108TH CONGRESS
1st Session

COMMITTEE PRINT

S. PRT.
108–29

DESCRIPTION OF THE PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003

TECHNICAL EXPLANATION OF PROVISIONS APPROVED BY THE COMMITTEE ON JUNE 12, 2003

COMMITTEE ON FINANCE
UNITED STATES SENATE

CHARLES E. GRASSLEY, *Chairman*

JUNE 2003

Printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE
87–725 WASHINGTON : 2003

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THE PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS

Current Law

No provision.

Explanation of Provision

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

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Subtitle A—Medicare Voluntary Presceiption Drug Delivery Program

SECTION 101. MEDICARE VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

Current Law

In general, Medicare does not cover most outpatient prescription drugs. Despite the general limitation, the law specifically authorizes coverage for the following drugs under specified conditions: drugs used in immunosuppressive therapy (such as cyclosporin) for individuals who have received a Medicare covered organ transplant; erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis; 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; hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision; and drugs that are necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment. The program also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccine.

Explanation of Provision

Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage. In 2006, "standard coverage" would have a $275 deductible, 50% cost-sharing for costs between $276 and $4,500, then no coverage until the beneficiary had out-of-pocket costs of $3,700 ($5,813 total spending); and 10% cost-sharing thereafter. Individuals with incomes

below 160% of poverty would receive additional assistance. The bill would rely on private plans to provide coverage and to bear a portion of the financial risk for drug costs. Coverage would be provided through Medicare Prescription Drug Plans or MedicareAdvantage plans.

NEW SECTION 1860D—DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN MEDICAREADVANTAGE PROGRAM

Current Law

No provision.

Explanation of Provision

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

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

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

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

The provision would specify that Part C requirements relating to MedicareAdvantage would be applied (unless otherwise specified) as if: (1) any reference to a MedicareAdvantage plan included a reference to a Medicare Prescription Drug plan; (2) any reference to a provider-sponsored organization included a reference to an eligi-

ble entity, (3) any reference to a contract included a reference to a drug plan contract, and (4) any reference to Part C included a reference to Part D.

Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

NEW SECTION 1860D–1. ESTABLISHMENT OF VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

Current Law

No provision.

Explanation of Provision

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

The program would begin January 2006 and would provide coverage for all therapeutic categories and classes of covered drugs (though not necessarily for all drugs within such categories and classes). Program costs would be paid from the Prescription Drug Account.

NEW SECTION 1860D–2. ENROLLMENT UNDER PROGRAM

Current Law

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

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

Explanation of Provision

The Administrator would establish an enrollment process which would be similar to that for Part B. An initial open enrollment period would be established. For beneficiaries eligible as of November

1, 2005, this would be the 6-month period beginning November 1, 2005. Persons becoming eligible after this date would have an initial 7-month enrollment period similar to that established for Part B.

Persons enrolling in Part D after their initial enrollment period would be subject to delayed enrollment penalties. The actuarially sound increase for each 12-month period of delayed enrollment would be determined by the Administrator.

Eligible beneficiaries with creditable drug coverage could elect to continue to receive such coverage, not enroll in Part D, and subsequently enroll in Part D without penalty if the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under the plan to below the actuarial value of standard prescription drug coverage. Subject to certain conditions, creditable drug coverage would include drug coverage through a Section 1115 waiver of Title XIX for persons who are not dual eligibles, a group health plan, state pharmaceutical assistance program, veterans programs, and Medigap. Entities offering creditable coverage would be required to disclose whether coverage equals or exceeds the actuarial value of standard coverage. A special enrollment period would apply for persons losing creditable coverage. In general, it would be the 63-day period beginning on the date the individual lost such coverage or the date the individual was notified of the termination of benefits, whichever is later. Entitlement would begin the first day of the first month following enrollment.

NEW SECTION 1860D–3. ELECTION OF A MEDICARE PRESCRIPTION DRUG PLAN

Current Law

The law establishes rules for beneficiary enrollment, disenrollment and termination of enrollment in Medicare+Choice plans.

Explanation of Provision

The Administrator would establish a process through which an eligible beneficiary who was not enrolled in a MedicareAdvantage Plan (except for an MSA plan or private-fee-for-service plan not offering qualified drug coverage) could enroll in a Medicare Prescription Drug plan serving the geographic area where the beneficiary resides. The beneficiary could make an annual election to change enrollment to another plan. A beneficiary in Part D who fails to enroll in a plan would be enrolled in a plan designated by the Administrator.

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

The enrollment process established by the Administrator would ensure that beneficiaries who enrolled in the first open enrollment period (beginning November 2005) would be permitted to elect an

eligible entity prior to January 1, 2006, in order to assure coverage was effective on that date.

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

NEW SECTION 1860D–4. PROVIDING INFORMATION TO BENEFICIARIES

Current Law

The law requires the Secretary to broadly disseminate information on Medicare+Choice plans to Medicare enrollees in order to promote informed selection of plans.

Explanation of Provision

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

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

NEW SECTION 1860D–5. BENEFICIARY PROTECTIONS

Current Law

Medicare+Choice plans are required to meet a number of beneficiary protection requirements. They are required to disclose plan information to enrollees. They are required to have procedures relating to coverage decisions, reconsiderations, and appeals. The appeals process would include an external appeal as under MedicareAdvantage. Further, they are required to assure the confidentiality and accuracy of enrollee records.

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

Explanation of Provision

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

materials would apply to information provided by entities on drug plans.

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

An entity would be required to establish a point-of-service method of operation under which the plan would provide access to any or all pharmacies not participating in the network and could charge beneficiaries, through adjustments in cost sharing, the additional costs associated with this option. This additional cost sharing would not count toward the program's cost-sharing requirements or benefit limits.

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

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

other sources of drug classification and categorizations that the Administrator determines are appropriate.

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

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

Premiums for a plan would not vary within a service area.

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

NEW SECTION 1860D–6. PRESCRIPTION DRUG BENEFITS

Current Law

No provision.

Explanation of Provision

Plans would be required to offer "qualified coverage." "Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage." Both would require access to negotiated prices. In 2006, "standard coverage" would be defined as having a $275 deductible, 50% cost-sharing for drug costs between $276 and

the initial coverage limit of $4,500, then no coverage, except that beneficiaries would have access to negotiated drug prices, until the beneficiary had out-of-pocket costs of $3,700 ($5,813 in total spending); and 10% cost-sharing thereafter. These amounts would be increased in future years by the percentage increase in average per capita expenditures for covered drugs for the year ending the previous July. Out-of-pocket costs counting toward the limit would include costs paid by the individual (or by another individual such as a family member), paid under Medicaid, or paid under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise could not be counted. Entities could offer more generous drug coverage, if approved by the Administrator, but only if they also offered a plan providing standard coverage. Entities could use a variety of cost control mechanisms including formularies, tiered copayments, selective contracting with drug providers, and mail order pharmacies.

A Medicare Prescription Drug Plan or MedicareAdvantage plan could offer a plan design different from standard coverage provided certain conditions were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of coverage would have to be at least equal to the unsubsidized value of standard coverage. Further, the coverage would be designed, based on a representative pattern of utilization, to cover the same percentage of costs up to the initial benefit limit as provided under the standard plan. The limitation on the deductible and out-of-pocket expenditures would be the same as under standard coverage. The entity would have to apply for and receive approval from the Administrator for an alternative benefit design.

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

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

NEW SECTION 1860D–7. REQUIREMENTS FOR ENTITIES OFFERING MEDICARE PRESCRIPTION DRUG PLANS; ESTABLISHMENT OF STANDARDS

Current Law

No provision.

Explanation of Provision

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

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

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

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

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

Subpart 2—Prescription Drug Delivery System

NEW SECTION 1860D–10. ESTABLISHMENT OF SERVICE AREAS

Current Law

No provision.

Explanation of Provision

The Administrator would be required to establish by April 15, 2005, and periodically review, service areas in which plans could offer benefits. The Administrator would establish service areas so that they maximized the availability of Medicare Prescription Drug Plans to eligible beneficiaries and minimized the ability of entities offering plans to favorably select beneficiaries. In establishing the

service areas, the Administrator would establish at least 10 service areas which would have to include at least one state. The Administrator could not divide states so that portions of a state were in different service areas. To the extent possible, the Administrator would include multi-state metropolitan statistical areas (MSAs) in a single service area. The Secretary could divide MSAs where it is necessary to establish service areas of such size and geography as to maximize plan participation. The Administrator could conform service areas to those established for preferred provider organizations under MedicareAdvantage.

NEW SECTION 1860D–11. PUBLICATION OF RISK ADJUSTERS

Current Law

No provision.

Explanation of Provision

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

NEW SECTION 1860D–12. SUBMISSION OF BIDS FOR PROPOSED MEDICARE PRESCRIPTION DRUG PLANS

Current Law

No provision.

Explanation of Provision

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

Service areas could either be the entire area of one of the service areas established by the Administrator or the entire area covered by Medicare. Entities could submit separate bids for multiple service areas, provided each bid was for a single service area.

NEW SECTION 1860D–13. APPROVAL OF PROPOSED PRESCRIPTION DRUG PLANS

Current Law

No provision.

Explanation of Provision

The Administrator could not approve a plan unless the premium, for both standard coverage and for any additional benefits, accurately reflected the actuarial value of the benefits less the actuarial value of reinsurance payments and any stabilization funds used. The Administrator is required to apply the Federal Employees Health Benefits Program (FEHBP) standard, stipulating that each bid submitted by an entity for a qualified plan must reasonably and equitably reflect the cost of benefits provided under that plan. The Administrator would have the authority to negotiate the terms and conditions of the proposed monthly premiums and other terms and conditions of proposed plans. The Administrator could disapprove, or limit enrollment in, a proposed plan based on costs to beneficiaries, the quality of coverage and benefits, the adequacy of the plan network, and other factors determined appropriate by the Administrator. The Administrator could approve a plan only if it provided the required benefits and was not designed to result in a favorable selection of beneficiaries. The Administrator shall approve at least 2 contracts to offer a Medicare Prescription Drug plan in an area. Contracts would be awarded for 2 years.

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

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

Beneficiary premiums for a fallback plan would be set at the premium amount that would apply if the plan premium equaled the national weighted average premium, as adjusted for geographic dif-

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

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

NEW SECTION 1860D–14. COMPUTATION OF MONTHLY STANDARD COVERAGE PREMIUMS

Current Law

No provision.

Explanation of Provision

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

NEW SECTION 1860D–15. COMPUTATION OF MONTHLY NATIONAL AVERAGE PREMIUM

Current Law

No provision.

Explanation of Provision

Each year, beginning in 2006, the Administrator would be required to compute a monthly national average premium equal to the average of the monthly standard coverage premium for each Medicare Prescription Drug plan and each MedicareAdvantage plan. The calculation would be a weighted average based on the number of enrollees in the plan in the previous year. The Administrator would establish a methodology for making this calculation which could take into account geographic differences in utilization and the results of the ongoing study on spending and utilization required under the Act. Any adjustment would be budget neutral.

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

NEW SECTION 1860D–16. PAYMENTS TO ELIGIBLE ENTITIES

Current Law

Medicare makes per capita monthly payments to Medicare+Choice organizations.

Explanation of Provision

The Administrator would pay each entity offering a Medicare Prescription Drug Plan an amount equal to the full monthly approved premium, with appropriate risk adjusters. Payment terms would be determined by the Administrator and be based on terms used for MedicareAdvantage plans. Payments to plans would be geographically adjusted in a budget-neutral manner to account for differences in prescription drug prices across service areas.

A portion of total payments to plans would be subject to risk. Entities would be required to notify the Administrator for each year (beginning in 2007) of the total actual costs the entity incurred in providing standard coverage in the preceding year and a breakdown for: each drug paid for by the plan, the negotiated price for each such drug, number of prescriptions, and average beneficiary coinsurance rate. The notification would not include spending for administrative costs, amounts spent for coverage in excess of standard coverage, or amounts for which the entity subsequently received reinsurance payments.

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

During 2006 and 2007, plans would be at full risk for drug spending within 2.5% above or below the target. Plans would be at risk for 25% of spending exceeding 2.5% (first threshold upper limit) and below 5.0% of the target (second threshold upper limit). That is their payments would equal 75% of the allowable costs for spending in this range. They would be at risk for 10% of the spending exceeding 5% of the target. That is their payments would equal 90% of the allowable costs for spending in this range. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 90% of any amounts below 5% of the target.

A special transition corridor would be established in the first two years. The Administrator would make a payment adjustment if the Administrator determined that 60% or more of all participating plans (including MedicareAdvantage plans) representing at least 60% of covered beneficiaries had allowable costs that were more

than 2.5% above the target. Risk corridor payments would equal 90% of any spending greater than 2.5% of the target but below 5% of the target.

For 2007–2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5.0% above or below the target level. Plans would be at risk for 50% of spending exceeding 5.0% and below 10% of the target level. They would be at risk for 10% of the spending exceeding 10% of the target level. Payments would be increased by 50% of allowable costs exceeding the first threshold upper limit and 90% of allowable costs exceeding the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 50% of the savings if costs fell between 5% and 10% below the target level, and 90% of any allowable amounts below 10% of the target. For years after 2011, the Administrator would establish risk corridors. The first threshold risk percentage could not be less than 5% and the second threshold risk percentage could not be less than 10%.

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

For purposes of making risk corridor calculations, allowable costs would be based on actual costs reported by the plan. The Administrator would adjust this amount in cases where actual costs for a covered drug exceeded the average negotiated price for such drug in the year.

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

The Administrator would be required to establish a stabilization reserve fund, within the Prescription Drug Account. Amounts in this fund would be made available to eligible entities beginning with their 2008 contract year. Payments to the fund would be determined as follows. If the target amount for a plan for any year 2006–2010 exceeded applicable costs by more than 3% for the year, the entity would pay the Administrator the amount of such excess; the Administrator would deposit such amount in the fund on behalf of the entity. Applicable costs would be defined as the sum of allowable costs and the amount by which monthly payments were reduced through application of the risk corridor provisions. At appropriate intervals, the Administrator would notify a participating entity of the balances in any of its stabilization accounts. Beginning in 2008, entities would be permitted to use account funds to stabilize or reduce plan premiums. Any amounts deposited for use by an entity that no longer had a Part D contract would revert to the use of the Prescription Drug Account.

NEW SECTION 1860D–17. COMPUTATION OF BENEFICIARY OBLIGATION

Current Law

No provision.

Explanation of Provision

If the plan's monthly approved premium for standard coverage was equal to the national monthly weighted average premium for such coverage, the beneficiary would pay: (1) the applicable percentage, established for the area, of the monthly national average. If the plan's monthly approved premium was less than the national average the beneficiary would pay: (1) the applicable percentage for the area, minus, (2) the difference between the national average and the plan's premium. If the plan's monthly premium was greater than the national average, the beneficiary would pay: (1) the applicable percentage for the area, plus (2) the difference between the national average and the plan's premium. The applicable percentage for an area would be 32% divided by 100% minus a percentage equal to: total reinsurance payments that will be made in a year divided by such amount plus total payments that would be made to plans in the year for standard coverage. This amount would be geographically adjusted in accordance with a methodology established by the Administrator. This methodology would take into account variations in input prices in different service areas. The adjustments would be budget neutral.

NEW SECTION 1860D–18. COLLECTION OF BENEFICIARY OBLIGATION

Current Law

Beneficiaries pay a monthly Part B premium. In general, this is collected through a withholding from social security checks.

Explanation of Provision

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

NEW SECTION 1860D–19. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

Current Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Medicaid is a federal-state program which provides health insurance coverage to certain low-income individuals. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual eligibles," Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides pro-

tection against the costs of services generally not covered by Medicare. Perhaps the most important service for the majority of dual eligibles is prescription drugs. These dual eligibles typically have comprehensive drug coverage with only nominal cost-sharing.

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

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

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

Qualifying Individuals (QI–1s) are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. The monthly income limit for QI–1 for an individual is $1,031 and for a couple $1,384 ($12,372 per year for an individual and $16,608 for a couple). Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium. In general, Medicaid payments are shared between the federal government and the states according to a matching formula. However, expenditures under the QI–1 program are paid 100% by the federal government (from the Part B trust fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. This temporary program, originally slated to end September 30, 2002, has been extended through September 30, 2003, by P.L. 108–7.

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

Explanation of Provision

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

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

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

Persons with incomes below 160% of poverty, not otherwise eligible for low-income benefits would have a sliding scale premium subsidy ranging from 100% of the premium at 135% of poverty to 0% at 160% of poverty with no additional premium costs provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average). The benefit package for this population would be defined as having a $50 deductible, 10.0% cost-sharing for costs below the initial coverage limit; 20.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and10.0% cost-sharing for costs above the catastrophic limit. Plans could waive or reduce cost-sharing otherwise applicable.

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

Eligibility for low-income individuals would be determined by states. A BIPA requirement that the Commissioner of Social Security would identify and notify individuals entitled to benefits under the Medicare Savings Program would be amended to include individuals eligible for low-income assistance under Part D. The Administrator would implement a process to notify the eligible entity or MedicareAdvantage plan that the individual is eligible for a cost-sharing subsidy and the amount of the subsidy. The entity would reduce the applicable cost-sharing and submit information to the Administrator on the amount of the reduction. The Administrator would periodically and on a timely basis reimburse the entity or organization for the amount of the reductions.

SECTION 1860D–20. REINSURANCE PAYMENTS FOR EXPENSES INCURRED IN PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE THE ANNUAL OUT-OF-POCKET THRESHOLD

Current Law

No provision.

