Medicare beneficiaries. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare+Choice organizations to leave Medicare; and (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration. The Ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

To the extent possible, the Beneficiary Ombudsman would work with the Health Insurance Counseling Programs authorized under Section 4360 of OBRA 1990, to facilitate the provision of information to Medicare beneficiaries regarding Medicare+Choice plans and any changes related to those plans. In addition, nothing in this section would preclude further collaboration, as appropriate, between the Beneficiary Ombudsman and these programs.

Effective Date. Once year after enactment.

Reason for Change. Beneficiaries confront a morass of bureaucracy and regulation, with no clear individual to assist them. This new ombudsman will help beneficiaries navigate Medicare's complicated rules and regulations.

(c) Funding.

Current Law. No provision

Explanation of Provisions. The provision would authorize appropriations of necessary sums in FY2003 and subsequently from the appropriate Medicare Trust Funds for the Ombudsman programs.

Effective Date. Upon enactment.

Reason for Change. The Committees acknowledge that implementing these new functions will have a cost and accordingly authorize necessary appropriations.

(d) Use of Central Toll Free Number (1-800 MEDICARE).

Current Law. The Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations to coverage to Medicare beneficiaries. The Secretary is also required to provide information via a toll-free telephone number.

Explanation of Provisions. The Secretary would be required to establish a toll-free number (1-800-MEDICARE), which will transfer individuals with questions or seeking help to the appropriate entities. The transfer would occur with no charge. This toll-free number would be the general information and assistance number listed on the annual notice provided to beneficiaries. GAO would be required to (1) monitor the adequacy, accuracy, and consistency of the information provided to Medicare beneficiaries through the toll-free 1-800 MEDICARE number and (2) examine the education and training of those providing the information through the toll-free number. GAO would be required to submit a report to Congress no later than one year from enactment.

Effective Date. Upon enactment.

Reason for Change. The beneficiary handbook currently provides many pages of phone numbers, which can be very confusing for beneficiaries, rather than a single number that then can triage and transfer beneficiaries to the appropriate person or entity. This provision will promote better access to information for beneficiaries.

Section 824. Beneficiary Outreach Demonstration Program.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of which would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness and (2) recommend whether the demonstration should be established on a permanent basis.

Effective Date. Upon enactment.

Reason for Change. This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration will test whether such outsourced Medicare specialists improve beneficiary utilization and understanding of the program, and beneficiary satisfaction.

SUBTITLE D—APPEALS AND RECOVERY

Section 831. Transfer of Responsibility for Medicare Appeals.

Current Law. Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal claims that are denied or payments that are reduced. Section 1869 of the Social Security Act, which covers the Medicare claims appeals process, was amended by BIPA in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that decision through a series of administrative appeals and then into federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an administrative

law judge (ALJ) in the Social Security Administration (SSA) with review by the Department Appeals Board (DAB) are components of the administrative appeals process.

Explanation of Provisions. By October 1, 2003, the Commissioner of SSA and the Secretary would develop a plan to transfer the functions of the administrative law judges (ALJs) who are responsible for hearing Medicare and Medicare related cases from SSA to HHS. The plan would be transmitted to Congress and GAO no later than October 1, 2003. The GAO would evaluate the plan and submit a report to Congress within 6 months of receiving the plan. The Secretary and the Commissioner of SSA would implement the transition plan and transfer the ALJ functions no earlier than July 1, 2004 and no later than October 1, 2004. The Secretary would (1) assure the ALJ's independence from the Centers of Medicare and Medicaid Services (CMS); and (2) locate the ALJs with an appropriate geographic distribution to ensure access. Subject to appropriations, the Secretary would be permitted to hire ALJs and support staff with priority given to ALJs with experience in handling Medicare appeals. Amounts previously paid to SSA for the ALJs performing the ALJ functions would be payable to the Secretary for the transferred functions. The Secretary would be permitted to enter into arrangements with SSA to share office space, support staff, and other resources with appropriate reimbursement from the Medicare trust funds. Increased appropriations would be permitted to increase the number of ALJs and support staff; improve education and training for ALJs and their staff; and increase DAB staff.

Effective Date. Upon enactment.

Reason for Change. The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The SSA Commissioner and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

The transition plan shall include information on the following:

1. Workload - The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.
2. Cost Projections - Funding levels required under this subsection to hear such cases in a timely manner.
3. Transition Timetable - A timetable for the transition.
4. Regulations - The establishment of specific regulations to govern the appeals process.