Explanation of Provision

The provision would provide for reinsurance payments. These payments would be made to plans in the case of individuals whose spending exceeded the out-of-pocket limit. Payments to plans would equal 80% of allowable drug costs exceeding the limit. Allowable costs would be equal to actual costs above the limit, subject to an adjustment. The Administrator would reduce actual costs to the extent such amount was based on costs for specific covered drugs that were greater than the average cost for the covered drug for the year (as determined under new Section 1860D–16). Entities would be required to notify the Administrator of the total actual costs (if any) incurred for providing benefits for an individual after the individual exceeded the out-of-pocket threshold. The entity would be required to provide a breakdown of: each drug paid by the plan over the limit, the negotiated price for each such drug, number of prescriptions, and the average beneficiary coinsurance rate. Administrative costs and costs for coverage in excess of the standard benefit would not be included.

Payment methods would be determined by the Administrator. Such methods could include the use of interim payments. Reinsurance payments could be made to qualifying entities, MedicareAdvantage plans and sponsors of qualified retiree prescription drug plan. Sponsors of qualified retiree prescription drug plans would have to attest that coverage under the retiree plan met or exceeded the requirements for qualified drug coverage.

NEW SECTION 1860D–21. DIRECT SUBSIDY FOR SPONSOR OF A QUALIFIED RETIREE PRESCRIPTION DRUG PLAN FOR ENROLLEES ELIGIBLE FOR, BUT NOT ENROLLED IN THIS PART

Current Law

No provision.

Explanation of Provision

The Administrator would make direct payments to sponsors of qualified retiree prescription drug plans (as defined under New Section 1860D–20) for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would equal the direct subsidy percent of the monthly national average premium for the year, as adjusted by risk adjusters. The direct subsidy percent would be 100% minus the applicable percent as defined under the new Section 1860D–17. The applicable percentage for an area would be 32% divided by 100% minus a percentage equal to: total reinsurance payments that will be made in a year divided by such amount plus total payments that would be made to plans in the year for standard coverage. This amount would be

geographically adjusted in accordance with a methodology established by the Administrator.

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

Subpart 3—Miscellaneous Provisions

NEW SECTION 1860D–25. PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

Current Law

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

Explanation of Provision

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

NEW SECTION 1860D–26. OTHER RELATED PROVISIONS

Current Law

No provision

Explanation of Provision

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

Entities offering a Medicare Prescription Drug plan or a MedicareAdvantage organization offering a MedicareAdvantage plan could enter into an agreement with a state pharmaceutical assistance program (including one established under a Section 1115 waiver) to coordinate coverage.

Within six months of enactment, the Secretary would be required to submit a legislative proposal for any necessary technical and conforming amendments.

Effective Date

Enactment.

SECTION 102. STUDY AND REPORT ON PERMITTING PART B ONLY INDIVIDUALS TO ENROLL IN MEDICARE VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

Current Law

No provision.

Explanation of Provision

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

Effective Date

Enactment.

SECTION 103. RULES RELATING TO MEDIGAP POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE

Current Law

Beneficiaries may purchase individual health insurance polices to supplement their Medicare benefits. These policies are referred to as Medigap policies. Individuals who first purchase a Medigap policy on or after July 30, 1992, 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 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.

Explanation of Provision

Effective January 1, 2006, Medigap drug policies could not be sold to Part D enrollees. Persons who had such policies could obtain Medigap coverage without drug benefits. Beneficiaries who sought to enroll during the Part D open enrollment period established for current beneficiaries would be guaranteed issuance of such non-drug policies (without an exclusion based on preexisting conditions).

Medigap insurers would not be required to participate as an eligible entity under the new Part D as a condition for issuing any other non-drug Medigap policies. A state would not be able to require an issuer to participate as an eligible entity under Part D as a condition of issuing any other non-drug Medigap policy.

Effective Date

Enactment.

SECTION 104. MEDICAID AND OTHER AMENDMENTS RELATED TO LOW-INCOME BENEFICIARIES

Current Law

States make eligibility determinations for their Medicaid populations as well as for the QMB/SLMB/QI–1 populations. Federal matching payments generally equal 50% of administrative costs.

Qualifying Individuals (QI–1s) are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. Expenditures under the QI–1 program are paid 100% by the federal government (from the Part B trust fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. This temporary program, originally slated to end September 30, 2002, has been extended through September 30, 2003, by P.L. 108–7.

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

Explanation of Provision

The provision would require states to make low-income eligibility determinations for low income subsidies. States would be required, for purposes of the transitional prescription drug card assistance program, to establish eligibility standards consistent with that program; establish procedures for providing presumptive eligibility determinations (similar to that which currently apply for low-income pregnant women and children); make eligibility determinations for the card program; and communicate to the Secretary information on eligibility determinations or discontinuations. For purposes of the low-income subsidies for the new Part D program, states would be required, beginning November 2005, to make eligibility determinations; establish procedures for providing presumptive eligibility determinations; inform the Administrator of cases where eligibility was established, and otherwise provide the Administrator with any information required to carry out Part D. States would be required to enter agreements with the Commissioner of Social Security to use all Social Security field offices in the state as information and enrollment sites for making eligibility determinations.

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

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

under the administrative simplification provisions of Title XI of the Social Security Act.

Medicaid beneficiaries who were eligible for full medical and drug benefits under their state Medicaid program would remain in Medicaid. Beginning January 1, 2006, States agreeing to provide a drug benefit to their dual eligible population that was at least equivalent to minimum standards would be relieved of their responsibility to pay Medicare Part B premiums for Medicaid and QMB eligibles between 74% and 100% of the federal poverty level. The minimum standards would be defined as follows. A state would be required to meet all current law coverage standards for dual eligibles under Medicaid, including nominal cost-sharing requirements. States would have to provide beneficiary protections equivalent to those provided under Part D. States could not place a limit on the number of prescriptions.

If, on the date of enactment, state provided medical assistance to aged and disabled persons up to 100% of the federal poverty level, it would be entitled to have the federal government assume the costs for Medicare Part A cost-sharing for that population. The federal government's assumption of Part A cost-sharing for these states would begin at 74% of the federal poverty level and would parallel the state's aged and disabled coverage level up to 100% of the federal poverty level. The Part A costs would be assumed so long as the state maintained the expanded coverage. The provision would apply effective January 1, 2006.

Residents of Puerto Rico and the territories would not be eligible for low-income subsidies under Part D. Instead, if they chose to provide drug coverage assistance to their low-income residents they would receive an increase in amounts otherwise paid to them under Medicaid. The aggregate amount available would be $22.5 million for the last 3 quarters of FY2006, and $30 million for FY2007. In subsequent fiscal years, the aggregate amount would be the amount available the previous year, increased by the percentage increase in prescription drug spending.

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

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

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

Effective Date

Enactment.

SECTION 105. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC)

Current Law

MedPAC is an independent federal body, established by the Balanced Budget Act of 1997 to advise the U.S. Congress on issues affecting the Medicare program.

Explanation of Provision

The provision would expand the membership to 19 and specify that the membership would include experts in the area of pharmacology and prescription drug benefit programs. MedPAC duties would be expanded to include review of competition among eligible entities offering Medicare Prescription Drug plans and beneficiary access to such plans and covered drugs, particularly in rural areas.

Effective Date

Enactment.

SECTION 106. STUDY REGARDING VARIATIONS IN SPENDING AND DRUG UTILIZATION

Current Law

No provision.

Explanation of Provision

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

Effective Date

Enactment.

Subtitle B—Medicare Prescription Drug Discount Card With Benefit Dollars for Low-Income Beneficiaries

SECTION 111. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD WITH BENEFIT DOLLARS FOR LOW-INCOME BENEFICIARIES

NEW SECTION 1807. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

Current Law

No provision.

Explanation of Provision

The provision would add a new Section 1807 to the Social Security Act, Medicare Prescription Drug Discount Card Endorsement Program. The Secretary would establish a program under which the Secretary would endorse card programs offered by prescription drug card sponsors meeting certain requirements and would make available information on such programs to beneficiaries. Eligible

sponsors would be entities with demonstrated experience and expertise in operating a prescription drug discount card program or similar program that the Secretary determined to be appropriate to provide benefits to Medicare beneficiaries. Such entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers, other entities, or any combination of these.

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

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

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

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

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

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

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

SECTION 1807A. TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES

Current Law

No provision.

Explanation of Provision

The provision would add a new Section 1807A to the Social Security Act, Transitional Prescription Drug Assistance Card Program for Eligible Low-Income Beneficiaries. The Secretary would award contracts to prescription drug card sponsors, offering a program that was endorsed by the Secretary under the new Section 1807, to offer a prescription drug card assistance program to eligible low-income beneficiaries. The program would begin no later than January 1, 2004. The Secretary would provide for a transition and dis-

continuation of the drug card program and the low-income assistance card program when the new Part D program became effective. The transitional programs would continue to operate at least 6 months after the date benefits first became available under Part D.

All individuals meeting the definition of QMB, SLMB, or QI–1, who were not eligible to receive drug benefits under Medicaid, could receive assistance with their prescription drug costs, effective January 1, 2004. These persons would have access, through a drug discount card, to up to $600 per year. The entire $600 benefit would be available for the entire year; any balance left on the card in one year could be carried forward. Beneficiaries would be subject to cost-sharing requirements which could not be less than 10% of the negotiated price for a drug. Cost-sharing charges would not count against the $600. At a minimum, card sponsors would provide low-income enrollees with a minimum of a 20% discount from the average wholesale price for each covered drug.

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

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

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

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

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

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

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

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

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

Effective Date

Enactment.

Subtitle C—Standards for Electronic Prescribing

SECTION 121. STANDARDS FOR ELECTRONIC PRESCRIBING

Current Law

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

Section 1171 defines health care clearinghouse, health care provider, health plan, personally identifiable health information, and standard setting organization. Section 1172 specifies that the administrative simplification standards apply to individual and group health plans, health care clearinghouses, and health care providers who transmit health information electronically in a standard format in connection with one of the transactions specified in Section 1173, or who rely on third-party billing services to conduct such

transactions. The Secretary is required either to adopt standards that have already been developed by standard setting organizations or to develop different standards, provided they substantially reduce administrative costs to health plans and providers. If no standard has been adopted by a standard setting organization, the Secretary must develop a new standard based on the recommendations of various specified organizations and agencies.

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

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

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

Explanation of Provision

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

consistent with the objective of improving patient safety and improving the quality of care.

The standards for transactions, and data elements for these transactions, must provide that prescriptions, written and transmitted electronically, must comply with the standards except in emergency cases. The standards would accommodate the electronic transmittal of a patient's medication history, eligibility, benefit and other prescription information among prescribing and dispensing professionals at the point of care. The information that could be transmitted using the standards would include information on the drugs prescribed for the patient, cost-effective alternatives (if any) to the drug prescribed, information on eligibility and benefits, including the drugs included in the applicable formulary and any requirements for prior authorization. This information would also include information on potential drug interactions, and other information to improve the quality of care, to reduce medical errors, and contain costs. The standards shall be designed so that, to the extent practicable, they do not impose an undue administrative burden on the practice of medicine, pharmacy, or other health professions.

The standards developed or adopted by the Secretary would be compatible with and are required to safeguard the privacy of any individually identifiable information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

The Secretary would adopt standards for the exchange of appropriate and necessary information among prescribing and insurance entities and other necessary entities. Prescribers and health plans would have to provide a written prescription, without any additional charges, if the patient requested one. In addition to the consultation requirements of Section 1172, the Secretary would be required to consult with the Attorney General to ensure that the standards resulted in the secure electronic transmission of prescriptions for controlled substances.

The Secretary would have to adopt the standards by Jan. 1, 2006, and would be permitted to modify them, but in a manner that minimized the disruption and cost of compliance. No individual or entity would be required to transmit or receive prescriptions electronically, but those that did would be required to comply with the standards. Entities covered by the standards would have 24 months to comply. Small health plans, as defined by the Secretary, would have an additional 12 months to comply.

The new Section 1180A would authorize the Secretary to award grants to health care providers to implement electronic prescription programs. There would be authorized to be appropriated such sums as may be necessary for each of fiscal years 2006, 2007, and 2008.

Effective Date

Effective upon enactment.

Subtitle D—Other Provisions

SECTION 131. ADDITIONAL REQUIREMENTS FOR ANNUAL FINANCIAL REPORT AND OVERSIGHT ON MEDICARE PROGRAM

Current Law

The trustees of the Medicare Hospital Insurance trust fund and the Medicare Supplementary Medical Insurance trust fund are required to submit annual reports to the Congress.

Explanation of Provision

The provision would require the trustees to submit a combined report on the status of the two trust funds including the Prescription Drug Account. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury and the percentage such amount bore to all other obligations of the Treasury in that year. This calculation would be made separately for Medicare benefits and for administrative and other expenses. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 50-year projections would also be required. The report would also provide a comparison of the rates of growth for both benefits and administrative costs to the rates of growth in the gross domestic product, health insurance costs in the private sector, employment-based health insurance costs in the public and private sectors, and other areas as determined appropriate by the Board of Trustees.

The section would express the sense of the Congress that the committees of jurisdiction would hold hearings on these reports.

Effective Date

The provision would apply with respect to fiscal years beginning on or after the date of enactment.

SECTION 132. TRUSTEES' REPORT ON MEDICARE'S UNFUNDED OBLIGATIONS

Current Law

The trustees of the Medicare Hospital Insurance trust fund and the Medicare Supplementary Medical Insurance trust fund are required to submit annual reports to the Congress.

Explanation of Provision

The 2004 reports would be required to include an analysis of the total amount of unfunded obligation of Medicare. The analysis would compare long-term obligations of Medicare to the dedicated funding sources for the program (not including general revenues).

Effective Date

Enactment.

TITLE II—MEDICAREADVANTAGE

Subtitle A—MedicareAdvantage Competition

SECTION 201. ESTABLISHMENT OF THE MEDICAREADVANTAGE PROGRAM

Current Law

General. Health Maintenance Organizations and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plans contracts in the 1970s and the Medicare risk contract program in the 1980s. Then, in 1997, Congress passed the Balanced Budget Act of 1977 (BBA, P.L. 105–33), replacing the risk contract program with the Medicare+Choice (M+C) program. M+C options include several different types of coordinated care plans, private fee-for-service plans, and on a demonstration basis, a combination of a medical savings account (MSA) plan and contributions to an M+C MSA. No enrollment is permitted in an MSA after 2002.

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

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

M+C Elections. When the M+C program was implemented, individuals were able to make and change election to an M+C plan on an ongoing basis. Beginning in 2005, elections and changes to elections will be available on a more limited basis. Individuals can make or change elections during the annual coordinated election period (November 15th through December 31st for 2003 and 2004, and the month of November, thereafter). Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2005 (or first 3 months of any subsequent year). Additionally, there are special enrollment rules for newly eligible aged beneficiaries as well as special enrollment periods for all enrollees in under limited situations such as an enrollee who changes place of residence.

Explanation of Provision

General. This provision would establish the MedicareAdvantage (MA) program, which would replace the M+C program. An MA plan could be a coordinated care plan such as a Health Management Organization (HMO), a Provider Sponsored Organization (PSO), a Medical Savings Account (MSA), a Private Fee-for-Service Plan (PFFS), or a regional Preferred Provider Organization (PPO). The statutory requirements for plans would remain largely the same, with modifications to reflect the new Medicare Part D drug benefit, requirements for enhanced benefits, and other changes. For MSAs, the deadline for enrollment would be extended through 2003.

Eligibility. In general, Medicare beneficiaries entitled to Part A of Medicare and enrolled in both Parts B and D could receive Medi-

care benefits through the FFS program or they could enroll in an MA plan.

Information requirements. In addition to information that the Secretary must disseminate under current law, he or she would be required to provide the following information about MA plans: (1) the MA monthly basic beneficiary premium, (2) the monthly beneficiary premium for enhanced medical benefits, (3) the MA monthly beneficiary obligation for qualified prescription drug coverage, (4) any beneficiary liability for balance billing under Medicare FFS, (5) the catastrophic coverage amount (including the maximum limitation on out-of-pocket expenses) and unified deductible for the plan, (6) the outpatient prescription drug coverage benefits, (7) any beneficiary cost sharing, including information on the unified deductible, (8) comparative information relating to prescription drug coverage, and (9) if applicable, any reduction in Medicare the Part B premium. Additionally, the Secretary would conduct a special information campaign to inform MA eligible individuals about plans, that would begin on November 15, 2005 and end on December 31, 2005.

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

SECTION 202. BENEFITS AND BENEFICIARY PROTECTIONS

Current Law

Benefits. M+C plans are required to include all Medicare-covered services. In some circumstances, plans may also be required to offer additional benefits or reduced cost sharing to their beneficiaries. The basic benefit package includes all of the Medicare-covered benefits (except hospice services) as well as the additional benefits, as determined by a formula which is set in law. The adjusted community rate (ACR) mechanism is the process through which health plans determine the minimum amount of additional benefits they are required to provide to Medicare enrollees and the cost sharing they are permitted to charge for those benefits. Medicare does not currently have a catastrophic limit.

Information requirements. An M+C organization must disclose, in clear, accurate and standardized form to each new enrollee and at least annually thereafter, certain information regarding the plan. The information includes service area, benefits, access, out-of-area coverage, emergency coverage, supplemental benefits, prior authorization rules, grievance and appeals procedures, a description of the quality assurance program, and other information upon request. The Secretary makes grants to states to provide information, counseling, and assistance for Medicare beneficiaries regarding health insurance coverage.

Quality Assurance Program. M+C plans must have a quality assurance program that: (1) stresses health outcomes and provides data permitting measurement of outcomes and other indices of

quality; (2) monitors and evaluates high volume and high risk services and the care of acute and chronic conditions; (3) evaluates the continuity and coordination of care that enrollees receive; (4) is evaluated on an ongoing basis as to its effectiveness; (5) includes measures of consumer satisfaction, and (6) provides the Secretary with certain information to monitor and evaluate the plan's quality.

Explanation of Provision

Benefits. Each MA plan (except an MSA, and in the case of prescription drug coverage, PFFS plans) would be required to offer: (1) all Medicare Parts A and B benefits (except hospice care) available to individuals residing in the area serviced by the plan, (2) qualified prescription drug coverage under Part D to individuals residing in the area, (3) a maximum limitation on out-of-pocket expenses and a unified deductible, and (4) any required additional benefits. The unified deductible would be defined as an annual deductible amount applied in lieu of the inpatient hospital deductible and the Part B deductible. This would not prevent an MA organization from requiring coinsurance or a copayment for inpatient hospital services, after the unified deductible is satisfied, subject to statutory limitations.

A PFFS plan could choose not of offer qualified prescription drug coverage under part D. Beneficiaries enrolling in such a PFFS plan could choose to enroll in an eligible entity under part D to receive their prescription drug coverage.

MA plans could choose to provide individuals with enhanced medical benefits that the Secretary could approve. The Secretary could deny any submission for enhanced benefits believed to discourage enrollment by MA eligible individuals. The Secretary could not approve any enhanced medical benefit that provided for the coverage of any prescription drug, other than those relating to covered prescription drugs under Part D.

This provision would give the Secretary the authority to disapprove any MA plan believed to attract a healthier population.

Information requirements. In addition to information that plans must disseminate under current law, they would also be required to provide the following information: (1) the maximum limitation on out-of-pocket expenses and the unified deductible, (2) qualified prescription drug coverage under Part D, and (3) enhanced medical benefits (including information as to whether or not these benefits were optional) and the monthly beneficiary premium amount for the enhanced medical benefits.

Quality Assurance Program. In addition to current law requirements for quality assurance, the quality assurance programs of an organization would also be required to provide access to disease management and chronic care services and to provide access to preventive benefits and information for enrollees on such benefits.

SECTION 203. PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS

Current Law

Payments. M+C plans are paid an administered monthly payment amount, (M+C payment rate), for each enrollee. The payment area rate is the highest of one of three amounts: (1) a minimum

payment (floor) rate, (2) a blend of an area-specific (local) rate and a national rate, or (3) a minimum increase from the prior year's rate. Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated by a measure of growth in program spending, the national growth percentage. The minimum increase is 2% over the prior year's amount.

After preliminary M+C payment rates are determined, a budget neutrality adjustment is required 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 can only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the direct and indirect costs of graduate medical education.

Risk Adjustment. M+C payments are risk-adjusted to reflect variations in the cost of providing health care among Medicare beneficiaries. Currently a risk adjustment system is being phased in that adjusts payments based on inpatient data using the 15 principal inpatient diagnostic cost groups (PIP–DCGs) adjuster and demographic factors, so that this system accounts for both demographic and health-status variations. Under this mechanism, the per capita payment made to a plan for an enrollee is adjusted if that enrollee had an inpatient stay during the previous year. Separate demographically-based payments are used for enrollees without a prior hospitalization, newly eligible aged persons, newly eligible disabled Medicare enrollees, and others without a medical history. This system will be replaced with a more comprehensive risk adjustment mechanism beginning in 2004. The new risk adjustment methodology will be phased-in based on data from inpatient hospitals and ambulatory settings, at the rate of 30% in 2004, 50% in 2005, and 75% in 2006. Beginning in 2007, risk adjustment will be based entirely on data from inpatient hospitals and ambulatory settings.

Explanation of Provision

Payments. The Secretary would pay each MA organization, for coverage of an individual for a month, a separate payment for benefits under the Parts A and B, and for benefits under the voluntary prescription drug program. Each year the Secretary would calculate a benchmark amount for each MA payment area for each month with respect to coverage of benefits available under Medicare FFS. MA plans would participate on a county basis. The benchmark would be the greater of 1/12 of the annual M+C capitation rate for the payment area for the year or the local fee-for-service rate. The local fee-for-service rate would be defined as the amount of payment for a month in an MA payment area for benefits, as well as associated claims processing costs, for an individual who elects to receive benefits under the Medicare FFS program and is not enrolled in an MA plan. In calculating the local fee-for-service rate, adjustments would be made to remove the costs for indirect medical and direct graduate medical education.

In order to equalize the federal contribution, the Secretary would ensure that the payment to the MA organization for an enrollee

would equal the MA benchmark amount for the payment area in which that individual resides, as adjusted. The benchmark amount for an area would be adjusted by multiplying it by the ratio of the payment amount (determined by the Secretary) to the weighted service area benchmark amount, and using such risk adjustment factors as specified by the Secretary.

Beginning in 2005, the Secretary would annually announce (at the same time as the announcement for risk adjustors for the prescription drug program—no later than April 15th of each year) the following payment factors; the benchmark amount for each MA payment area and the factors to be used for adjusting payments under the comprehensive risk adjustment methodology.

For payments before 2006, the payment would be the same as under current law—the highest of the blend, minimum amount (floor), or minimum update. Beginning in 2014, the minimum amount (floor) would be annually updated by the percentage increase in the Consumer Price Index for all urban consumers for the 12-month period ending with June of the previous year. The Secretary would calculate and publish the annual M+C capitation rates and would use those rates for purposes of determining the benchmark amount.

Beginning in 2006, MA plans would be paid based on the following new methodology. First, each plan would submit a bid (see Section 204, below) including assumptions with respect to the number of enrollees and their mix by health status. The Secretary would calculate a weighted service area benchmark amount for the benefits under FFS for each plan equal to the weighted average of the benchmark amounts for benefits under Medicare FFS for the payment areas included in the service are of the plan, using assumptions contained in the plan bid. The Secretary would determine the difference between each reviewed plan bid and the weighted service area benchmark amount for purposes of determining the payment amount to plans, any required additional benefits and the MA monthly basic beneficiary premium. The Secretary would pay plans as follows: (1) for plan bids that equal or exceed the weighted service area benchmark, the MA organization would receive the weighted service area benchmark amount, and (2) for plan bids below the weighted service area benchmark, the plan would receive the weighted service area benchmark reduced by the amount of any premium reduction elected by the plan. The Secretary would adjust payments using the comprehensive risk adjustment methodology. Further adjustments to the benchmark or payment amounts could be made for significant increases in costs to MA plans due to national coverage determinations or legislative changes.

Risk Adjustment. This provision would modify risk adjustment in 2005, so that the Secretary would apply the comprehensive risk adjustment methodology to 100% of the amount of payments to plans. This would apply to all types of plans. Organizations would be required to submit data and other information, in order to carry out risk adjustment. The Secretary could revise the comprehensive risk adjustment methodology from time to time to improve payment accuracy.

SECTION 204. SUBMISSION OF BIDS; PREMIUMS

Current Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107–188, temporarily moved plan deadlines for submitting ACRs and other information from no later than July 1 to no later than the second Monday in September for 2002, 2003, and 2004.

Each year an M+C organization submits an adjusted community rate (ACR) proposal, estimating their proposed cost of serving Medicare beneficiaries for the following contract year. The ACR process is a mechanism through which health plans determine the minimum amount of additional benefits they are required to provide to Medicare enrollees and the cost sharing they are permitted to charge for those benefits. Under Medicare's rules, a plan may not earn a higher return from its Medicare business than it does in the commercial market. The Secretary reviews this information and approves or disapproves the premiums, cost-sharing amounts, and benefits. The Secretary does not have the authority to review the premiums for either MSA plans or private fee-for-service plans.

Beneficiaries share in any projected cost savings between Medicare's per capita payment to a plan and what it would cost the plan to provide Medicare benefits to its commercial enrollees. To accomplish this, plans must provide either reduced cost sharing or additional benefits to their Medicare enrollees that are valued at the difference between the projected cost of providing Medicare-covered services and the expected revenue for Medicare enrollees. Additionally, beginning in 2003, plans may also reduce the Medicare part B premium. Plans can choose which additional benefits to offer, however, the total cost of these benefits must at least equal the "savings" from Medicare-covered services. Plans may also place the additional funds in a stabilization fund or return funds to the Treasury.

Cost sharing. The actuarial value of deductibles, coinsurance, and copayments applicable on average to individuals enrolled in an M+C plan for required services may not exceed the actuarial value of deductibles, coinsurance, and copayments on average for individuals in traditional Medicare. However, this average may be achieved by having higher copayments for some M+C services and lower for other services.

Explanation of Provision

Each MA organization would be required to submit information by the 2nd Monday in September, including: (1) notice of intent and information on the service area of the plan, (2) the plan type for each plan, (3) specific information for coordinated care and PFFS plans, (4) enrollment capacity, (5) the expected mix, by health status of enrolled individuals, and 6) other information required by the Secretary. For coordinated care plans and PFFS plans, the plans would be required to submit the plan bid (the total amount that the plan is willing to accept for FFS benefits not taking into account the application of comprehensive risk adjustment), the assumptions used in preparing the bid with respect to the number of enrollees in each payment area and the mix by health status,

and any required information for prescription drug coverage. For any enhanced medical benefit package a plan chooses to offer, it would be required to provide the following information: (1) the adjusted community rate, (2) the portion of the actuarial value of such benefits package (if any) that would be applied toward satisfying the requirement for additional benefits, (3) the MA monthly beneficiary premium for enhanced benefits, (4) cost-sharing requirements, (5) the description of whether the unified deductible had been lowered or if the maximum out-of-pocket limitation had been decreased, and (6) other information required by the Secretary. Each plan bid would be required to reasonably and equitably reflect the cost of benefits provided under that plan. The Secretary could disapprove a plan bid if he or she determined that the deductible, coinsurance or copayments discouraged access to covered services or were likely to result in favorable selection of MA eligible individuals.

The monthly amount of the premium, if any, charged to an MA enrollee would be the sum of any MA monthly basic beneficiary premium, any premium for enhanced medical benefits and any obligation for prescription drug coverage. If the weighted service area benchmark exceeded the plan bid, the Secretary would require the plan to provide additional benefits, and if the plan bid exceeded the weighted service area benchmark, the plan could charge an MA monthly basic beneficiary premium.

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

Cost Sharing. The monthly basic beneficiary premium and the actuarial value of the deductible, coinsurance and copayments, would have to equal the actuarial value of the deductible, coinsurance and copayments applicable on average to individuals who elected to receive benefits under FFS, if such individual were not a member of an MA organization (adjusted to account for geographic differences and for the plan cost and utilization differences). Similarly for enhanced medical benefits, the sum of the MA monthly beneficiary premium for enhanced medical benefits and the actuarial value of the deductible, coinsurance, and copayments, must equal the Adjusted Community Rate (ACR) for such benefits for the year minus the actuarial value of any required additional benefits. The Secretary could disapprove a bid if he or she determined that the deductible, coinsurance, or copayments discouraged access to covered services or could likely result in favorable selection of MA eligible individuals.

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

SECTION 205. SPECIAL RULES FOR PRESCRIPTION DRUG BENEFITS

Current Law

No provision.

Explanation of Provision

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

SECTION 206. SPECIAL RULES FOR EMPLOYER SPONSORED PLANS

Current Law

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

Explanation of Provision

Employers would be permitted to sponsor a plan or pay premiums for qualified retirees who enroll in a PPO. If a PPO contracts with an employer group health plan that covers enrollees in a PPO, the enrollees must be provided the same benefits as all other enrollees in the PPO, with the EGHP benefits enhancing the PPO benefits. The Secretary may waive or modify requirements that hinder the ability of employer or union group health plans from offering a plan.

SECTION 207. ADMINISTRATION BY THE CENTER FOR MEDICARE CHOICES

Current Law

The M+C program is currently administered by the Centers for Medicare and Medicaid Services (CMS).

Explanation of Provision

Beginning January 1, 2006, the MA program would be administered by the Center for Medicare Choices, and each reference to the Secretary made shall be deemed to be a reference to the Administrator of the Center for Medicare Choices.

SECTION 208. CONFORMING AMENDMENTS

Current Law

Contracts between M+C organizations and CMS are subject to statutory requirements.

Explanation of Provision

The Secretary could determine that an MA organization failed to meet the terms of its contract. In addition to specifications included in current law, an organization would also not be allowed to charge any individual an amount in excess of the MA monthly beneficiary obligation for qualified prescription drug coverage, provide coverage that is not qualified prescription drug coverage, offer prescription drug coverage but not make standard prescription drug coverage available, or provide coverage for drugs other than that relating to prescription drugs covered under Part D as an enhanced or additional benefit.

SECTION 209. EFFECTIVE DATE

Current Law

No provision.

Explanation of Provision

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

Subtitle B—Preferred Provider Organizations

SECTION 211. ESTABLISHMENT OF MEDICAREADVANTAGE PREFERRED PROVIDER PROGRAM OPTION

Current Law

PPOs are permitted to be offered as coordinated care plans under the Medicare+Choice program.

Explanation of Provision

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

There would be at least 10 regions. Each region would have to include at least 1 state. The Secretary could not divide states so that portions of the state were in different regions. To the extent possible, the Secretary would include multi-state metropclitan statistical areas (MSAs) in a single region, except that he or she could divide an MSA where necessary to establish a region of such size and geography to maximize the participation of PPOs. The Secretary could use the same regions established for the prescription drug program, under Part D. The service area of a PPO would be

the region. The Secretary could disapprove any PPO believed to attract a population that is healthier than the average population of the region serviced by the plan. PPOs would be required to establish a sufficient number and range of health care professionals and providers willing to provide services under the plan's terms. The Secretary would consider this requirement to be met if the organization had a sufficient number of contracts and agreements with a sufficient number and range of providers.

The Secretary would make separate monthly payment with respect to benefits under FFS and benefits under the voluntary prescription drug program under part D. The Secretary would establish separate rates of payment for individuals with ESRD. The Secretary would apply the comprehensive risk adjustment methodology to 100% of the plan payment. The Secretary would also establish a methodology for adjusting spending variations within a region, similar to method for equalizing the federal contribution under Section 203 of this legislation.

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

Each plan would submit a bid for coverage of required benefits, with assumptions about the number of enrollees. The Secretary would calculate a regional benchmark amount for each plan equal to the regional benchmark adjusted for the number of enrollees assumed in the plan bid. The Secretary would determine the difference between each adjusted plan bid and the plan's regional benchmark amount to determine the payment amount, additional of benefits required, and the MA monthly basic beneficiary premium. The Secretary would accept the three lowest-cost credible bids in a region that meet or exceed the quality and minimum standards.

The Secretary would pay plans as follows: (1) for bids that equal or exceed the regional benchmark, the MA organization would receive the regional benchmark amount and (2) for bids below the regional benchmark, the plan would receive the regional benchmark reduced by the amount of any premium reduction elected by the plan.

No later than the second Monday in September, a PPO would have to submit notice of intent, information on which region the plan is bidding, and information similarly required for other MA plans. The PPO would also have to indicate the total amount the plan is willing to accept after application of risk adjustment, geographic variation, and for 2006 and 2007 risk corridors. The Secretary shall limit the number of plans in a region to the three lowest-cost credible plans that meet or exceed the quality or minimum standards. The monthly premium charged to an enrollee would equal the sum of any MA monthly basic beneficiary premium, any

MA monthly beneficiary premium for enhanced medical benefits, and any MA monthly obligation for qualified prescription drug coverage. Premiums could not vary among MA eligibles in a region. Unlike other MA plans, PPOs would not be permitted to segment a region.

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

Risk corridors would be established so that PPOs would not initially be responsible for all the risk of the medical benefits, in 2006 and 2007. If the total amount of costs for the year were not more than the first threshold upper limit of the risk corridor, then no additional payment would be made (or conversely, if total costs were not less than the first threshold lower limit, no reduced payment would be made). If the total amount of costs for the plan were more than the first threshold, the plan would receive 50% of the amount of costs above the first threshold up to the second threshold, and 10% of the costs that were more than the second threshold. Similarly if costs were less, the payment would be reduced by 50% of the amount such total costs were less than the first threshold lower limit and not less than the second threshold, and 10% of the amount such costs were less than the second threshold. For 2006 and 2007, the first threshold lower limit would be the target amount minus 5% of the target, and the second threshold would be the target amount minus 10% of the target. For the upper limit, the first threshold upper limit would be the target amount plus 5%, and the second threshold would be the target amount plus 10%. The target amount would be defined as an amount equal to the sum of total monthly payments made to the organization for plan enrollees for the year and the total MA basic beneficiary premium for such enrollees. PPOs would be at full risk for all enhanced medical benefits. A beneficiary's liability would not be affected by these risk corridors in the given years.

Subtitle C—Other Managed Care Reforms

SECTION 221. EXTENSION OF REASONABLE COST CONTRACTS

Current Law

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

Explanation of Provision

This provision would allow a reasonable cost contract to be extended or renewed until December 31, 2009. Beginning in 2004 these plans would have to comply with certain provisions of the M+C program (and beginning in 2006 the MA program), including provisions relating to ongoing quality assurance programs, limitations on physician incentive plans, requirements of uniform pre-

mium amounts for individuals enrolled in the plan, restrictions on the imposition of premium taxes, compliance with standards established by regulation—including provisions relating to state law, the authority of organizations to include supplemental health care benefits subject to the Secretary's approval, provisions of Part C relating to timelines for benefit filings, contract renewals and beneficiary notifications, and proposed cost-sharing under the contract being subject to review by the Secretary.