5. Case Tracking - The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the Medicare program.
6. Feasibility of Precedential Authority - The feasibility of developing a process to give binding, precedential authority to decisions of the Departmental Appeals Board in the Department of Health and Human Services that address broad legal issues.
7. Access to Administrative Law Judges - The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or video-conference technologies.

Section 832. Process for Expedited Access to Judicial Review

(a) Expedited Access to Judicial Review.

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 to establish deadlines for filing appeals and for making decisions in the Medicare appeals process. Generally, an initial determination is to be completed no later than 45 days from the date a claim for benefits is received; an individual dissatisfied with an initial determination is entitled to a redetermination by a carrier or fiscal intermediary if requested within 120 days of the determination date. The redetermination is to be completed no later than 30 days from the request date. The Secretary may reopen or revise any initial determination or reconsidered determination under guidelines established by regulation.

An individual dissatisfied with the redetermination is entitled to a reconsideration by a qualified independent contractor (QIC) if the request is initiated within 180 days of the notice of the adverse redetermination. With certain exceptions, a QIC reconsideration decision is to be completed within 30 days from the date a timely request has been filed. After a QIC's reconsideration, if the remaining contested amount is greater than \$100, an individual is entitled to a hearing by an administrative law judge and then a review by the DAB. Both the ALJ hearing and the DAB review are to be completed within 90 days of a timely filed request for such an action.

If the dispute is not satisfactorily resolved and the contested amounts are greater than \$1,000, the individual is entitled to judicial review of the decision. Under certain circumstances, a beneficiary is entitled to an expedited determination with accelerated deadlines. BIPA also provides for an expedited hearing under Section 1869, where the moving party alleges that no material issues of fact are in dispute; the Secretary makes an expedited determination as to whether any such facts are in dispute and, if not, renders a decision expeditiously.

Explanation of Provisions. The Secretary would establish an appeals process for a provider, supplier, or beneficiary, which permits access to judicial review when a review panel determines that no entity in the administrative appeals process has authority to decide the question of law or regulation in controversy and where material facts are not in dispute. The appellant would be able to make such request only once with respect to a question of law or regulation for a specific dispute. If the appellant requests this determination and submits appropriate supporting documentation, the review panel would make this determination in writing no later than 60 days after the receiving the request. A review panel would consist of a panel of three members who are ALJs, members of the DAB, or qualified individuals associated with a QIC or other independent entity designated by the Secretary to make these determinations. The determination by the review panel would be considered a final decision and not subject to review by the Secretary. Given such a determination or a failure to make the determination within the 60-day deadline, the appellant would be able to request judicial review before a civil court. The filing deadline for this civil action would be within 60 days of the determination or within 60 days of the end of the deadline to make such determination. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court for the District of Columbia. The amount in controversy would be subject to annual interest beginning on the first day of the first month beginning after the 60-day deadline for filing. Interest would be equal to the rate of interest on obligations issued for purchase by the Medicare trust funds effective for the month that the civil action is authorized to commence. The interest payments would not be deemed to be Medicare reimbursement.

Effective Date. See section (c).

(b) Application to Provider Agreement Determinations.

Current Law. Section 1866(h) of the Social Security Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider).

Explanation of Provisions. An agency or institution's appeal concerning program participation under Section 1866 would have access to expedited judicial review under Section 1869 provisions. This provision would not be construed to affect remedies applied to assure quality of care in skilled nursing facilities (under Section 1819) while such appeals are pending.

(c) Effective Date.

Explanation of Provision. Amendments in the section would apply to appeals filed on or after October 1, 2003.

Reason for Change. The provisions in 402 (a-c) on expedited access to judicial review ensure that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This will facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations. To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

(d) Expedited Review of Certain Provider Agreement Determinations.

Current Law. No provision.

Explanation of Provisions. The Secretary would develop and implement a process under 1866(h) to expedite provider agreement determinations including those instances where participation is terminated or other sanctions (including denials of new admissions or appointment of temporary management) against skilled nursing facilities have been imposed. Priority would be given to termination of provider agreements. Increased appropriations from the Medicare trust funds in FY2003 and subsequently would be authorized in order to (1) reduce the average time for administrative determinations on provider participation appeals by 50 percent; (2) increase the number of ALJs and their staff; and (3) educate the ALJs and their staff on long term care issues.

Effective Date. Upon enactment.

Section 833. Revisions to Medicare Appeals Process.

(a) Requiring Full and Early Presentation of Evidence.

Current Law. No provision.

Explanation of Provision. A provider or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

Effective Date. On or before October 1, 2003.