The Secretary would approve a new application for an HMO to enter into a reasonable cost contract, if as of January 1, 2004 the HMO: (1) provided at least 85% of the services of a physician which are provided as basic health services through a medical group, and (2) met other requirements for such entities under this section.

SECTION 222. 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. EverCare, receives a fixed capitated payment, based on a percentage of the AAPCC, for all nursing home resident Medicare enrollees.

Explanation of Provision

This provision would establish a new M+C option—specialized M+C plans for special needs beneficiaries (such as the EverCare demonstration). 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, 2008. No later than December 31, 2006 the Secretary would be required to submit a report to Congress that assessed the impact of specialized M+C plans for special need beneficiaries on the cost and quality of services provided to enrollees. No later than 1 year after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

SECTION 223. PAYMENT BY PACE PROVIDERS FOR MEDICARE AND MEDICAID SERVICES FURNISHED BY CONTRACT PROVIDERS

Current Law

The Program of All-Inclusive Care for the Elderly (PACE) was created as a demonstration project in Omnibus Reconciliation Act (OBRA) 86. The Secretary was required to grant waivers of certain Medicare and Medicaid requirements to a maximum of 10 (expanded to 15 in OBRA 90) community-based organizations to provide health and long-term care services on a capitated basis to frail elderly persons at risk of being institutionalized. BBA of 1997 made PACE a permanent part of Medicare and a state option for the Medicaid program.

Explanation of Provision

For the Medicare program, this provision would apply limitations on balance billing to PACE providers, individuals enrolled with such PACE providers, and noncontract physicians and other entities in the same manner as applies to M+C organizations, individuals enrolled with such organizations, and physicians and other entities. For the Medicaid program, with respect to services covered under the State plan (but not under Medicare) that are furnished to an individual enrolled in a PACE program. The PACE program would not be required to pay a provider an amount greater than required under the State plan.

SECTION 224. INSTITUTE OF MEDICINE EVALUATION AND REPORT ON HEALTH CARE PERFORMANCE MEASURES

Current Law

No provision.

Explanation of Provision

No later than 2 months after enactment, the Secretary would enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (Institute) would conduct an evaluation of leading health care performance measures and options to implement policies that align performance with payment under the Medicare program. The Act specifies the information to be catalogued, reviewed and evaluated by the Institute. No later than 18 months after enactment, the Institute would submit a report to the Secretary, the House Committee on Ways and Means, the House Committee on Energy and Commerce, and the Senate Finance Committee that describes the findings and recommendation for an overall strategy and approach for aligning payment with performance in the Medicare program. There are authorized to be appropriated $1 million for conducting the evaluation and preparing the report.

SECTION 225. EXPANDING THE WORK OF MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS OF INCLUDE PARTS C AND D

Current Law

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

Explanation of Provision

This provision would expand the work of Medicare quality improvement organizations, effective January 1, 2004. Quality improvement assistance relating to prescription drug therapy would be provided to providers, practitioners, prescription drug card sponsors, eligible entities under Part D, M+C plans and MA plans.

TITLE III—CENTER FOR MEDICARE CHOICES

SECTION 301. ESTABLISHMENT OF THE CENTER FOR MEDICARE CHOICES

Current Law

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires that the Administrator of the Centers for Medicare & Medicaid Services (CMS formerly known as the Health Care Financing Administration) be appointed by the President with the advice and consent of the Senate. Title 5 of the U. S. Codes sets the Administrator's salary at level IV of the Executive Schedule.

Explanation of Provision

The section would amend title XVIII to add new section 1808 which, under subsection (a), would establish a new Center for Medicare Choices (CMC) within the Department of Health and Human Services by no later than March 1, 2004 to administer parts C and D of Medicare.

Subsection (b) would provide for an Administrator of CMC who would be appointed by the President with the advice and consent of the Senate for 5-year terms. The Administrator would be able to appoint a Deputy Administrator. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 5-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of CMC and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of CMC, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the CMC except for any unit, component, or provision provided by section 1808. The Administrator may assign duties, delegate, or authorize redelegations of authority to CMC officers and employees as needed. The Secretary of Health and Human Services shall ensure appropriate coordination between the Administrator of CMC and the Administrator of the Centers for Medicare & Medicaid Services in administering the Medicare program.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the CMC. In administering parts C and D of Medicare, the Administrator would be required to negotiate, enter into and enforce contracts with MedicareAdvantage plans and with eligible entities for Medicare prescription drug plans. The Administrator would be required to carry out any duty provided for under part C or D of Medicare in-

cluding demonstration programs (that are carried out in whole or in part under parts C or D). The Administrator of the agency, to the extent possible, would not be able to interfere in any way with negotiations between eligible entities, MedicareAdvantage organizations, hospitals, physicians, other entities or individuals furnishing items and services under this title (including contractors for such items and services), and drug manufacturers, wholesalers, or other suppliers of covered drugs. The Administrator would be required to submit a report to Congress and the President on the administration of the voluntary prescription drug delivery program not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be able to employ management staff as determined appropriate. The Administrator would be able to compensate such managers up to the highest rate of basic pay for the Senior Executive Service. Any such manager would be required to have demonstrated, by their education and experience (either in the public or private sectors) superior expertise in the review, negotiation, and administration of health care contracts, the design of health care benefit plans, actuarial sciences, compliance and health plan contracts, consumer education and decision-making.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within CMC to make Medicare eligibility determinations, enroll beneficiaries into Medicare, provide Medicare benefit and appeals information, and carry out any other activities relating to Medicare beneficiaries under title XVIII. Within the Office of Beneficiary Assistance, a Beneficiary Ombudsman would be established who is appointed by the Secretary. The Ombudsman would be required to receive complaints, grievances, and requests for information submitted by a Medicare beneficiary regarding any aspect of the Medicare program; to provide assistance with the complaints, grievances and requests including assisting beneficiaries with appeals; and with problems arising from disenrolling from a MedicareAdvantage plan or a prescription drug plan. The Ombudsman would be required to submit annual reports to Congress, the Secretary, and the Medicare Competitive Policy Advisory Board describing the activities of the Ombudsman's office and including any recommendations for improvement in the administration of title XVIII. The Ombudsman would also be required to coordinate with state medical ombudsmen programs, and with state-and community-based consumer organizations to provide information about the Medicare program and to conduct education outreach regarding resolution or avoidance of problems under the Medicare program.

Subsection (e) would establish the Medicare Competitive Policy Advisory Board (the Board) within the CMC to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C and D. The Board would be required to report to Congress and to the Administrator of CMC such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C and D including: stability and solvency of the program, increasing competition, improving the qual-

ity of benefits, incorporating disease management, improving competition and access to plans in rural areas, and improving beneficiary information and education for the entire Medicare program. The reports would be required to be published in the Federal Register. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the Federal Register. The Administrator of CMC is required to provide information and assistance to the Board as is requested to carry out its functions.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair. The Board is required to have an executive director who, with the approval of the Board, may appoint staff as appropriate.

Subsection (f) would authorize an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

The provision would also require that the Secretary provide 1–800–Medicare as a means by which individuals seeking information about or assistance with Medicare can receive assistance. The Secretary would be required to route calls to the appropriate entity to provide the assistance or information. The 1–800–Medicare number would be required to be published in the Medicare handbook in place of the listing of phone numbers of individual contractors.

SECTION 302. MISCELLANEOUS ADMINISTRATIVE PROVISIONS

Current Law

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

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

Explanation of Provision

Subsection (a) would add the Administrator of CMC as Co-Secretary of the Board of Trustees of the Medicare Trust Funds.

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

Effective Date

The CMC would be required to be established by the Secretary no later than March 1, 2004.

TITLE IV—MEDICARE FEE-FOR-SERVICE PROVISIONS

Subtitle A—Provisions Relating to Part A

SECTION 401. EQUALIZING URBAN AND RURAL STANDARDIZED PAYMENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM

Current Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6% larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (P.L. 108–7) provided for a temporary payment increase for rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, will be paid on the basis of the large urban area amount.

Explanation of Provision

Medicare would pay hospitals in rural and small urban areas using standardized amounts that are equal to ½ of the difference between amounts paid to hospitals in large urban areas and hospitals in other areas for discharge during the last 3 quarters of FY2004. For 2005 discharges and thereafter, the Secretary would compute a standardized amount equal to that for hospitals in large urban areas to pay hospitals in any area within the United States.

Effective Date

Upon enactment.

SECTION 402. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PPS WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX

Current Law

Medicare's payments to acute hospitals are adjusted, either increased or decreased as appropriate, by the wage index of the area where the hospital is located or where it has been reassigned. Presently, approximately 71% of the standardized amount for each hospital discharge is adjusted by the area wage index. Decreasing this proportion or labor-related share would increase Medicare payments to hospitals in areas with wage indices below one and decrease Medicare payments to hospitals in areas with wage indices above one.

Explanation of Provision

For cost reporting periods beginning on or after October 1, 2004, the Secretary would be required to decrease the labor-related share to 68% of the standardized amount only if such change would result in higher total payments to the hospital. This provision would

be applied without regard to certain budget-neutrality requirements.

Effective Date

Upon enactment.

SECTION 403. MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS

Current Law

Medicare pays inpatient acute hospital services on a discharge basis without regard for the number of beneficiaries discharged from any given hospital. Under certain circumstances, however, sole community hospitals (SCHs) and Medicare dependent hospitals with more than a 5% decline in total discharges from one period to the next may apply for an adjustment to their payment rates to partially account for higher costs associated with a drop in patient volume due to circumstances beyond their control.

Explanation of Provision

The provision would require the Secretary to develop a graduated adjustment to Medicare's inpatient payment rates to account for the higher unit costs associated with low-volume hospitals. Certain hospitals with fewer than 2,000 total discharges during the 3 most recent cost reporting periods would be eligible for up to a 25% increase in their Medicare payment amount starting for FY2005 cost reporting periods. Eligible hospitals would be located at least 15 miles from a similar hospital or those determined by the Secretary to be so located due to factors such as weather conditions, travel conditions, or travel time to the nearest alternative source of appropriate inpatient care. Certain budget-neutrality requirements would not apply to this provision.

Effective Date

Upon enactment.

SECTION 404. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS

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, starting with discharges occurring on or after April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH patient percentage or threshold amount exceeds 15%. Different formulas are used to establish a hospital's DSH payment adjustment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). Although a SCH or RRC can qualify for a higher DSH adjustment, generally, the DSH adjustment that a small urban or rural hospital can receive is limited to 5.25%. Large (100 beds and more) urban hospitals and large rural hospitals (500 beds and more) are eligible for a higher adjustment that can be significantly greater; the amount of the DSH adjustment received by these larg-

er hospitals will depend upon its DSH percentage. Certain urban hospitals (Pickle hospitals) receive DSH payments under an alternative formula that considers the proportion of a hospital's patient care revenues that are received from state and local indigent care funds.

Explanation of Provision

Starting for discharges on or after October 1, 2004, a hospital that qualifies for a DSH adjustment when its DSH patient percentage exceeds the 15% DSH threshold would receive the DSH payments using the current formula that establishes the DSH adjustment for a large urban hospital. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Effective Date

The provision would apply to discharges occurring on or after October 1, 2004.

SECTION 405. CRITICAL ACCESS HOSPITAL (CAH) IMPROVEMENTS

(a) Permitting CAHs To Allocate Swing Beds and Acute Care Inpatient Beds Subject to a Total Limit of 25 Beds

Current Law

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH is limited to 15 acute-care beds, but can have an additional 10 swing beds that are set up for skilled nursing facility level care. While all 25 beds in a CAH can be used as swing beds, only 15 of the 25 can be used for acute care at any time.

Explanation of Provision

A CAH would be able to operate up to 25 swing beds or acute care beds. The requirement that only 15 of the 25 beds be used for acute care at any time would be dropped.

Effective Date

The provision would be effective for designations made on or after October 1, 2004.

(b) Elimination of the Isolation Test for Cost-Based CAH Ambulance Services

Current Law

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

Explanation of Provision

The provision would drop the requirement that the CAH or the related entity be the only ambulance provider with a 35-mile drive

in order to receive reasonable cost reimbursement for the ambulance services.

Effective Date

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

(c) Coverage of Costs for Certain Emergency Room On-Call Providers

Current Law

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

Explanation of Provision

The provision would expand reimbursement of on-call emergency room providers to include physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services provided on or after January 1, 2005.

Effective Date

The provision would apply to costs incurred for services on or after January 1, 2005.

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

Current Law

Eligible hospitals, skilled nursing facilities, and hospices which meet certain requirements receive Medicare periodic interim payments (PIP) every 2 weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

Explanation of Provision

Starting with payments made on or after January 1, 2005, an eligible CAH would be able to receive payments made on a PIP basis for inpatient services.

Effective Date

The provision would apply to payments for inpatient CAH services furnished on or after January 1, 2005.

(e) Exclusion of New CAHs From PPS Hospital Wage Index Calculation

Current Law

Certain qualified small hospitals are converting to CAHs. After conversion, these facilities are paid on a reasonable cost basis and are not paid under the hospital inpatient prospective payment sys-

tem (IPPS). Medicare's IPPS payments to acute hospitals are adjusted by the wage index of the area where the hospital is located or has been reassigned. Although the hospital wage index is recalculated annually, the wage index for any given fiscal year is based on data submitted as part of a hospital's cost report from 4 years previously. Presently wage data from hospitals that have converted to CAHs are included in the PPS wage index calculation.

Explanation of Provision

The Secretary would be required to exclude wage data from hospitals that have converted to CAHs from the PPS wage index calculation starting for cost reporting periods on or after January 1, 2004.

Effective Date

Upon enactment.

(f) Provisions Related to Certain Rural Grants

Current Law

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. For example, the Medicare Rural Hospital Flexibility Grant Program awards grants to states for rural health care planning and implementation activities, rural network development and implementation, and for CAH designations.

The Secretary may also award grants to hospitals to assist eligible small rural hospitals in implementing data systems required under BBA 1997. Small rural hospitals are short term general hospitals with less than 50 beds that are located in rural areas. The authorization to award the grants expired in FY2002.

Explanation of Provision

The provision would permit the Secretary to award grants under the Small Rural Hospital Improvement Program to hospitals that have submitted applications to assist eligible small rural hospitals in reducing medical errors, increasing patient safety, protecting patient privacy, and improving hospital quality. These grants would not exceed $50,000 and could be used to purchase computer software and hardware, educate and train hospital staff, and obtain technical assistance. The provision would authorize appropriations of $40 million each year from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund for grants to States for specified purposes. States that are awarded grants would be required to consult with the hospital association and rural hospitals in the state on the most appropriate way to use such funds. The provision would also authorize $25 million each year from FY2004 through FY2008 for the Small Rural Hospital Improvement Program. This amount would be appropriated from amounts in the treasury not otherwise appropriated.

Effective Date

The provisions would be effective upon enactment. They would apply to grants awarded on or after the date of enactment and

would apply to grants awarded prior to the date of enactment to the extent that the funds have not yet been obligated.

SECTION 406. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES

Current Law

Medicare requires a hospice to provide certain core services directly. These core services include nursing care, medical social services, and counseling services. The remaining hospice services may be provided directly by the hospice or under arrangements with others. If services are provided through arrangement with other providers, the hospice must maintain professional management responsibility for all such services, regardless of the facility in which the services are furnished.

Explanation of Provision

A hospice would be permitted to enter into arrangements with another hospice program to provide core service in extraordinary circumstances, such as unanticipated high patient loads, staffing shortages due to illness or temporary travel by a patient outside the hospice's service area; and bill and be paid for the hospice care provided under these arrangements.

Effective Date

The provision would apply to hospice care provided on or after October 1, 2004.

SECTION 407. SERVICES PROVIDED TO HOSPICE PATIENTS BY NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND PHYSICIAN ASSISTANTS

Current Law

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of the patient's medical care when the patient makes an election to receive hospice care.

Explanation of Provision

When a beneficiary elected to receive hospice care, a beneficiary would be able to choose a physician's assistant, a nurse practitioner or a certified nurse specialist instead of a physician as the health care provider as having the most significant role in the determina-

tion and delivery of the beneficiary's medical care. This physician's assistant, a nurse practitioner or a certified nurse specialist would not be able to certify the beneficiary as terminally ill.

Effective Date

The amendments would apply to hospice care furnished on or after October 1, 2004.

SECTION 408. AUTHORITY TO INCLUDE COSTS OF TRAINING OF PSYCHOLOGISTS IN PAYMENTS TO HOSPITALS UNDER MEDICARE

Current Law

Medicare pays hospitals for its share of direct costs associated with approved hospital-based training programs for nurses and certain other allied health professionals including inhalation therapists, nurse anesthetists, occupational and physical therapists. Medicare will not pay for such costs associated with psychologists' training.

Explanation of Provision

Medicare would reimburse its share of the reasonable costs of approved education activities of psychologists under the allied health professional training provisions.

Effective Date

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

SECTION 409. REVISION OF FEDERAL RATE FOR HOSPITALS IN PUERTO RICO

Current Law

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25% of the federal national amount and 75% of the local amount to a blended amount based on a 50/50 split between national and local amounts.

Explanation of Provision

Hospitals in Puerto Rico would receive Medicare payments based on 100% of the federal rate for discharges on or after October 1, 2004 and before October 1, 2009. For services provided on or after October 1, 2009, the payment would be based on a 50/50 split below national or local amounts.

Effective Date

Upon enactment.

SECTION 410. AUTHORITY REGARDING GERIATRIC FELLOWSHIPS

Current Law

Geriatrics is a subspecialty of family practice, internal medicine and psychiatry. A 1-year fellowship is required for certification in

geriatrics, following an initial residency in one of those three areas. The certifying boards agreed to reduce the minimum fellowship requirement from 2 years to 1 year, beginning with the 1998 exam. Those physicians interested in an academic career in geriatrics are encouraged to pursue 2-year and 3-year fellowships.

Explanation of Provision

The Secretary would be able to establish that geriatric training programs are eligible for 2 years of fellowship programs for the purposes of direct graduate medical education payments.

SECTION 411. CLARIFICATION OF CONGRESSIONAL INTENT REGARDING THE COUNTING OF RESIDENTS IN A NONPROVIDER SETTING AND A TECHNICAL AMENDMENT REGARDING THE 3-YEAR ROLLING RATIO AND THE IME RATIO

Current Law

Medicare has different resident limits for counting residents in its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed. Prior to BBA 1997, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in nonhospital sites for the purposes of IME. Medicare's DGME payment to a teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialities are allowed additional years in their initial residency period. Residents who are graduates from foreign medical schools do not count unless they pass certain exams.

Generally, the resident counts for both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. It may differ from the IME limit because in 1996 residents training in nonhospital sites were eligible for DGME payments but not for IME payments. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and nonrural hospitals operating training programs in rural areas) can be reimbursed for 130% of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits

into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a 3-year rolling average of resident counts; that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years. The rolling average calculation includes podiatry and dental residents.

CMS has proposed regulations that limit Medicare's graduate medical payments when existing residents are transferred from a nonhospital entity to a teaching hospital, particularly when the nonhospital entity has historically paid for the training costs without hospital funding. CMS seeks to limit reimbursement to those residents who rotate from a hospital setting to nonhospital sites in order to (1) encourage hospitals to broaden physician training in ways that will encompass different primary care settings; and (2) prevent cost shifting from existing support within the community to Medicare.

Explanation of Provision

The Secretary would be required to reimburse teaching hospitals for residents in non-hospital locations, when hospitals incur all, or substantially all, the costs of the training in that site starting from the effective date of a written agreement between the hospital and the entity owning or operating the non-hospital site. The effective date of the written agreement would be determined according to generally accepted accounting principles. The Secretary could not take into account the fact that the hospital costs incurred are lower than actual Medicare reimbursement. In addition, dental and podiatric residents would be removed from the 3–year rolling average calculation.

Effective Date

Upon enactment.

SECTION 412. LIMITATION ON CHARGES FOR INPATIENT HOSPITAL CONTRACT HEALTH SERVICES PROVIDED TO INDIANS BY MEDICARE PARTICIPATING HOSPITALS

Current Law

The Indian Health Service (IHS) provides health care both directly, through tribes and tribal consortia, and through urban Indian organizations. The Indian Health Care Improvement Act (P.L. 94–437) authorized IHS to collect directly from Medicare, Medicaid, and other third party insurers for health services covered by those programs. In addition to care provided directly from IHS and tribal providers, contract health services are purchased by IHS and the tribes from more than 2,000 private providers, if the local facility is unable to provide the needed care. These health services are provided principally for members of tribes who live in contract health service delivery areas. Contract support funding across all IHS programs has been insufficient to cover all IHS and tribal costs. When the costs are not reimbursed through appropriations, the tribes and IHS use program funds to make up the difference.

Explanation of Provision

The provision would prohibit Medicare providers from charging more than the Medicare established rates for inpatient hospital services. The provision also would reduce the demand on program funds to reimburse the providers who have agreed to operate within the constraints of the Medicare program.

Effective Date

The provisions would be applicable as of a date specified by the Secretary. In no case would these provisions apply to Medicare participation agreements in effect or entered into later than 6 months from the date of enactment.

SECTION 413. GAO STUDY AND REPORT ON APPROPRIATENESS OF PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

Current Law

No provision.

Explanation of Provision

The Comptroller General of the United States (GAO) would be required to use the most current data available to conduct a study to determine (1) the appropriate level and distribution of Medicare payments to short-term general hospitals under the inpatient prospective payment system (IPPS) and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs. The study, including recommendations for necessary legislative and administrative action, would be due to Congress within 24 months of enactment.

Effective Date

Upon enactment.

Subtitle B—Provisions Relating to Part B

SECTION 421. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC ADJUSTMENTS OF PAYMENT FOR PHYSICIANS' SERVICES

Current Law

Medicare's payment for services under the physician fee schedule has three components: the relative value for the service, geographic adjustment factors and a conversion factor into a dollar amount. A service's relative value is made up of a physician work component, a practice expense component, and a malpractice expense component. Each of these is then adjusted by a separate geographic adjustment factor and combined together to calculate an indexed relative value for that service provided in a given location. This locality-adjusted relative value unit is multiplied by the conversion factor to calculate Medicare's payment for a service provided by a physician in a given area.

The geographic adjustment factors are indices that reflect the relative cost difference in a given area in comparison to the national average. An area with costs above the national average would have an index greater than 1.00; alternatively, an area with

costs below the national average would have an index less than 1.00. The physician work geographic adjustment factor is based on a sample of median hourly earnings in six professional specialty occupational categories. Unlike the other geographic adjustments, the work adjustment factor reflects only one-quarter of the cost differences in an area. The practice expense adjustment factor is based on employee wages, office rents, medical equipments and supplies, and other miscellaneous expenses. The malpractice adjustment factor reflects differences in malpractice insurance costs.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

Explanation of Provision

For services furnished after January 1, 2004, the Secretary would be required to increase the value of any work geographic index that is below .980 to .980. The values for work index would be raised to 1.0 for services furnished in 2005, 2006, and 2007. The practice expense and malpractice geographic indices in low value localities areas would be raised to 1.00 for services furnished in 2005 through 2007.

Effective Date

Upon enactment.

SECTION 422. MEDICARE INCENTIVE PAYMENT (MIP) PROGRAM IMPROVEMENTS

Current Law

Physicians providing services in a health professional shortage area (HPSA) are entitled to an incentive payment from the Medicare program. This incentive payment is a 10% increase over the amount which would otherwise be paid under the physician fee schedule.

Explanation of Provision

The Secretary would be required to establish procedures to determine when the physician is eligible for a bonus payment. The Secretary would also be required to (1) establish an ongoing program to educate physicians about the incentive program; (2) establish an ongoing study of the incentive program to determine whether beneficiaries' access to physician's services within the HPSA has improved; and (3) submit annual reports including appropriate recommendations for necessary administrative or legislative action concerning improvements to the program. GAO would be required to conduct an ongoing study of the MIP program's impact on beneficiary access to services and submit an annual report, including appropriate recommendations, no later than 1 year after enactment.

Effective Date

Upon enactment.

SECTION 423. INCREASE IN RENAL DIALYSIS COMPOSITE RATE

Current Law

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment. BBRA increased the composite rates by 1.2% for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the mandated 2001 update to 2.4%, an increase that was to be implemented on the following schedule in order to avoid a disruption in claims processing: for services furnished from January through March, 2001, the 1.2% increase specified by BBRA applied; for the remainder of 2001, a transition increase of 2.79% applied. Effective January 1, 2002, the composite rates reflected the 2.4% increase. There is no rate increase scheduled for ESRD composite payment rate in 2004.

Explanation of Provision

The composite rate would be increased by 1.6% for services furnished in 2005 and 2006.

Effective Date

Upon enactment.

SECTION 424. EXTENSION OF HOLD HARMLESS PROVISION FOR SMALL RURAL HOSPITALS AND TREATMENT OF CERTAIN SOLE COMMUNITY HOSPITALS TO LIMIT DECLINE IN PAYMENT UNDER THE OPD PPS

Current Law

The PPS for services provided by outpatient departments (OPD) was implemented in August 2000 for most acute care hospitals. Under hold harmless provisions, rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered OPD services provided before January 1, 2004.

Explanation of Provision

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be applied for services provided in 2006.

Effective Date

Upon enactment.

SECTION 425. INCREASE IN PAYMENTS FOR CERTAIN SERVICES FURNISHED BY SMALL RURAL HOSPITALS UNDER MEDICARE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Current Law

Under the OPD PPS, which was implemented in August 2000, Medicare pays for covered services using a fee schedule based on

ambulatory payment classifications (APCs). Beneficiary copayments are established as a percentage of Medicare's fee schedule payment and differ by APC. Certain hospitals, including rural hospitals with no more than 100 beds, are protected from financial losses that result from implementation of the new outpatient PPS under hold harmless provisions.

Explanation of Provision

The provision would increase Medicare payments for covered outpatient clinic and emergency room visits that are provided by rural hospitals with up to 100 beds on or after January 1, 2005 and before January 1, 2008. Applicable Medicare outpatient fee schedule amounts would be increased up by 5%. The beneficiary copayment amounts for these services would not be affected. The resulting increase in Medicare payments would not be considered as PPS payments when calculating whether a rural hospital's PPS payments are less than its pre-BBA payment amounts under the temporary hold harmless provisions. Also, the budget-neutrality provisions for Medicare's outpatient PPS would not be applicable. Finally, these increased payments would not affect Medicare payments for covered outpatient services after January 1, 2007.

Effective Date

Upon enactment.

SECTION 426. INCREASE FOR GROUND AMBULANCE SERVICES FURNISHED IN A RURAL AREA

Current Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 1997 provided for the establishment of a national fee schedule which was to be implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002 with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

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

Explanation of Provision

The payments for ground ambulance services originating in a rural area or a rural census tract would be increased by 5% for services furnished on or after January 1, 2005 through December 31, 2007. These increased payments would not affect Medicare payments for covered ambulance services in subsequent periods.

Effective Date

Upon enactment.

SECTION 427. ENSURING APPROPRIATE COVERAGE OF AIR AMBULANCE SERVICES UNDER AMBULANCE FEE SCHEDULE

Current Law

Medicare pays for ambulance services under a fee schedule. Seven categories of ground ambulance services, ranging from basic life support to specialty care transport, and two categories of air ambulance services are established. Payment for ambulance services can only be made if other methods of transportation are contraindicated by the patient's medical conditions, but only to the extent provided in regulations.

Explanation of Provision

The regulations governing ambulance services would be required to ensure that air ambulance services be reimbursed if: (1) the air ambulance service is medically necessary based on the health condition of the patient being transported at or immediately prior to the time of the transport service; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary. An air ambulance service would be considered medically necessary when requested: (1) by a physician or hospital in accordance with their responsibilities under the Emergency Medical Treatment and Active Labor Act; (2) as a result of a protocol established by a state or regional emergency medical service agency; (3) by a physician, nurse practitioner, physician assistant, registered nurse, or emergency medical responder who reasonably determines or certifies that patient's condition is such that the time involved in land transport significantly increases the patient's medical risks; or (4) by a Federal or State agency to relocate patients following a natural disaster, an act of war, or a terrorist act. Air ambulance services would be defined as a fixed wing or rotary wing air ambulance services.

Effective Date

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

SECTION 428. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED BY A SOLE COMMUNITY HOSPITAL

Current Law

Generally, hospitals that provide clinical diagnostic laboratory tests under Part B are reimbursed using a fee schedule. Sole community hospitals (SCHs) that provide some clinical diagnostic tests 24 hours a day qualify for a 2% increase in the amounts established in the outpatient laboratory fee schedule; no beneficiary cost-sharing amounts are imposed.

Explanation of Provision

SCHs that provide clinical diagnostic laboratory tests covered under Part B in 2005 and 2006 would be reimbursed their reasonable costs of furnishing the tests.

Effective Date

Upon enactment.

SECTION 429. IMPROVEMENT IN RURAL HEALTH CLINIC REIMBURSEMENT

Current Law

BBA 1997 extended the per visit payment limits that had existed for independent rural health clinics to provider-based rural health clinics (RHCs) except for those clinics based in small rural hospitals with fewer than 50 beds. For services rendered from January 1, 2003 through February 28, 2003, the RHC upper payment limit is $66.46, which reflects a 2.6% increase in the 2002 payment limit as established by the 2002 Medicare Economic Index (MEI). For services rendered from March 1, 2003 through December 31, 2003, the Medicare RHC upper payment limit is $66.72, which reflects a 3.0% increase in the 2002 payment limit as established by in the 2003 MEI. The 2002 MEI was used as an update for 3 months because of the delayed implementation of the 2003 MEI.

Explanation of Provision

The RHC upper payment would be increased to $80.00 for calendar year 2005. The MEI applicable to primary care services would be used to increase the payment limit in subsequent years.

Effective Date

Upon enactment.

SECTION 430. ELIMINATION OF CONSOLIDATED BILLING FOR CERTAIN SERVICES UNDER THE MEDICARE PPS FOR SKILLED NURSING FACILITY SERVICES

Current Law

Under Medicare's prospective payment system (PPS), skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment varies depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF–PPS and paid separately under Part B.

Explanation of Provision

Services provided by a rural health clinic (RHC) and a federally qualified health center (FQHC) after January 1, 2005 would be excluded from SNF–PPS if such services would have been excluded

if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. Outpatient services that are beyond the general scope of SNF comprehensive care plans that are provided by an entity that is 100% owned as a joint venture by two Medicare-participating hospitals or critical access hospitals would also be excluded from the SNF–PPS.

Effective Date

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

SECTION 431. FREEZE IN PAYMENTS FOR CERTAIN ITEMS OF DURABLE MEDICAL EQUIPMENT AND CERTAIN ORTHOTICS; ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DME PROVIDERS

Current Law

Medicare pays for durable medical equipment (DME), using a different fee schedule for each class of covered items. Under the fee schedule, covered items are classified into six major categories, one of which is prosthetics and orthotic devices. In general, fee schedule payments are a weighted average of either local and regional prices, subject to national limits (both floors and ceilings), that are updated each year by the consumer price index for urban consumers (CPI–U) for the 12-month period ending with June of the previous year.

Medical devices are classified into three categories: Class I devices represent minimal potential for harm, and are subject to the least regulatory control (e.g., elastic bandages and enema kits). Class II devices are moderate risk (e.g., some surgical lasers). Class III devices are devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval, the most stringent regulatory control.

Explanation of Provision

Medicare would not increase the DME fee schedule amounts in any of the years from 2004 through 2010 and would update the amounts by the CPI–U in each subsequent year. Payments for orthotic devices that have not been custom-fabricated would be similarly affected. Class III medical devices would be exempt from the freeze in DME payments. Prosthetics, prosthetic devices, and custom-fabricated orthotics would be updated by the percentage change in the CPI–U. The provision would also subject DME companies to an accreditation and quality assurance process. The Secretary would be required to designate independent accreditation organizations no later than 6 months from enactment after consultation with an expert outside advisory panel. Finally, the Secretary would be required to establish and implement quality standards for DME providers. These quality standards would be phased in over a 3-year period.

Effective Date

Upon enactment.

SECTION 432. APPLICATION OF COINSURANCE AND DEDUCTIBLE FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Current Law

Medicare pays laboratories directly for laboratory services provided to ambulatory patients in an outpatient setting. Three main types of laboratories serve these outpatients: independent laboratories, physician office laboratories, and hospital-based laboratories. Clinical lab services are paid on the basis of area-wide fee schedules. The fee schedule amounts are periodically updated. Assignment is mandatory. No beneficiary cost-sharing is imposed.

Explanation of Provision

Medicare would pay all clinical laboratories 80% of the applicable fee schedule amount. Hospital-based, physician office and independent laboratories would be able to charge beneficiaries a 20% coinsurance amount. The Medicare Part B deductible would apply to clinical diagnostic laboratory tests furnished across all settings.

Effective Date

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

SECTION 433. BASING MEDICARE PAYMENTS FOR COVERED OUTPATIENT DRUGS ON MARKET PRICES

(a) Medicare Payment Amount

Current Law

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is specifically authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are based on 95% of the average wholesale price (AWP). The term "AWP" is not defined in statute, but generally, the AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on reported prices as published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. To differing degrees, the published prices on which Medicare payments are based are often higher than the amounts actually paid to acquire a given prescription drug.

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

Explanation of Provision

Drugs or biologicals furnished before January 1, 2004 would be paid at 95% of the AWP. After January 1, 2004, existing drugs and biologicals would be paid the lower of the AWP or 85% of the listed AWP as of April 1, 2003. In subsequent years, this price would increased by the change in the consumer price index (CPI) for medical care for the previous year ending in June. Existing drugs and biologicals are those first available for payment on or before April 1, 2003. After January 1, 2004, payments for influenza virus, pneumococcal pneumonia, and hepatitis B vaccines would be equal to the AWP.

The Secretary would be required to establish a process to determine whether the widely available market price to physicians and suppliers for drugs and biologicals furnished in a year is different from the AWP amounts. This determination would be based on: (1) any report on market price published by the Inspector General (IG) of the Department of Health and Human Services (HHS) or GAO after December 31,1999; (2) a review of market prices by the Secretary including information from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers or any other appropriate source as determined by the Secretary; (3) data submitted by the manufacturer of the drug or biological or by another entity; and (4) other appropriate information as determined by the Secretary. If the market price for a drug or biological determined through this process differs from the AWP amount, that market price shall be treated as the AWP amount when determining Medicare's payment for a drug or biological in 2004 and subsequently. The Secretary would be able to make subsequent determinations with respect to the widely available market price for a given drug or biological. If not, the prior market price determination will be considered as the basis for Medicare's payment amount for such an item.