Reason for Change. The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal. When deciding whether there is good cause to introduce new evidence, the adjudicator should ensure, after consideration of the totality of the

circumstances, that disallowing the introduction of such new evidence would unfairly prejudice the case. The totality of the circumstances may include, but is not limited to, the following: evidence is not yet available; the appellant was not represented at a lower level of appeal; the appellant was not aware of her rights; or the appellant did not understand the proceeding.

(b) Use of Patients' Medical Records.

Current Law. BIPA established QIC reconsiderations as part of the Medicare's administrative review process. To reconsider whether a service is reasonable and necessary, a QIC will employ panel of physicians or other appropriate health care professionals to review the facts and the circumstances of the initial determination. The QIC reconsideration is to be based on applicable information, including clinical experience, and medical, technical, and scientific evidence.

Explanation of Provisions. Medical records of the individual involved in the appeal would be included as part of the applicable information used by QICs in their reconsideration process.

Effective Date. Upon enactment.

Reason for Change. In the determination of whether an item or service is reasonable and necessary for an individual, a beneficiary's medical records should be considered with other relevant information.

(c) Notice Requirements for Medicare Appeals.

Current Law. Section 521 of BIPA (which is not yet implemented) amends Section 1869 appeals process in its entirety, but did not establish specific notice requirements for each part of Medicare appeals process.

Explanation of Provisions. The provisions would establish that a written notice of an initial determination associated with a claims denial be provided. The notice would include: (1) the reason for the denial and, upon request, the policy, manual or regulation used to make the decision; (2) the procedures for obtaining additional information concerning the determination; and (3) the notification of appeal rights and associated instructions.

The provisions would amend the existing requirement that a reconsideration decision be written and establish that the decision would have to be provided in printed form and written in a manner that could be understood by the beneficiary; the notice would include: as appropriate, a summary of the clinical or scientific evidence used to make the decision; upon request, the policy manual or regulation used to make the decision; and a detailed explanation of the decision to the

extent appropriate. The requirement that the reconsideration decision include a notice of appeal rights and relevant instructions would also be established.

Comparable requirements would be extended to ALJ decisions. These decisions would have to be written in an understandable manner and include the specific reasons for the decision, an appropriate summary of the evidence, the procedures for obtaining additional information about the decision, and a notification of appeal rights and instructions.

The current requirements that a QIC prepare documentation and an explanation of the issues for an appeal to an ALJ would be modified: a QIC would be required to submit the information required in an appeal of a Medicare contractor's decision to the ALJ.

Reason for Change. Currently, Medicare only provides beneficiaries with a brief statement about the initial determination of her claim on the Medicare Summary Notice. This provision provides additional information to beneficiaries (or providers who appeal on their behalf) about Medicare's denial of their claim for benefits; the reasons for the denial, and the rights to further appeal so that beneficiaries can have a clear and concise understanding of decisions affecting their medical care.

(d) Qualified Independent Contractors.

Current Law. BIPA established Qualified Independent Contractor (QIC) reconsiderations as part of Medicare's administrative review process. A QIC is an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations and that meets the established requirements for sufficient training and expertise in medical science and legal matters to make such reconsiderations. QIC reviews include consideration of the facts and circumstances by a panel of physicians or appropriate health professionals. No physician or health care professional employed by a QIC may review determinations regarding services provided to a patient, if directly responsible for furnishing the services to that patient. Review of home health care services is also prohibited by physicians and other professionals who have a significant direct or indirect financial interest in the agency or institution providing the care. This prohibition extends to physicians and professionals who have family members with such significant financial interests.

Explanation of Provisions. To qualify as a QIC, an entity would be required to have sufficient medical, legal and other expertise, including knowledge of the Medicare program as well as sufficient professional qualifications, independence and staffing to make reconsideration decisions. A QIC would be required to assure that reviewers meet qualification and compensation requirements. If a reconsideration request indicates that the item or service was furnished by a physician, each reviewing professional should be a physician. Entities and their professional reviewers would have to meet independence requirements and may not: (1) be a related party; (2)

have a material familial, financial, or professional relationships with a related party; or (3) have a conflict of interest with respect to a related party. QIC's compensation would not be contingent on any decision by the QIC or by any reviewing professional. A reviewer's compensation would not be contingent on any decision rendered by the reviewer. In this context, a related party to a Medicare case involving an individual beneficiary is (1) the Secretary, the Medicare administrative contractor involved, any fiduciary, officer, director or employee of HHS or such Medicare contractor; (2) the individual or authorized representative; (3) the health professional, institution or entity that provides or manufactures the item or service involved in the case; and (4) any other party with substantial interest in the case, as defined by regulation.

Individuals affiliated with a fiscal intermediary, carrier or other contractor would be able to act as a QIC reviewer if (1) a individual is not involved with the provision of the item or service of the case; (2) individual is not an employee of the Medicare contractor and does not provide services exclusively or primarily to or on behalf of the contractor; and (3) the fact of the relationship is disclosed to the Secretary and the Medicare beneficiary or authorized representative who do not object. Individuals with staff privileges at the institution where treatment occurs would be able to serve as a reviewer if the affiliation is disclosed and there is no objection. Each reviewing professional shall be a allopathic or osteopathic physician or health care professional who is legally authorized to furnish items and services that are the subject of review in one or more states; and has medical expertise in the appropriate field for the case.

Effective Date. As if included in BIPA.

Reason for Change. The BIPA 2000 law laid out broad provisions for revision of the Medicare appeals process. These provisions strengthen the appeals process by enhancing the criteria related to the independence and expertise of the reviewers and review entities.

Section 834. Prepayment Review.

Current Law. No provision.

Explanation of Provisions. Medicare administrative contractors would be able to conduct random prepayment reviews in order to develop contractor-wide or program-wide claims payment error rates or under additional circumstances as established by regulations that are developed in consultation with providers and suppliers. Medicare administrative contractors would be permitted to conduct random prepayment reviews in accordance with a standard protocol developed by the Secretary. The Secretary would not be able to initiate non-random prepayment review based on the initial identification by a provider or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations relating to the termination, including termination dates, of non-random prepayment

review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment reviews. No provision would prevent the denial of payment for claims actually reviewed under random prepayment review. These provisions would be applied to fiscal intermediaries and carriers.

Effective Date. No later than one year from enactment. The Secretary would be required to issue regulations before that deadline; the random prepayment review protocols would apply to reviews after a date specified by the Secretary (but no later than one year from enactment.)

Reason for Change. These provisions build greater consistency and predictability into Medicare's rules for prepayment review, while protecting program integrity.

Section 835. Recovery of Overpayments

Current Law. No provision with respect to repayment plans. Section 1833(j) of the Social Security Act provides that interest accrues on underpayments or overpayments starting within 30 days of the date of the final determination of the accurate payment amount.

Explanation of Provisions. Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers on request would be allowed to repay the overpayment amount (by offset or otherwise) over a period of at least six months up to three years when their obligation exceeds a ten percent threshold of their annual payments from Medicare. The Secretary would be able to establish a repayment period of up to five years in cases of extreme hardship. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish a process under which newly-participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plans would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where the Secretary has reason to suspect that bankruptcy may be declared or that the provider or supplier may otherwise cease to do business or discontinue participating in the Medicare program, or where fraud or abuse against Medicare is indicated. This provision would not affect the application of existing no-fault provisions, which preclude recovery under certain circumstances where incorrect payment has been made to an individual who is without fault or where the recovery would decrease payments to another person who is without fault.

Upon enactment, the Secretary would not be able to initiate any recovery action if the provider or supplier has sought a reconsideration of the Medicare overpayment by a qualified independent contractor (QIC) until the date of the reconsideration decision. If QIC's are not yet in place, the recovery would not be initiated until the date of a redetermination decision by a fiscal

intermediary or a carrier. If monies have been offset or repaid, the Secretary would return those amounts plus applicable interest if the original overpayment determination is reversed. If such an overpayment determination is upheld, interest would accrue beginning on the date of the original overpayment notice; the interest amount would be the rate otherwise applicable for Medicare overpayments.

Not later than one year after enactment, a Medicare contractor would not be able to use extrapolation to make overpayment determinations initiated after the date of enactment, unless, as determined by the Secretary, a sustained or high level of payment error exists or a documented educational intervention did not correct the payment error.

Where providers and suppliers have previously been overpaid, Medicare contractors would be able to require periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that a previous practice has been discontinued.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. Before entering into any consent settlements after the date of enactment, the Secretary would be required to communicate to a provider or supplier that based on a preliminary evaluation of a medical records review, an overpayment may exist; the nature of the identified problems; and the necessary steps to address the problem. The Secretary would provide 45-days where additional information may be submitted concerning the claims for which the medical records have been reviewed. After considering the additional information, the Secretary would provide notice and explanation of any remaining overpayment determination and would offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Not later than one year after enactment, the Secretary would be required to establish, in consultation with health care associations, a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that may be over-utilized.