If, however, the first market price determination for a given drug or biological would result in a payment amount that is 15% less than would otherwise be made, the Secretary would provide for an appropriate transition period where the price is reduced in annual increments equal to 15% of Medicare's payment amount in the previous year. At the end of the transition period, the market price (as determined) would serve as basis for Medicare's payment amount. This transition period would not apply to a drug or biological where a generic version of that drug or biological first enters the market on or after January 1, 2004. The generic version would not be required to be marketed under the chemical name of the given drug or biological.

New drugs and biologicals, those that are first available for Medicare payment after April 1, 2003, would be subject to certain

requirements in order to obtain a code and receive Medicare payment. A manufacturer would be required to provide the Secretary with necessary and appropriate information on the estimated price that the manufacturer expects physicians and suppliers to pay to routinely obtain the drug or biological; the manufacturer would be able to provide the Secretary with other appropriate information as well. During the first year that the drug or biological is available for Medicare payment, the manufacturer would be required to provide the Secretary with updated information on the actual market prices paid by physicians or suppliers for such drugs and biologicals. These market prices would be equal to the lesser of the average wholesale price for the drug or biological or the amount determined by the Secretary based on information originally submitted by the manufacturer supplemented by other appropriate information. The market price of the drug or biological during the second year after becoming available for Medicare payment is subject to the same conditions as in the first year. In subsequent years, the market price would be equal to the lesser of the average wholesale price or the widely available market price as determined by the Secretary in the same fashion as for existing drugs. If no market price determination occurs, then Medicare's payment for drug or biological in the prior year is updated by the change in the CPI for medical care for the previous year ending in June.

Effective Date

Upon enactment.

(b) Adjustments to Payment Amounts for Administration of Drugs and Biologicals

This subsection contains the following provisions

Adjustments in the Physician Practice Expense Relative Values; Payment for Multiple Chemotherapy Agents Furnished on a Single Day Through the Push Technique; and Treatment of Other Services Currently in the Nonphysician Work Pool

Current Law

The relative value associated with a particular physician services is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense include both direct costs (such as clinical personnel time and medical supplies used to provide a specific service to an individual patient) indirect costs (such as rent, utilities, and business costs associated with running a practice). When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (P.L. 103–432) required the Secretary to develop a methodology for a resource-based system for calculating practice expenses for use in CY1998. BBA 1997 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use

data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

Explanation of Provision

The Secretary would be required to establish the practice expense relative value for the physician fee schedule in CY2004 using the survey data collected from a physician specialty organization if the data covers the practice expenses for oncology administration services and meets the Secretary's criteria for acceptable survey data. The Secretary would also be required to review and appropriately modify Medicare's payment policy for the administration of more than one anticancer chemotherapy agent to an individual patient on a single day. The increase in expenditures resulting from this provision would be exempt from the budget-neutrality requirement. Also, the Secretary would be required to adjust the nonphysician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

Effective Date

Upon enactment.

Administration of Blood Clotting Factors

Current Law

Medicare will pay for blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision as well as the items related to the administration of such factors.

Explanation of Provision

The Secretary would be required to review a GAO report, "Payment for Blood Clotting Factors Exceeds Providers Acquisition Costs" (GAO–03–184) and provide a separate payment for the administration of these factors. The total amount of payments for blood clotting factors furnished in CY2004 would not exceed the amount that would have otherwise been expended. In CY2005 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June.

Effective Date

Upon enactment.

Increase in the Composite Rate for End Stage Renal Disease Facilities

Current Law

As discussed in Section 423 of this legislation, dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed, prospectively determined payment amount (the composite rate) for each dialysis treatment, regardless of whether services are provided at the facility or in the patient's home. Medicare pays separately for erythropoietin (EPO) which is used to treat anemia for persons with chronic renal failure who are on dialysis. Congress has set Medicare's payment for EPO at $10 per 1,000 units whether it is administered intravenously or subcutaneously in dialysis facilities or in patients' homes. Providers receive 95% of the AWP for separately billable injectable medications other than EPO administered during treatments at the facility.

Explanation of Provision

The composite rate for dialysis services furnished during 2005 and 2006 would be increased as specified in earlier and then further increased. These composite rates would be increased so that facility payments would equal the composite rate payments (as increased by this an earlier provision in the legislation) plus payments made for separately billed drugs and biologicals (not including EPO) as if the drug pricing provisions of this legislation were not enacted. During 2005, the ESRD composite rate would be increased by 0.05 percent. During 2006 and subsequently, the ESRD composite rate of the previous year (calculated without the temporary increase specified earlier in this legislation) would be increased by 0.05 percentage points. These payment amounts, methods or adjustments would not be subject to administrative or judicial review under the statutory appeals processes when established by Section 1869 of the Social Security Act (SSA), by the Provider Reimbursement Review Board established by Section 1878 of the SSA, or otherwise.

Effective Date

Upon enactment.

Home Infusion and Inhalation Drugs

Current Law

Medicare will cover outpatient prescription drugs and biologicals if they are necessary for the effective use of covered durable medical equipment (DME), including those drugs which must be put directly into the equipment such as tumor chemotherapy agents used with infusion pump (home infusion drugs) or respiratory drugs given through a nebulizer (inhalation drugs).

Explanation of Provision

The Secretary would be able to make separate payments for infusion drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. Total amount of payments for the infusion drugs in the

year could not exceed the total amount of spending that would have occurred without enactment of this legislation.

The Secretary would be able to increase payments for covered DME associated with inhalation drugs and biologicals and make separate payments for such drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. The associated spending attributed to the increased and separate payments for the covered DME and inhalation drugs and biologicals in the year would not exceed the 10% of the difference between the savings in total spending for these drug and biologicals attributed to the prescription drug pricing changes enacted in this legislation.

Effective Date

Upon enactment.

Pharmacy Dispensing Fee for Certain Drugs and Biologicals

Current Law

Medicare pays for certain outpatient prescription drugs and biologicals. For instance, Medicare pays a dispensing fee in conjunction with inhalation therapy drugs used in nebulizers. Medicare does not pay a dispensing fee to pharmacists or providers who supply oral drugs.

Explanation of Provision

Medicare would pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti nausea drugs used as part of an anti-cancer chemotherapeutic regimen. Medicare would be able to pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for other drugs and biologicals.

Effective Date

Upon enactment.

Payments for Discarded Drugs

Current Law

Medicare does not pay for chemotherapy drugs that purchased by physicians, are not dispensed, and must be discarded.

Explanation of Provision

The Secretary would be able to compensate a physician for chemotherapy drugs that are purchased with a reasonable intent to administer to a Medicare beneficiary but which cannot be administered despite the physician's reasonable efforts, because the beneficiary is too sick or the beneficiary's condition changes and the physician must discard the drugs. The Secretary would be able to increase the Medicare payment amount for all covered chemotherapy drugs, but the total amount of the increase could not exceed one percent of the payment for chemotherapy drugs. The beneficiary's cost sharing amounts would not be affected.

Effective Date

Upon enactment.

(c) Linkage of Revised Drug Payments and Increases for Drug Administration

Current Law

No provision.

Explanation of Provision

The Secretary would not be able to implement the revisions in payment amounts specified in subsection (a) for a category of drug or biological unless the Secretary concurrently implements the adjustments to payment amounts for administration of such category of drug or biological as specified in subsection (b).

Effective Date

Upon enactment.

(d) Prohibition Of Administrative and Judicial Review

Current Law

Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal adverse determinations regarding claims for benefits under Part A and Part B. Section 1869 of the SSA allows those parties who have been denied coverage of an item or service the right to appeal that decision through a series of administrative appeals and then into federal district court under certain circumstances. Section 1878 of the SSA allows providers who are dissatisfied with certain cost reporting determinations that affect their reimbursement amounts the right to appeal that decision in front of the Provider Reimbursement Review Board and then into federal district court if the certain thresholds regarding the amount in dispute are met at each step of the appeals process.

Explanation of Provision

The provisions concerning Medicare's determination of payment amounts for existing and new drugs and biologicals including the administration of blood clotting factors, home infusion drugs and inhalation drugs would not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise.

The provisions affecting the adjustments affecting the practice expense relative values, multiple chemotherapy agents administered on a single day, and treatment of other services currently in the nonphysician workpool would not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise.

Effective Date

Upon enactment.

(e) Studies and Reports.

Current Law

No provision.

Explanation of Provision

GAO would be required to conduct a study that examines the impact of the drug payment and adjustment provisions in this legislation on access of Medicare beneficiaries' to covered drugs and biologicals. The report, including appropriate recommendations, would be due to Congress no later than January 1, 2006. The HHS IG would be required to conduct one or more studies that examine the market prices for Medicare covered drugs and biologicals which are widely available to physicians and suppliers. The report would examine those drugs and biologicals that represent the largest portion of Medicare spending on such items and include a comparison of market prices with Medicare payment amounts.

Effective Date

Upon enactment.

SECTION 434. INDEXING PART B DEDUCTIBLE TO INFLATION

Current Law

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has been set at $100 since 1991.

Explanation of Provision

The Medicare Part B deductible would be set at $100 through 2005 and then increased to $125 in 2006. Effective January 1 of subsequent years, the Part B deductible would be increased annually by the percentage change in the CPI–U for the previous year ending in June. The amount would be rounded to the nearest dollar.

Effective Date

Upon enactment.

SECTION 435. REVISIONS TO REASSIGNMENT PROVISIONS

Current Law

Generally, beneficiaries are the parties who are entitled to receive Medicare payments under the Medicare statute. However, beneficiaries can assign these rights to participating physicians, suppliers, and other providers who directly provide the care and then submit claims for Medicare payment. Medicare also permits physicians to reassign their right to payment to certain other entities, such as the hospitals or other facilities where services are performed, or to their employers. Physicians cannot reassign their right to payment to staffing companies (entities that retain physicians on a contractual basis).

Explanation of Provision

Staffing companies (individuals or entities) would be able to submit claims to Medicare for physician services provided under contractual arrangement between the company and the physician, if the arrangement meets appropriate program integrity and other safeguards established by the Secretary.

Effective Date

The provisions would apply to payments made on or after the date that is 30 days after the Secretary publishes a final rule with respect to the amendments made by this section.

SECTION 436. EXTENSION OF TREATMENT FOR CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE

Current Law

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a 2-year period starting on January 1, 2001 and ending December 31, 2002.

Explanation of Provision

Direct payments for the technical component for these pathology services would be made for services furnished during 2005.

Effective Date

Upon enactment.

SECTION 437. TREATMENT OF PASS-THROUGH DRUGS AND THE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

Current Law

Under the hospital outpatient prospective payment system (HOPD–PPS), Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through payment; (2) as a separate APC payment; or (3) as packaged APC payment with other services. Transitional pass-through payments are supplemental payments to cover the incremental cost associated with certain medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for 2 or 3 years, the costs are incorporated into the APC relative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiopharmaceutical drugs and biological products; and new drugs and biologi-

cal agents. Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95% of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision.

Explanation of Provision

The Secretary would be required to treat the amount of payment for pass-through drugs in HOPD–PPS as if Section 433 of this legislation was not enacted. GAO would be required to study the appropriateness of the payments made to drugs that are no longer eligible for the pass-through payment amounts in HOPD–PPS. GAO would consider the appropriateness of payments for drug handling and acquisition in this study. The report including recommendations would be submitted to Congress no later than July 1, 2004.

Effective Date

Upon enactment.

SECTION 438. LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD

Current Law

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

Explanation of Provision

The Secretary would be prohibited from publishing regulations that apply a functional equivalence standard to a drug or biological for transitional pass-through payments under HOPD–PPS. This prohibition would apply to the application of the functional equivalence standard on or after the date of enactment, unless such application was made prior to enactment.

Effective Date

Upon enactment.

SECTION 439. MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS

Current Law

No explicit statutory authorization. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis or treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service; items and services not used in the direct clinical management of the patient; and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.

Explanation of Provision

The routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act would be covered.

Effective Date

The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or before or after January 1, 2005.

SECTION 440. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILIARY RETIREES; SPECIAL ENROLLMENT PERIOD

Current Law

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

Explanation of Provision

This provision would waive the late enrollment penalty in the case of certain military retirees who enrolled in part B during 2002, 2003, 2004 or 2005. The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2005.

Effective Date

The provision would apply to premiums for months beginning with January 2005. The Secretary would be required to establish a method for providing rebates of premium penalties for months on or after January 2005 if they had been collected.

SECTION 441. DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE

Current Law

No specific provision with respect to a demonstration project. Medicare covers limited chiropractic services, specifically manual manipulation for correction of a dislocated or misaligned vertebra or subluxation.

Explanation of Provision

The Secretary would be required to establish a 3-year demonstration program at 6 sites to evaluate the feasibility and desirability of covering additional chiropractic services under the Medicare program. These projects may not be implemented before October 1, 2004. The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform. An eligible beneficiary participating in the demonstration project including those enrolled in Medicare+Choice or MedicareAdvantage plans would not be required to receive approval by physician or other

practitioner in order to receive chiropractic services under the demonstration project. The Secretary would be required to consult with chiropractors, organizations representing chiropractors, beneficiaries and organizations representing beneficiaries in establishing the demonstration projects. Participation by eligible beneficiaries would be on a voluntary basis. The 6 sites would be equally split between rural and urban areas; at least one of the sites would be in a health professional shortage area. The Secretary would be required to evaluate the demonstration projects to determine (1) whether the participating beneficiaries used fewer Medicare covered services than those who did not participate; (2) the cost of providing such chiropractic services under Medicare; (3) the quality of care and satisfaction of participating beneficiaries; and (4) other appropriate matters. The Secretary would be required to submit a report, including recommendations, to Congress on the evaluation no later than 1 year after the demonstration projects conclude. The Secretary would waive Medicare requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. Appropriations from the Federal Supplementary Insurance Trust Fund are authorized as necessary to conduct this demonstration.

Effective Date

The Secretary shall not implement the demonstration project before October 1, 2004.

SECTION 442. MEDICARE HEALTH CARE QUALITY DEMONSTRATION PROGRAMS

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) the provision of incentives to improve the safety of care provided to beneficiaries; (2) the appropriate use of best practice guidelines; (3) the reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) the encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve care, safety, and efficiency; (6) the appropriate use of culturally and ethnically sensitive care; and (7) the related financial effects associated with these changes. The participants would include appropriate health care groups including physician groups, integrated health care delivery systems, or regional coalitions. The demonstration projects may incorporate approved alternative payments, include modification to the traditional fee-for-service benefit package, and would be subject to budget-neutrality restriction. The Secretary would be able to waive Medicare and Medicaid requirements as necessary and may direct agencies within Health and Human Services (HHS) to evaluate, analyze, support, and assist in the demonstration project. The dem-

onstration program would be subject to a budget-neutrality requirement.

Effective Date

The Secretary shall not implement the demonstration project before October 1, 2004.

SECTION 443. MEDICARE COMPLEX CLINICAL CARE MANAGEMENT PAYMENT DEMONSTRATION

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a three-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. Six sites would be designated for the demonstration, three in urban areas and at least one in a rural area. One site would be required to be located in Arkansas. Any Medicare beneficiary enrolled in part B who has at least four complex medical conditions such as and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.

Each principal care physician who agrees to manage the complex clinical care of a beneficiary eligible to participate would be required to agree to: (1) serve as the primary contact of the beneficiary in accessing items and services under Medicare; (2) maintain medical information related to care and services furnished by other health care providers including clinical reports, medication and treatments prescribed by other physicians, hospital and hospital outpatient services, skilled nursing home care, home health care, and medical equipment services; (3) monitor and advocate for the continuity of care of the beneficiary and the use of evidence-based guidelines; (4) promote self-care and family care giver involvement where appropriate; (5) have appropriate staffing arrangements to conduct patient self-management and other care coordination activities as specified by the Secretary; refer the beneficiary to community services organizations and coordinate the services of such organizations with the care provided by health care providers; and (7) meet such other complex care management requirements as the Secretary may specify.

The Secretary would pay each principal care physician a monthly complex care management fee developed by the Secretary. The fee would be the full payment for all the functions performed by the principal care physician including any functions performed by other qualified practitioners acting on behalf of the physician, appropriate staff under the supervision of the physician, and any other person under a contract with the physician, including any person who conducts patient self-management and caregiver education.

Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented.

The Secretary would be required to report to Congress on the demonstration program six months after its completion.

Effective Date

The Secretary shall not implement the demonstration project before October 1, 2004.

SECTION 444. MEDICARE FEE-FOR-SERVICE CARE COORDINATION DEMONSTRATION PROGRAM

Current Law

No provision.

Explanation of Provision

The Secretary would be required to establish a demonstration program that uses qualified care management organizations to provide health risk assessment and care management services to Medicare beneficiaries who are at high-risk (as defined by the Secretary but including beneficiaries with multiple sclerosis or other disabling chronic conditions, nursing home residents or beneficiaries at risk for nursing home placement, or beneficiaries that are also eligible for Medicaid). The Secretary would select six sites, giving preference to sites located in rural areas. The demonstration program would last five years, and would not be implemented before October 1, 2004.