For audits initiated after enactment, Medicare contractors would be required to provide a written notice (which may be in electronic form) of the intent to conduct a post-payment audit to those selected as audit candidates. Medicare contractors would be required to provide those who have been audited a full review and understandable explanation of the findings that: (1) permits the development of an appropriate corrective action plan; (2) provides information on appeal rights as well as consent settlements (which are at the discretion of the Secretary); and (3) provides for an opportunity to supply additional information to the contractor. Medicare contractors would be required to take into account the information provided on a timely basis. The provisions requiring notice of audit and findings would not apply if pending law enforcement activities would be compromised or findings of law enforcement-related audits would be revealed.

Not later than one year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a claims sample for a review of abnormal billing patterns.

These provisions would apply to Medicare administrative contractors including fiscal intermediaries and carriers as well as those eligible entities with MIP contracts.

Effective Date. Upon enactment.

Reason for Change. These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments, while protecting program integrity.

Section 836. Provider Enrollment Process; Right of Appeal.

Current Law. Providers and, to some extent suppliers, have access to certain appeal mechanisms if their application to participate in Medicare is denied or terminated. Section 1866(h) of the Social Security Act provides for a hearing and for judicial review of that hearing for any institution or agency dissatisfied with a determination that it is not a provider (or that it can no longer be a provider). There is no statutory provision extending such judicial appeal rights to suppliers. Sections 1128(a) and (b) of the Act provide for the exclusion of certain individuals or entities because of the conviction of crimes related to their participation in Medicare; Section 1128(f) provides for hearing and judicial review for exclusions. In 1999, the Health Care Financing Administration (HCFA- now the Centers for Medicare and Medicaid Services or CMS) published a proposed regulation that would revise existing Medicare Part B administrative appeals procedures and extend them to all suppliers not currently covered.

Explanation of Provision. The Secretary would be required to (1) establish by regulation an enrollment process for providers and suppliers which would include deadlines for actions on enrollment applications within six months of enactment; (2) monitor the performance of Medicare administrative contractors in meeting the deadlines; (3) consult with providers and suppliers in making changes to the enrollment forms made on or after January 1, 2003. In establishing an enrollment process for providers and suppliers, the Secretary would build upon existing Medicare practice.

Providers and suppliers whose application to enroll or reenroll has been denied and who are dissatisfied with the determination would be entitled to a hearing and judicial review of the determination under the procedures that currently apply to providers. This provision would apply to denials after a date specified by the Secretary, which could not be later than one year from enactment.

Effective Date. Upon enactment.

Reason for Change. This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

Section 837. Process for Correction of Minor Errors and Omissions on Claims Without Pursuing Appeals Process.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors and omissions can be corrected and resubmitted without appealing the claims denial.

Effective Date. Upon enactment.

Reason for Change. Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Committees would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committees intend that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 838. 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.

However, in most circumstances either the beneficiary or the provider will be liable in the event that Medicare does not cover an item or service. There are detailed rules on beneficiary and provider liability in the statute. 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, the provider may limit his liability by providing an acceptable advance notice of Medicare's possible denial of payment to the patient. 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. Currently, when there is a question about coverage, there is no way for a beneficiary or provider to find out in advance whether or not Medicare will cover that item or service for that particular beneficiary.

Explanation of Provisions. The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain items and services before such services are provided. An eligible requestor would be either a physician or a Medicare beneficiary who receives an advance beneficiary notice (ABN) from a physician. Eligible items and services for review are those physicians' services under 1848(f)(4)(A) for which a physician may be paid directly. The provisions would establish: (1) 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) contractors' prior 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. This section also requires that whenever a physician requests a pre-service determination (or redetermination), beneficiaries must still receive notices that include information explaining the beneficiary's right to receive the service and request access to the appeals process under section 1869. The calculation of the sustainable growth rate for physician updates is modified so that the increase in utilization from this provision is included. These provisions would not affect a Medicare beneficiary's rights in any future appeal or judicial action. The Secretary must establish the process to allow for the processing of such requests beginning 18 months after enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary and provider 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.

Reason for Change. The Committees believe that when there is a question of whether Medicare will cover certain care for a beneficiary, the beneficiary should have the right to find out what will be covered before getting the service and risking financial liability. Doctors also should be able to make such a request on behalf of a particular patient. This provision is particularly important for seniors and disabled individuals who tend to be risk adverse and live on fixed incomes.

SUBTITLE E—MISCELLANEOUS PROVISIONS

Section 841. 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 on or after enactment for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians (both generalists and specialists) after assessment by the physician community; (2) based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the desired objectives; and (5) are preceded the establishment of an appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The Secretary would be required to modify E&M guidelines to (1) identify clinically relevant documentation: (2) decrease non-clinically pertinent documentation; (3) increase the reviewers' accuracy; and (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be (1) conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists); (2) be of sufficient length to educate physicians and contractors on E&M guidelines and (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established and include at least one project that (1) uses a physician peer review method; (2) uses an alternative method based on face-to-face encounter time with the patient; (3) is in a rural area; (4) is outside a rural area; and (5) involves physicians billing 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. The Secretary, in consultation with practicing physicians including those in groups practices as well as generalists and specialists, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative

simplification requirements and report results of the study to Congress by October 1, 2004. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

The Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommendations to Congress no later than October 1, 2004.