Any high-risk beneficiary residing in a designated area who is not a member of a Medicare+Choice plan may participate if the beneficiary identifies a care management organization who agrees to furnish care management services to the beneficiary under the demonstration program. The Secretary would be required to contract with care management organizations to provide care management services to beneficiaries eligible to participate in the demonstration. The Secretary may contract with more than one care management organization in a geographic area.

The Secretary would pay the care management organization a fee based on bids submitted by care management organizations. The fee would be required to place the care management organization partially at risk. Payment of the full fee would depend upon the care management organization meeting benchmarks for quality and cost. The Secretary may cancel a contract with a care management organization if the organization does not meet negotiated savings or quality outcome targets for the year. Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented.

The Secretary would be required to report to Congress six months after the completion of the demonstration on the program.

Effective Date

The Secretary shall not implement the demonstration project before October 1, 2004.

SECTION 445. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES

Current Law

No provision.

Explanation of Provision

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialities and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component; (4) an evaluation of the economic basis for the floors on the geographic adjustments established previously in this legislation; and (5) an evaluation of the effect of the geographic adjustments on physician retention, recruitment costs, physician mobility as well as the appropriateness of extending such adjustment. The study should include a comparative analysis regarding the cost of physician recruitment and retention in rural areas versus urban areas, and make recommendations concerning use of more current data and use of cost data rather than price proxies. The study would be due to Congress within 1 year of enactment.

Effective Date

Upon enactment.

Subtitle C—Provisions Relating to Parts A and B

SECTION 451. INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA

Current Law

The Medicare home health PPS which was implemented on October 1, 2000 provides a standardized payment for a 60–day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10% for home health services furnished in the home of beneficiaries living in rural areas during the 2-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

Explanation of Provision

The provision would provide a temporary payment increase of 5% for home health care services furnished in a rural area on or after October 1, 2004 and before October 1, 2006 without regard to certain budget-neutrality requirements. The temporary additional payment would not be considered when determining future home health payment amounts.

Effective Date

Upon enactment.

SECTION 452. LIMITATION ON REDUCTION IN AREA WAGE ADJUSTMENT FACTORS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR HOME HEALTH SERVICES

Current Law

Home health agencies are paid under Medicare using the prospective payment system. In calculating payment, the portion of the base payment amount that is attributable to wages and wage related costs is required to be adjusted for those costs. The Secretary is required to calculate an area wage adjustment factor that is actually used to adjust the base payment amount. The factors change annually as new wage data are reported and areas change in relative costliness.

Explanation of Provision

The provision would limit any reduction in the home health area wage adjustment factor for fiscal years 2005 and 2006. Any reduction could be no more than 3% less than the area wage adjustment factor applicable to home health services for the area in the previous year.

Effective Date

Upon enactment.

SECTION 453. EXCEPTION TO PHYSICIAN REFERRAL LIMITATION FOR CERTAIN TRANSFERS FROM SPECIALTY HOSPITALS TO GENERAL HOSPITALS

Current Law

Physicians are generally prohibited from referring Medicare patients to facilities in which they (or their immediate family member) have financial interests. Physicians, however, are not prohibited from referring patients to whole hospitals in which they have investment interests.

Explanation of Provision

The Secretary would be required to establish guidelines for physician investments in ho pitals designated by the Secretary as primarily or exclusively devoted to cardiac, orthopedic, surgical or another specialty. The whole hospital exception to these facilities would only apply if the hospital offers a comprehensive spectrum of inpatient and outpatient services and the specialty and self referrals of the physician are insignificant relative to the overall scope of services offered by the hospital.

Effective Date

The provision would only apply on or after January 1, 2004, except to those hospitals that were substantially complete before June 12, 2003.

SECTION 464. DEMONSTRATION PROJECT FOR SUBSTITUTE ADULT DAY SERVICES

Current Law

No provision.

Explanation of Provision

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95% of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The 3-year demonstration project would be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2-year period. A medical adult day care facility would (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous 2-year period; (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions and (2) recommendations concerning the extension, expansion, or termination of the project.

Effective Date

The Secretary shall not implement the demonstration project before October 1, 2004.

TITLE V—REGULATORY RELIEF

Subtitle A—Regulatory Reform

SECTION 501. RULES FOR THE PUBLICATION OF A FINAL REGULATION BASED ON THE PREVIOUS PUBLICATION ON AN INTERIM FINAL REGULATION

Current Law

The Secretary is required to prescribe regulations that are necessary to administer the Medicare program. The Secretary must publish proposed regulations in the Federal Register, with at least 30 days to solicit public comment before issuing the final regulation except in the following circumstances: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementing a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest.

Explanation of Provision

The Secretary would be required to publish a final regulation within 12 months of the publication of an interim final regulation or the interim final regulation would no longer be effective. Subject to appropriate notice, the Secretary would be able to extend this deadline for up to 12 additional months. The Secretary would be required to publish a notice in the Federal Register 6 months after the date of enactment providing the status of each interim final regulation for which no final regulation has been published and providing the date by which the final regulation is planned to be published.

Effective Date

The requirement for publishing the final regulation following the interim final regulation would be effective on the date of enactment and would apply to interim final regulations published on or after the date of enactment.

SECTION 502. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES

Current Law

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital*, the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

Explanation of Provision

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary de-

termines retroactive application is needed to comply with the statute or is in the public interest. No substantive change would take effect until 30 days after the change is issued or published unless the change is needed to comply with statutory changes or is in the public interest. Compliance actions could be taken for items and services furnished only on or after the effective date of the change.

Effective Date

The prohibition of retroactive application of substantive changes would apply to changes issued on or after the date of enactment. The provisions affecting compliance with substantive changes would apply to compliance actions undertaken on or after the date of enactment.

SECTION 503. REPORT ON LEGAL AND REGULATORY INCONSISTENCIES

Current Law

No provision.

Explanation of Provision

Requires the Secretary to report to Congress in two years, and every three years thereafter, on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

Effective Date

Upon enactment.

Subtitle B—Appeals Process Reform

SECTION 511. SUBMISSION OF PLAN FOR TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS

Current Law

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an administrative law judge (ALJ). The ALJs that hear Medicare cases are employed by the Social Security Administration—a legacy from the inception of the Medicare program when Medicare was part of Social Security.

Explanation of Provision

The Secretary and Commissioner of Social Security would be required to develop and transmit to Congress a plan for transferring the functions of administrative law judges (ALJs) responsible for hearing cases under Medicare from the Social Security Administration to HHS no later than April 1, 2004. The plan would be required to include information on: workload; cost projections and financing; transition timetable; regulations; development of a case tracking system; feasibility of precedential authority; feasibility of electronic appeals filings and teleconference; steps needed to assure independence of ALJs, including assuring that they are in an office

that is operationally and functionally separate from the Centers for Medicare and Medicaid Services and the Center for Medicare Choices; geographic distribution of ALJs; hiring of ALJs; performance standards of ALJs; sharing resources with Social Security regarding ALJs; training; and recommendations for further Congressional action. The GAO would be required to evaluate the Secretary's and Commissioner's plan and report to Congress on the result of the evaluation within 6 months of receiving the plan. The Secretary would be prohibited from implementing the plan developed until no earlier than 6 months after the GAO report.

Effective Date

Upon enactment.

SECTION 512. EXPEDITED ACCESS TO JUDICIAL REVIEW

Current Law

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

Explanation of Provision

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a review entity (a panel of no more than three members from the Departmental Appeals Board) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest is assessed on any amount in controversy and is awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would be permitted for cases where the Secretary does not enter into or renew provider agreements.

The Comptroller General would be required to report to Congress on the access of Medicare beneficiaries and health care providers to judicial review of actions of the Secretary and HHS after February 29, 2000 (the date of the decision of *Shalala* v. *Illinois Council on Long Term Care, Inc.* (529 U.S. 1 (2000)). The report would be due not later than one year after enactment.

Effective Date

The provision would be effective for appeals filed on or after October 1, 2004.

SECTION 513. EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS

Current Law

The statute prohibits approval of nurse aide training programs in skilled nursing facilities that have been subject to extended survey (that is, found to provide substandard care), have had serious sanctions imposed, or have waivers for required licensed nurse staffing.

Explanation of Provision

The Secretary would be required to develop and implement a process to expedite review for certain remedies imposed against skilled nursing facilities (SNFs) including termination of participation, immediate denial of payments, immediate imposition of temporary management, and suspension of nurse aide training programs.

This provision would authorize the appropriation of such sums as needed for FY2004 and subsequent years to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

Effective Date

Upon enactment.

SECTION 514. REVISIONS TO MEDICARE APPEALS PROCESS

Current Law

The overall appeals process is established in the statute. The Benefits Improvement and Protection Act (BIPA) of 2000 changed the appeals process and created a new independent review (the qualified independent contractors or QICs). BIPA established timeframes for each of the four levels of appeals as follows: 30 days at the contractor redetermination level, 30 days at the QIC reconsideration level, 90 days at the administrative judge level, and 90 days at the Departmental Appeals Board level. BIPA called for the establishment of at least 12 QICs. The BIPA claims appeals provisions were effective October 1, 2002.

Explanation of Provision

Subsection (a) would establish a 90-day timeframe for completing the record in a hearing before an administrative law judge (ALJ) or the HHS Departmental Appeals Board (DAB), but provides extensions for good cause. Subsection (b) would provide for the use of beneficiaries' medical records in qualified independent contractors reconsiderations. Subsection (c) would require that notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision and the process for further appeal. Subsection (d) would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and prohibitions on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from 12 to four. Subsection (e) would delay the effective date of certain appeals provisions until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. The provision would allow the transitional use of peer review organizations (now called quality improvement organizations by the Secretary) to conduct expedited determinations until the QICs are operating.

Effective Date

The provisions of this section would be effective as if they were enacted in BIPA.

SECTION 515. HEARING RIGHTS RELATED TO DECISIONS BY THE SECRETARY TO DENY OR NOT RENEW A MEDICARE ENROLLMENT AGREEMENT; CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS

Current Law

Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors. A provider denied a provider agreement is entitled to in a hearing by the Secretary.

Explanation of Provision

The Secretary would be required to develop a process for providers and suppliers to appeal denials or non-renewals of provider agreements. The Secretary would be required to consult with providers and suppliers before changing the provider enrollment forms.

Effective Date

The process for appealing denials or non-renewals of provider agreements would be required within 18 months after enactment. The requirement for consultation before changing the enrollment forms would be effective upon enactment.

SECTION 516. APPEALS BY PROVIDERS WHEN THERE IS NO OTHER PARTY AVAILABLE

Current Law

No provision.

Explanation of Provision

In the case where a beneficiary dies before assigning appeal rights, the Secretary would be required to permit a provider or supplier to appeal a payment denial by a Medicare contractor.

Effective Date

The provision would be effective for items and services furnished on or after enactment.

SECTION 517. PROVIDER ACCESS TO REVIEW OF LOCAL COVERAGE DETERMINATIONS

Current Law

Only beneficiaries have standing to appeal local coverage decisions by Medicare contractors.

Explanation of Provision

The parties that have standing to appeal local coverage decisions would be expanded to include providers or suppliers adversely affected by the determination. The Secretary would be required to establish a process whereby a provider or supplier may request a

local coverage determination under certain circumstances. A provider or supplier could seek a local coverage determination if the Secretary determined that: (A) there have been at least five reversals by an ALJ of redeterminations made by a medicare contractor in at least two different cases; (B) that each reversal involved substantially similar material facts; (C) each reversal involved the same medical necessity issue; and (D) at least 50% of the total claims submitted by the provider within the past year involving the requisite facts and medical necessity issue have been denied and then reversed by an ALJ. Such sums as necessary to carry out the provisions above would be authorized to be appropriated. Also the provision would require the Secretary to study and report to Congress on the feasibility and advisability of requiring Medicare contractors to track the subject and status of claims denials that are appealed and final determinations.

Effective Date

The expansion in standing would be effective for any review or request of any local coverage determination filed on or after October 1, 2003 and for any local coverage determination made on or after October 1, 2003. The requirement to establish a process for a provider or supplier to request a local coverage determination would be effective for requests filed on or after the date of enactment. The report would be due to Congress not later than one year after the date of enactment.

Subtitle C—Contracting Reform

SECTION 521. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION

Current Law

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. For Medicare part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries (FIs) and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the

extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

Explanation of Provision

This provision would add Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 6 years. All contracts would be required to be re-competed at least every 6 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes. MACs would be required to designate at least one different person to serve as medical director in each state, and would be required to use the medical director in developing local coverage determinations. The MAC would appoint a contractor advisory committee for each state to provide a formal mechanism for physicians

in the State to be informed of, and participate in, the development of local coverage determination in an advisory capacity.

The provision would limit liability for Medicare payments of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken.

The Secretary would be required to submit a legislative proposal to Congress providing for any needed technical and conforming amendments relating to this provision within six months of enactment. By October 1, 2004, the Secretary is required to submit a report to Congress and the GAO that describes the plan for an appropriate transition. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

Effective Date

The provision would take effect October 1, 2005, except as otherwise specified.

Subtitle D—Education and Outreach Improvements

SECTION 531. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

Current Law

Medicare's provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). The statute requires toll-free lines that beneficiaries can call with questions or to report suspicious bills. Under administrative authority, CMS requires the contractors to have internet sites and to respond to written inquiries.

Explanation of Provision

Subsection (a) would require the Secretary to coordinate the educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers. Subsection (b) would require the Secretary to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach pro-

grams for providers and suppliers. It would require the Comptroller General to study the adequacy of the methodology and make recommendations to the Secretary, and the Secretary would be required to report to Congress regarding how he intends to use the methodology in assessing Medicare contractor performance. Subsection (c) would provide increased funding for the Medicare Integrity Program of $35 million beginning with FY 2004 for increased provider and supplier education. Also would require Medicare contractors to take into consideration the special needs of small providers or suppliers when conducting education and training activities and permits provision of technical assistance beginning January 1, 2004. Subsection (d) would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review.

Effective Date

Upon enactment.

SECTION 532. ACCESS TO AND PROMPT RESPONSES FROM MEDICARE CONTRACTORS

Current Law

No specific statutory provision. The Medicare statute generally requires that the Medicare contractors communicate information about Medicare administration.

Explanation of Provision

This provision would require the Secretary to develop a process for Medicare contractors to communicate with beneficiaries, providers, and suppliers. Also, the provision would require Medicare contractors to provide a clear, concise written response to inquiries within 45 business days. The Secretary would be required to ensure that Medicare contractors provide a toll-free number where beneficiaries, providers and suppliers can obtain billing, coding, claims, coverage and other information. The Medicare contractors would be required to maintain a system for identifying the staff person who provided information and monitoring the accuracy, consistency and timeliness of information provided. The provision would require the Secretary to establish standards regarding accuracy, consistency, and timeliness and to evaluate the Medicare contractors on these standards. The provision would authorize to be appropriated such sums as necessary to carry out the provision.

Effective Date

The provision would be effective October 1, 2004.

SECTION 533. RELIANCE ON GUIDANCE

Current Law

No provision.

Explanation of Provision

If a provider or supplier reasonably relies on written guidance provided by the Secretary or a Medicare contractor when fur-

nishing items or services or submitting a claim and the guidance is inaccurate, under this provision the provider or supplier would not be required to pay any penalty or interest relating to items or services provided or claim submitted.

Effective Date

The provision would be effective for penalties imposed on or after the date of enactment.

SECTION 534. MEDICARE PROVIDER OMBUDSMAN

Current Law

No provision.

Explanation of Provision

This provision would direct the Secretary to create a Medicare Provider Ombudsman within the Department of Health and Human Services and provide appropriate staff. The Provider Ombudsman would provide confidential assistance to entities and individuals providing items and services, including covered drugs under part D, that are covered under Medicare. The Ombudsman would also submit recommendations to the Secretary for improving the administration of Medicare, recommendations regarding recurring patterns of confusion under Medicare and recommendations to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums as necessary would be authorized to be appropriated for FY2004 and subsequent years.

Effective Date

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

SECTION 535. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM

Current Law

No provision.

Explanation of Provision

Subsection (a) would require the Secretary to conduct a three-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least six local Social Security offices (two would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress.

Subsection (b) would require that the Secretary establish a demonstration project to test the administrative feasibility of providing a process for Medicare beneficiaries, providers, suppliers and other individuals or entities furnishing items or services under Medicare, where an advance beneficiary notice is issued, to request and receive a determination as to whether the item or service is covered under Medicare by reasons of medical necessity, before the item or

service involved is furnished to the beneficiary. The Secretary would be required to evaluate the demonstration and report to Congress by January 1, 2006.

Effective Date

Upon enactment.

Subtitle E—Review, Recovery, and Enforcement Reform

SECTION 541. PREPAYMENT REVIEW

Current Law

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

Explanation of Provision

The conduct of random prepayment review would be limited only to those done in accordance with a standard protocol developed by the Secretary. Non-random reviews would be prohibited unless a likelihood of sustained or high level of payment error (as defined by the Secretary) existed and the Secretary would be required to establish protocols for terminating the non-random reviews within one year of enactment. The Secretary would be required to publish implementing regulations and develop and publish protocols not later than one year after enactment.

Effective Date

The provision would be effective for random reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment).

SECTION 542. RECOVERY OF OVERPAYMENTS

Current Law

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

Explanation of Provision

This provision would add a new subsection (h) to 1874A that would in paragraph (1) require establishment of at least a one year repayment plan—but not longer than three years—when a provider requests a repayment plan, unless the Secretary believes the provider may declare bankruptcy. If a provider or supplier fails to make a scheduled payment, the Secretary could immediately offset or recover the outstanding balance. The Secretary would be required to develop standards for the recovery of overpayments not later than one year after enactment. Paragraph (2) would bar the Secretary from recouping any overpayments until a reconsideration-level appeal was decided (if one was requested). The paragraph provides that interest would be required to be paid to the provider if the appeal was successful (beginning from the time the

overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary). Paragraph (3) would require that if post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities. Paragraph (4) would require the Secretary to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class. The process would be required not later than one year after enactment. Paragraph (5) would require the Secretary, not later than one year after enactment, to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns. Paragraph (6) would permit the Secretary to use a consent settlement process to settle projected overpayments under certain specified conditions.

Effective Date

The provisions affecting post-payment audits and consent settlements would be effective to audits initiated and consent settlements entered into after the date of enactment. Other provisions would be effective for action taken one year after enactment.

SECTION 543. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS ON CLAIMS WITHOUT PURSUING APPEALS PROCESS

Current Law

No provision.

Explanation of Provision

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment.

Effective Date

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

SECTION 544. AUTHORITY TO WAIVE A PROGRAM EXCLUSION

Current Law

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

Explanation of Provision

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

Effective Date

Upon enactment.

TITLE VI—OTHER PROVISIONS

Subtitle C—Other Provisions

SECTION 601. INCREASE IN MEDICAID DSH ALLOTMENTS FOR FISCAL YEARS 2004 AND 2005

Current Law

Hospitals that serve a large number of uninsured patients and Medicaid enrollees receive additional Medicaid disproportionate share hospital (DSH) payments. As established in the BBA 1997, the federal share of Medicaid DSH payments is capped at specified amounts for each state for FY1998 through FY2002. For most states, those specified amounts declined over the 5-year period. A state's allotment for FY2003 and for later years is equal to its allotment for the previous year increased by the percentage change in the consumer price index for urban consumers (CPI–U) for the previous year. In addition, each state's DSH payment for FY 2003 and subsequent years is limited to no more than 12% of spending for medical assistance in each state for that year.

BIPA provided states with a temporary reprieve from the declining allotments by establishing a special rule for the calculation of DSH allotments for 2 years, raising allotments for FY2001 and for FY2002. The provision also clarified that the FY2003 allotments were to be calculated as specified above, using the lower, pre-BIPA levels for FY2002 in those calculations.

Explanation of Provision

The special DSH rule established by BIPA that raised DSH allotments, subject to the current law limit of 12% of spending for medical assistance, would be extended for FY2004 and FY2005. Allotments for FY2004 would be calculated to be equal to FY2004 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by BIPA 2000) increased by the percentage change in the CPI–U for each of fiscal years 2002 and 2003, and (b) FY2004 allotments (as established by BBA 1997). Allotments FY2005 would be calculated to be equal to FY2005 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by the BIPA 2000) increased by the percentage change in the CPI–U for each of fiscal years, 2002, 2003, and 2004, and (b) FY2005 allotments (as established by BBA 1997). For FY2006 and thereafter, DSH allotments would be calculated based on the previous years' amount (as established by BBA 1997 and subject to the current law limit of 12% of spending

for medical assistance) increased by the percentage change in the CPI–U for the previous fiscal year. All allotments would remain subject to the current law limit of 12% of medical assistance spending.

A separate calculation of the DSH allotment for the District of Columbia for FY2004 would be specified. The DSH allotment for the District of Columbia for FY2004 would be raised, subject to the current law limit of 12% of spending for medical assistance, by multiplying $49 million by the percentage change in the CPI–U for each of FY2000, FY2001, FY2002, and FY2003.

Effective Date

Upon enactment.

SECTION 602. INCREASE IN THE FLOOR FOR TREATMENT AS AN EXTREMELY LOW DSH STATE UNDER THE MEDICAID PROGRAM FOR FISCAL YEARS 2004 AND 2005

Current Law

Extremely low DSH states are those states whose FY1999 federal and state DSH expenditures (as reported to CMS on August 31, 2000) are greater than zero but less than 1% of the state's total medical assistance expenditures during that fiscal year. DSH allotments for the extremely low DSH states for FY2001 would be equal to 1% of the state's total amount of expenditures under their plan for such assistance during that fiscal year. For subsequent fiscal years, the allotments for extremely low DSH states would be equal to their allotment for the previous year, increased by the percentage change in the CPI–U for the previous year, subject to a ceiling of 12% of that state's total medical assistance payments in that year.

Explanation of Provision

Allotments for certain extremely low DSH states for FY2004 and FY2005 would be increased. For states with DSH expenditures for FY2000 (as reported to CMS as of August 31, 2003) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year, the provision would raise the DSH allotments for FY2004 to 3% of the state's total amount of expenditures for such assistance during that fiscal year. States with DSH expenditures for FY2001 (as reported to CMS as of August 31, 2004) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year would have the DSH allotments for FY2005 equal to such state's DSH allotment for FY2004 increased by the percentage change in the CPI–U for FY2004.

A DSH allotment adjustment for states with a statewide Section 1115 waiver that was implemented on January 1, 1994 would be specified for FY2004 and FY2005. If such a state-wide Section 1115 waiver is revoked or terminated during FY2004 and/or FY2005, the Secretary of HHS would permit the state to submit an amendment to their state plan that would describe the methodology to be used by the State to identify and make payments for disproportionate share hospitals (including children's hospitals, and institutions for

mental diseases, or other mental health facilities—other than State-owned institutions or facilities), based on the proportion of patients served by such hospitals that are low-income patients with special needs. The state would be required to provide data for the computation of an appropriate DSH allotment that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated.

Effective Date

Upon enactment.

SECTION 603. INCREASED REPORTING REQUIREMENTS TO ENSURE THE APPROPRIATENESS OF PAYMENT ADJUSTMENTS TO DISPROPORTIONATE SHARE HOSPITALS UNDER THE MEDICAID PROGRAM

Current Law

BBA 1997 required each state to submit to the Secretary an annual report describing the disproportionate share payments made to each disproportionate share hospital (DSH) and the methodology used by the state for prioritizing payments to such hospitals.

Explanation of Provision

As a condition of receiving federal Medicaid payments for FY2004 and each fiscal year thereafter, the provision would require each state to submit to the Secretary an annual report (for the previous fiscal year) identifying each disproportionate share hospital that received a payment, the amount such hospital received, as well as other information the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year.

Effective Date

Upon enactment.

SECTION 604. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM

Current Law

Medicaid drug rebates are calculated based on the difference between the Average Manufacturer's Price and the manufacturer's "best price". In determining the "best price" for a drug sold by a manufacturer, certain discounted prices and fee schedules are excluded. The special discounted prices for outpatient drugs negotiated by the Office of Pharmacy Affairs (of HHS) with drug manufacturers on behalf of certain clinics and safety net providers are one example of prices excluded from Medicaid's best price determination. Because of this exclusion from Medicaid's best price definition, the discounts available to safety net providers have no bearing on the calculation of drug rebates under the Medicaid program allowing those providers to negotiate better rates with manufacturers—since Medicaid rebates will not change with the size of their negotiated discounts. Discounted prices for inpatient drugs for many safety net providers, however, are included in the Medicaid best price.

Explanation of Provision

The provision would modify the definition of "best price" for the purpose of calculating Medicaid drug rebates, to also exclude the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals would also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's "best price" determination.

Effective Date

Upon enactment.

SECTION 605. ASSISTANCE WITH COVERAGE OF LEGAL IMMIGRANTS UNDER THE MEDICAID PROGRAM AND SCHIP

Current Law

"Qualified aliens" who entered the United States after the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, August 22, 1996) are not eligible to receive federally funded benefits under Medicaid or SCHIP for 5 years. Qualified aliens who entered the United States prior to the enactment of PRWORA are eligible for federally funded Medicaid coverage at state option, as are qualified aliens arriving after August 22, 1996 who have been present in the United States for more than 5 years.

A person who executed an affidavit of support for an alien under Section 213A of the Immigration and Nationality Act (INA) is liable to reimburse the federal or state government for the public benefits received by the sponsored alien until the alien naturalizes or has accumulated 40 quarters of work. Section 213A was enacted as a part of PRWORA on August 22, 1996.

Explanation of Provision

The provision would lift the 5-year ban and would allow states the option to provide medical assistance to certain lawfully residing individuals under Medicaid (including under a waiver authorized by the Secretary) or SCHIP for any of fiscal years 2005 through 2007. Those eligible would include lawfully residing women during pregnancy and the 60-day period after delivery, and children otherwise eligible for Medicaid or SCHIP as defined by the state plan. States opting to provide coverage to such lawfully residing individuals under SCHIP must also provide coverage to such individuals under Medicaid. If services are provided under the Medicaid program, the alien's sponsor would not be liable to reimburse the federal or state government for the cost of such services.

Effective Date

This provision would go into effect at the beginning of FY 2005.

SECTION 606. ESTABLISHMENT OF CONSUMER OMBUDSMAN ACCOUNT

Current Law

The Omnibus Budget Reconciliation Act of 1990 established State Health Insurance Counseling Assistance grants to states to

provide education and information to Medicare beneficiaries. Funding has been subject to annual appropriations.

Explanation of Provision

A Consumer Ombudsman Account would be established in the Medicare Trust Fund and $1 for every Medicare beneficiary would be appropriated to the account from the Trust Fund beginning with fiscal year 2005. The account would be used to make grants to State Health Insurance Counseling Programs.

Effective Date

Upon enactment.

SECTION 607. GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR LOW-INCOME BENEFICIARIES

Current Law

No provision.

Explanation of Provision

The provision would require the General Accounting Office (GAO) to conduct a study to determine the extent to which drug utilization and access to covered drugs differs between: (1) individuals who qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries (including qualified Medicare beneficiaries, specified low-income medicare beneficiaries or qualifying individuals under Section 1860(D)), and (2) individuals who do not qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries solely as a result of the application of an assets test to the income eligibility requirements of such individuals. The GAO would be required to submit to Congress the final report (including recommendations for legislation) no later than September 30, 2007.

Effective Date

Upon enactment.

SECTION 608. HEALTH CARE INFRASTRUCTURE IMPROVEMENT

Current Law

No provision.

Explanation of Provision

A loan program would be established to improve the cancer-related health care infrastructure in certain geographic areas of the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital, medical research facility or other medical facility or the purchase of any equipment to be used in a hospital, research facility or other medical research facility. In order to receive assistance, project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute

(NCI) or be designated by the State as the sole official comprehensive cancer effort for the State; and (3) be located in a State that on the date of enactment of this title has a population of less than 3 million individuals. $49 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, $2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the projects that have received assistance under this program, including recommendations on the future operation of the program.

Effective Date

Upon enactment.

SECTION 609. CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM

Current Law

The Public Health Services Act establishes a fund in the Treasury from which the Secretary of HHS can make loans or loan guarantees in the amounts that have been specified in appropriations Acts from time to time. Under the Medicare Rural Hospital Flexibility Program established as part of Title XVIII, the Secretary may award grants to rural hospitals to cover the implementation costs associated with data systems needed to meet the BBA 97 requirements.

Explanation of Provision

The Secretary would be able to make loans to any rural entity to acquire land, renovate buildings, purchase major moveable equipment or other appropriate projects. A rural entity would include rural health clinics, a medical facility with less than 50 beds in a county that is not part of a metropolitan statistical area or is in a rural census tract of such area, a hospital that is a rural referral center or a sole community hospital. An entity that has been geographically reclassified for the purposes of Medicare reimbursement would not be precluded from being considered a rural provider. Loan guarantees and interest subsidies of up to 3% of the net effective interest rate would be authorized. The total of the government's exposure with respect to this program would not exceed $50 million per year. The total of the principal amount of all loans directly made or guaranteed in any year may not exceed $250 million per year. In addition, rural providers could apply to receive $50,000 planning grants to help assess capital and infrastructure needs. The grants awarded in any year would not exceed $2.5 million. The program would expire after September 30, 2008.

Effective Date

Upon enactment.

SECTION 610. FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES FURNISHED TO UNDOCUMENTED ALIENS

Current Law

The Balanced Budget Act of 1997 (BBA97) provided $25 million in funding for state emergency health services furnished to undocumented aliens for each of FY1998 through 2001. Funds were distributed among the 12 states with the highest number of undocumented aliens. In a fiscal year, each state's portion of the total funds available was based on its share of total undocumented aliens in all of the eligible states. The allotments for each year were based on the estimates provided by the Statistics Division of the Immigration and Naturalization Service (INS).

Explanation of Provision

For each of fiscal years 2005 through 2008 the provision would appropriate for allotment among states $250 million in additional federal funding for emergency health services furnished to undocumented aliens. For each such fiscal year the Secretary would distribute $167 million of $250 million among all states. Each state would receive an amount equal to the product of the total amount available in each fiscal year, and the proportion of the state's share of undocumented aliens to the total count of undocumented aliens residing in all states as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the decennial census.

For each of fiscal years 2005 through 2008, the Secretary would distribute $83 million of $250 million among the 6 states with the highest number of undocumented alien apprehensions for such fiscal year. Each such state would receive an amount that bears the same ratio to the total amount available for allotments to such states (in each fiscal year) as the ratio of the number of undocumented alien apprehensions in the state (in each fiscal year) to the total number of undocumented alien apprehensions for all such states (in each fiscal year) based on the 4 most recent quarterly apprehensions rates for undocumented aliens as reported by the Immigration and Naturalization Service.

Subject to the total funds available from the state allotments as determined above, the Secretary would pay directly to local governments, hospitals, or other providers located in the state (including providers of services rendered through an Indian Health Service facility) for costs incurred in providing emergency health care services furnished to undocumented aliens during that fiscal year (even if the care is furnished to aliens who have been allowed to enter for the sole purpose of receiving emergency health care services). No later that September 1, 2004, the Secretary would be required to establish a process, that includes measures to protect against fraud and abuse, under which entities would apply for reimbursement from the state's allotments for claims associated with emergency health care services furnished to undocumented aliens. Advanced payments would be made quarterly based on the applicants projected expenditures. The Secretary would also be required to set up a process to allow for prior period adjustments resulting from

underpayment or over payment to an entity in a prior quarter. Funds shall remain available until they are expended.

Effective Date

Upon enactment.

SECTION 611. INCREASE IN APPROPRIATION TO THE HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT

Current Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, PL.104–91) established the Health Care Fraud and Abuse Control (HCFAC) Program which is administered by the HHS Office of Inspector General and the Department of Justice. Funds for the HCFAC program are appropriated from the Federal Hospital Insurance Trust Fund. HIPAA provided for annual increases of 15% in HCFAC funding through 2003, after which the appropriation for HCFAC and the amount earmarked for HHS-OIG remains the same. In FY2003 the available appropriation for HCFAC was $240,558,320 of which $150 million to $160 million was available to the HHS-OIG.

Explanation of Provision

Additional appropriations to HCFAC would be authorized. In FY2004, the increase would be $10 million over the FY2003 appropriation limit; in FY2005 the increase would be $15 million over the FY2003 limit; in FY2006 the increase would be $25 million above the FY2003 limit. Subsequent years appropriations would be at the 2003 limit. The HHS-OIG earmarked appropriations would increase as well: to $170 million in FY2004, $175 million in FY2005, $185 million in FY2006. In subsequent years, it would be not more than $150 million and not more than $160 million.

Effective Date

Upon enactment.

SECTION 612. INCREASE IN CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT

Current Law

The False Claims Act imposes a liability on those who knowingly present or cause to be presented a false or fraudulent claim for payment by the Government. In certain instances, the person may be liable for a civil penalty of not less than $5,000 and not more than $10,000, plus treble damages.

Explanation of Provision

For violations occurring on or after January 1, 2004, the minimum amount of the civil penalty would be increased from $5,000 to $7,500 and the maximum amount would increase from $10,000 to $15,000.

Effective Date

The provision would be effective for violations occurring on or after January 1, 2004.

SECTION 613. INCREASE IN CIVIL MONETARY PENALTIES UNDER THE SOCIAL SECURITY ACT

Current Law

The Office of the Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs) on any person (including an organization or other entity, but not a beneficiary) who knowingly presents, or causes to be presented, to a state or federal government employee or agent certain false or improper claims for medical or other items or services. CMPs may also be imposed for other fraudulent activities such as inflating charges for services, providing services when not a properly licensed physician, billing for medically unnecessary services, falsely certifying that an individual meets the requirements for home health services, and offering or soliciting remuneration to influence the provision of medical services. Depending upon the violation, Section 1128A of the SSA authorizes the imposition of CMPs up to $10,000 for each item or service involved, up to $15,000 for individuals who provide false or misleading information in certain instances, and up to $50,000 per act in other instances as well as treble damages.

Explanation of Provision

The amount of penalties would be increased for violations that occur on or after January 1, 2004. In instances where penalties are limited to $10,000 would be increased to $12,500; those penalties that are limited to $15,000 would be increased to $18,750; and those that are limited to $50,000 would be increased to $62,500.

Effective Date

The provision would be effective for violations occurring on or after January 1, 2004.

SECTION 614. EXTENSION OF CUSTOMS USER FEES

Current Law

The U.S. Customs Service, the federal government's oldest revenue collecting agency is responsible for regulating the movement of persons, carriers, merchandise, and commodities between the United States and other countries. Its authority to impose user fees for certain services will lapse on September 30, 2003.

Explanation of Provision

The authority would be extended until September 30, 2013.

Effective Date

Upon enactment.

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