Effective Date. Upon enactment.

Reason for Change. This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 842. Improvement in Oversight of Technology and Coverage.

(a) Improved Coordination Between FDA and CMS on Coverage of Breakthrough Medical Devices.

Current Law. No provision.

Explanation of Provision. Upon request and to the extent feasible, the Secretary would be required to ensure that appropriate information from the review for application for premarket approval of class III medical devices conducted by the FDA for coverage decisions. Within 6 months of enactment, the Secretary would be required to submit an report to the appropriate Congressional committees on the implementation plan to shorten the delay between FDA's premarket approval and Medicare's coding and coverage decisions. This provision would not change Medicare's coverage nor FDA's premarket approval criteria. Nothing in this subsection will be construed to lengthen the time for premarket approval under the FFDCA.

Effective Date. Upon enactment.

Reason for Change. After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

(b) Council for Technology and Innovation.

Current Law. No provision.

Explanation of Provision. The Secretary is required to establish a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS). The council would be composed of senior CMS staff with an Executive Coordinator, who is designated or appointed by the Secretary and reports to the CMS administrator. The Chairperson would serve as a 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.

Reason for Change. CMS personnel responsible for coverage, coding and payment of medical innovation are often not well coordinated. This provision creates a focal point for technology and innovation within the Centers for Medicare and Medicaid Services by creating a Council to coordinate across the different Centers and Offices with responsibilities in this area. The Executive Coordinator also provides a single point of contact for outside groups, similar to recent initiatives launched by the Secretary for specific issues and types of providers.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Current Law. No provision.

Explanation of Provision. GAO would be required to conduct a study analyzing which external data can be collected by CMS for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information. The report would be submitted to Congress no later than October 1, 2003.

Effective Date. Upon enactment.

(d) IOM Study on Local Coverage Determinations.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to arrange for a study by the Institute of Medicine (IOM) that would examine Medicare's local coverage determinations. The study would examine: (1) the consistency of definitions used in the determinations; (2) the types of evidence that are the basis of the determinations; (3) the advantages and disadvantages of local coverage decisionmaking and of maintaining local Medicare contractor advisory committees; and (4) the manner in which local coverage decisions are used to develop data to support national coverage determinations. The IOM study would be due to the Secretary no later than 3 years after enactment when it would be promptly transmitted to Congress.

Effective Date. Upon enactment.

(e) Methods For Determining Payment Basis for New Lab Tests.

Current Law. Outpatient clinical diagnostic laboratory tests are paid on the basis of areawide fee schedules. The law establishes cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

Explanation of Provisions. The Secretary would be required to establish procedures (by regulation) for determining the basis and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new Health Care Procedure Coding System (HCPCS) code on or after January 1, 2004. 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. Upon enactment.

Reason for Change. The Secretary of Health and Human Services is required to establish by regulation an open process for any clinical diagnostic laboratory test. Under the regulations, the Secretary shall develop criteria for use in determining whether a laboratory test should be established through gap-filling or cross-walking to an existing code. When existing services are not

sufficient and gap filling must be used, the criteria shall explain the basis of the data, the collection of the data, and the methodology for computing the rate.

The intent of Congress is to open the process to allow CMS to have access to information from beneficiaries, physicians, health care experts and laboratories. Using the information it receives through this new process, CMS shall develop and make available to the public the information used to arrive at a final determination. The information will include the rationale for each such determination, the data on which the determination is based, and responses to public comments.

Section 843. Treatment of Hospitals for Certain Services Under the Medicare Secondary Payor (MSP) Provisions.

Current Law. In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payor 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 payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Effective Date. Upon enactment.

Reason for Change. Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

Section 844. 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 EMTALA requirements may face civil monetary penalties and termination of their provider agreement. After a state investigation of an EMTALA complaint, the CMS Regional Office may ask their local peer review organization (PRO) to perform a 5-day review to obtain additional medical expertise. This review is discretionary. However, prior to imposing a civil monetary penalty, the Secretary is required to request that a PRO 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 of individuals, 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, 2003, 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 the time of admission or visit. The Secretary shall also not count the provision of the item or service during such an admission or visit when considering the frequency with which the item or service is furnished on subsequent occasions.

The Secretary would be required to establish a procedure to notify hospitals and physician 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 violation. The current period of review for the discretionary review -5 business days- would apply for such review. The Secretary shall provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment.

Effective Date. Upon enactment.

Reason for Change. Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses-if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on LMRPs that set frequency limits for certain tests-if the test's use in the emergency room exceeds a frequency limit, payment is denied. In its January 2001 report entitled *The Emergency Medical Treatment and Labor Act: The Enforcement Process*,@ the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program for an EMTALA violation. This section

implements that recommendation, making the current discretionary PRO review process mandatory in cases that involve a question of medical judgment.

Section 845. Emergency Medical Treatment and Active Labor (EMTALA) Task Force.

Current Law. No provision.

Explanation of Provision. The Secretary would be required to establish a 19-member technical advisory group under specified requirements to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA). The advisory group would be comprised of: the CMS Administrator; the OIG; four hospital representatives who have EMTALA experience, (including one person from a public hospital and two of whom have not experienced EMTALA violations) seven practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a State survey organization and one representative from a 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; and (3) terminate 30 months after the date of its first meeting. 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.

Reason for Change. In its January 2001 report entitled *The Emergency Medical Treatment and Labor Act: The Enforcement Process*,¹ the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders to help the agency resolve any emerging issues related to implementation of the law. Some of these current issues include specialists who refuse to service on call panels and inconsistencies between State and Federal law governing emergency medical services. In its June 2001 report entitled *Emergency Care: EMTALA Implementations and Enforcement Issues*,² the GAO also concluded that the establishment of a technical advisory group could help CMS work with hospitals and physicians to achieve the goals of EMTALA and avoid creating unnecessary burdens for providers. This section implements the OIG recommendation, establishing a 19-member technical advisory group within HHS.

Section 846. Authorizing Use of Arrangements with Other Hospice Programs to Provide the Core Hospice Services in Certain Circumstances.

Current Law. Hospice programs are not permitted to use services provided under arrangement to deliver hospice services. Under arrangement services are permitted for providers delivering Part A and Part B hospital services as well as skilled nursing services. However, the originating hospital or skilled nursing facility is required to bill for the service and be responsible for the quality of care delivered by the subcontractor.

Explanation of Provision. Hospice programs may enter into arrangements with another certified hospice program to provide services. The provision for under arrangement services is limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program continues to bear the legal responsibility for billing and maintaining quality of care.

Effective Date. For hospice care provided after enactment.

Reason for Change. Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

Section 847. 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. Applies to hospitals as of July 1, 2003.

Reason for Change. Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar requirements on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

Section 848. 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. This provision makes technical corrections related to the Medicare Coverage Advisory Committee by transferring the provisions from Title 11 to Title 18 and by removing incorrect cross references to the establishment authority.

Effective Date. As if included in BIPA.

Section 849. Conforming Authority to Waive A Program Exclusion.

Current Law. The Secretary is required to exclude individuals and entities from participation in Federal Health Programs who 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 financed or operated by the Federal, State or local government; or (4) convicted of a felony related to a controlled substance. At the request of a state, the Secretary is permitted to waive a program exclusion with respect to Medicare or Medicaid, but only for exclusions described in (1) above.

Explanation of Provisions. The Administrator of a Federal health program would be permitted to request a waiver of a program exclusion if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. This conforming change would extend the same waiver authority currently in Medicare and Medicaid to federal health programs. In addition, waivers could be requested for Medicare, Medicaid, and federal health programs with respect to all exclusions except those related to patient abuse or neglect.

Effective Date. Upon enactment.

Reason for Change. This technical correction was requested by the Office of Inspector General.

Section 850. Treatment of Certain Dental Claims.

Current Law. Under current law, providers of services and suppliers submitting claims to Medicare must be enrolled in the Medicare program. However, certain services are specifically excluded from coverage under Medicare. Under current law, no payment may be made under part A

or part B of the Medicare program for any services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except in the case of inpatient hospital services associated with the provision of these dental services if the individual's underlying medical condition and clinical status or the severity of the dental service require hospitalization.

Explanation of Provision. This provision would prohibit group health plans from requiring a Medicare claims determination for dental benefits that are specifically excluded from Medicare coverage as a condition of making a determination for coverage under the group health plan. In so doing, this provision would ensure that dentists would not have to submit claims to the Medicare program (and thus enroll in the Medicare program) when the services they are providing are clearly those that are categorically excluded from coverage. In those cases that involve or appear to involve inpatient hospital services or dental services expressly covered by Medicare, a group health plan may require the claim to be first submitted to the Medicare program.

Effective Date. 60 days after enactment.

Reason for Change. The Committees are concerned about private insurers requiring dentists to submit claims to Medicare for non-covered services before making a determination for coverage under the group health plan. Because of this requirement, dentists have been forced to enroll in the Medicare program to submit claims for services that are categorically excluded from Medicare coverage. Dentists view Medicare's enrollment application process as overly burdensome, particularly in light of the fact that most dental services are not covered by Medicare. This provision would alleviate the enrollment burden placed on dentists providing services clearly excluded from Medicare coverage, consistent with the overarching goal of this legislation to reduce regulatory burdens.

Section 851. Annual Publication of List on National Coverage Determinations

Current Law. No provision.

Explanation of Provisions. The Secretary would be required to provide, in an annual report that will be publicly available, a list of Medicare's national coverage determinations made in the previous year and include information on how to learn more about such determinations.

Effective Date. Upon enactment.

Clarifications and Instructions to the Secretary

First, the Committee is pleased that the Secretary has published a notice of proposed rulemaking to provide Medicare payment for clinical psychology internship training programs that would not qualify under Medicare's existing provider-operated criteria. The Committee notes that Congress has consistently urged the Secretary to initiate payment for the training of clinical psychologists since 1997. Supportive language has been included in conference reports accompanying Medicare legislation in 1999 (Report 106-479), and in 2000 (Senate Report 106-293).

The Committee is concerned, however, that a delay in the rule may mean that hospitals and institutions will reduce or eliminate psychology training programs and urges implementation of the rule as soon as possible. The Committee notes that clinical psychologists provide valuable and unique services to Medicare beneficiaries during their training. Regarding their training, clinical psychologists are distinguishable from other health care professionals in that they are the only doctoral level mental health professionals fully participating in Medicare whose clinical training is not currently reimbursed. In addition, their clinical internship training is entirely controlled, administered, supervised, evaluated, and certified by the hospital or institution, separately accredited, and distinct from any university training they receive. Clinical psychologists are hospital-based in the final stages of their training functioning in a parallel status to medical interns and residents, not medical nursing or health professional students. Where a clinical psychologist has clearly finished their educational curriculum and is training solely in the hospital setting, it is the intention of Congress that the hospital be reimbursed if that training is hospital-based.

Second, Congresses original intent on BIPA section 422(a)(2) on the dialysis composite rate has not been correctly interpreted by CMS. The intent was not to bar end stage renal disease (ESRD) composite rate exception relief for facilities that are not presently being paid under an exception to the composite rate. It is the Committee's expectation that CMS will evaluate ESRD composite rate exception requests submitted in 2002 and subsequent years by new renal dialysis facilities and existing facilities that do not have an exception.

Title IX – Medicaid and Public Health Act

To be provided by the Committee on Energy and Commerce.

Title X - Healthcare Related Tax-Provisions

Section 1001. Medicare+Choice MSAs.

Current Law. There are no Medicare+Choice MSAs in the Medicare program, despite their enactment as part of the Balanced Budget Act. The proposal would treat policies selected as part of the Medicare+Choice MSA plan as high deductible plans for purposes of Archer MSAs. Thus, individuals who have a Medicare+Choice MSA plan would also be eligible individuals for Archer MSA purposes (such individuals are referred to as “Medicare-eligible individuals”). The maximum deductible contribution that could be made to an Archer MSA with respect to a Medicare-eligible individual would be 100 percent of the deductible under the Medicare+Choice MSA policy.

Explanation of Provision. The proposal would also allow employers or former employers of Medicare-eligible individuals to make contributions to an Archer MSA on behalf of such individuals. The cap on Archer MSAs would not apply to MSAs established by persons in Medicare+Choice, and such MSAs would not be taken into account in applying the cap to other Archer MSAs.

Section 1002. Coal Act.

Explanation of Provision. Technical change that allows employers subject to the Coal Act to access Medicare premium subsidies in the same way other employers do.

Expand Human Clinical Trials Eligible for the Orphan Drug Credit

Current Law. Taxpayers may claim a 50-percent credit for expenses related to human clinical testing of drugs for the treatment of certain rare diseases and conditions. Qualifying expenses are those paid or incurred by the taxpayer after the date on which the drug is designated as a potential treatment for a rare disease or disorder by the Food and Drug Administration (“FDA”) in accordance with section 526 of the Federal Food, Drug, and Cosmetic Act.

Explanation of Provision. The proposal would expand qualifying expenses to include those expenses related to human clinical testing paid or incurred after the date on which the taxpayer files an application with the FDA for designation of the drug under section 526 of the FFDC.