CMS Legislative Summary

April 2004

Summary of H.R. 1

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173

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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173
Enacted December 8, 2003

Subtitle C—Other Provisions

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101.—Medicare prescription drug benefit.

PART D-VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1- Part D Eligible Individuals and Prescription Drug Benefits

Sec. 1860D—1. Eligibility, Enrollment, and Information

Current Law:

- None. Medicare currently lacks an outpatient prescription drug benefit. The program's drug coverage is limited to drugs that are incident to a physician's services or delivered in institutional settings.

Provisions:

- A new Medicare Part D is created, providing access to prescription drug insurance coverage to individuals who are entitled to Part A or enrolled in Part B. Participation in Part D is voluntary and requires an affirmative election to join. Coverage will begin January 1, 2006.

- The benefit will be administered by private health plans. Eligible individuals in the traditional fee-for-service Medicare program may obtain the coverage through a stand-alone prescription drug plan, called a PDP. Those enrolled in private health plans under Part C (formerly Medicare+Choice, hereby renamed Medicare Advantage) may only obtain drug coverage through those plans, with two exceptions. Enrollees in a Medicare Advantage Private Fee-For-Service (PFFS) plan that does not offer qualified Part D drug coverage may also enroll in a stand-alone PDP. All enrollees in Medical Savings Account (MSA) plans may also enroll in a stand-alone PDP.

- A coordinated enrollment process for all plan types will be established, similar to the process currently in use for Medicare+Choice and governed by similar plan requirements. An initial enrollment period will begin on November 15, 2005, and extend through May 15, 2006. Enrollment periods in subsequent years will run from November 15 through December 31. Eligible individuals residing in the plans' service areas may choose among the options available to them. Individuals who are eligible for both Medicare and full benefits under Medicaid and who fail to elect a plan during the initial enrollment period will be assigned to a plan by the Secretary.

- Similar to Part B, eligible individuals who do not enroll in Part D at the first opportunity will face a late enrollment penalty when they do join. They may avoid the penalty if they maintain "creditable" prescription drug coverage outside Medicare (through an employer's retiree plan, for example). If an individual involuntarily loses the creditable coverage, a

special enrollment period commences during which he or she may join Part D without being subject to the late enrollment penalty.

- At least 30 days prior to the initial enrollment period, the Secretary will disseminate information about plan options to eligible individuals, including comparative information on plan features and performance. This information will be distributed in writing, via 1-800-MEDICARE, and via the Internet.

- The Secretary may also provide plans with information about eligible individuals to facilitate their Part D marketing and enrollment.

Effective Date:

- January 1, 2006

Sec. 1860D—2. Prescription Drug Benefits

Current Law:

- None. See discussion above.

Provisions:

- A standard Part D benefit is established. In 2006, it features a $250 deductible, 25% enrollee cost-sharing (or 25% enrollee cost-sharing on average) for drug costs above the deductible up to an initial coverage limit of $2250, and catastrophic drug coverage once the enrollee has reached $3600 in out-of-pocket costs (this translates to $5100 in total drug spending). The enrollee then pays the greater of $2 and $5 co-pays or 5% coinsurance for drug costs in the catastrophic range. The $2 co-pays apply to generic or preferred multiple-source drugs, while the $5 co-pays apply to other drugs. In later years, all dollar figures are indexed to the per capita growth in spending for covered Part D drugs and rounded.

- Medicare drug plans must also provide enrollees with access to negotiated drug prices (including for drugs purchased in the coverage gap).

- Part D plans may offer the standard benefit (defined above) or an actuarially equivalent benefit that meets a multi-part test. The test requires that:

    - The total actuarial value of the alternate coverage equals or exceeds the total actuarial value of standard coverage.

    - The unsubsidized value of the alternate coverage (defined as the amount by which the total actuarial value exceeds the total actuarial

value of federal subsidies) equals or exceeds the unsubsidized value of standard coverage.

- The total payments made for costs below the initial coverage limit under the alternate coverage equals or exceeds the total payments made at that same limit under standard coverage.
- The alternate deductible does not exceed the standard deductible.
- The alternate coverage provides the same out-of-pocket limit and beneficiary cost sharing in the catastrophic coverage range as standard coverage.

- Plans may also offer supplemental coverage that reduces the enrollee's cost sharing, subject to the "true out-of-pocket" feature (below).
- The true out-of-pocket rule states that only amounts actually paid by the enrollee or another person on the enrollee's behalf (or by certain state programs) for covered Part D drugs included (or treated as included) in the Part D plan's formulary count toward the out-of-pocket limit. Amounts reimbursed by a third-party insurer, including an employer-sponsored retiree plan or a supplemental package within a Part D plan, do not count. The Secretary is directed to establish procedures to ascertain what third-party insurance enrollees may have, and plans may request this information from their enrollees. Those who materially misrepresent their third-party insurance may be terminated from their Part D or Medicare Advantage plans.
- Covered Part D drugs are defined as those drugs covered under the Medicaid program plus insulin, insulin-related supplies, certain vaccines and smoking cessation agents. Drugs currently covered in Parts A and B of Medicare will continue to be covered there, rather than Part D. The definition excludes certain drugs, such as barbiturates and benzoiazepines.
- Drug prices negotiated by PDPs, MA plans and qualified retiree plans are not included in the establishment of a "best price" for the Medicaid program.

Effective Date:

- January 1, 2006

Sec. 1860D—3. Access to a Choice of Qualified Prescription Drug Coverage

Current Law:

- None.

Provision:

- The Secretary will invoke a fallback contract in areas where fewer than two qualifying plans are available. At least one of the qualifying plans must be a prescription drug plan, while the second can be either a PDP or a Medicare Advantage plan that offers basic coverage (or supplemental coverage for no additional premium). To qualify for purposes of avoiding fallback, the plans may not all be offered by the same sponsor. The Secretary may approve limited risk plans (defined in 1860D-11) in an effort to avoid fallback and may only invoke fallback if the approval of limited risk plans fails to achieve the two-plan requirement.

Effective Date:

- January 1, 2006

Sec. 1860D—4. Beneficiary Protections for Qualified Prescription Drug Coverage

Current Law:

- None

Provision:

Information the PDP sponsor must provide

- The PDP sponsor must provide beneficiaries with information, in a standardized form, about the plan offered, including its service area, benefits, and out-of-area coverage. The sponsor must also provide information about access to covered drugs, how the plan's formulary functions, and cost-sharing requirements.

- In response to enrollee questions, the PDP sponsor must provide information through a toll-free telephone number or in writing. The PDP sponsor also must post any changes it makes to its formulary on an Internet website.

- Upon request of an eligible individual, the PDP sponsor must provide information the Secretary determines is "similar" to information provided under Medicare Advantage, which includes, for example, information about the plan's utilization controls and aggregate statistics about its grievance and appeals process.

- With a frequency specified by the Secretary, the PDP must furnish to each enrollee an explanation of benefits and a description of where the enrollee stands in relation to the initial coverage limit and the annual out-of-pocket limit. The explanation will incorporate information about "true out-of-pocket" spending to the extent practicable.

Assuring Pharmacy Access

- The PDP sponsor must permit any pharmacy willing to meet the plan's terms and conditions to participate, though the plan may also set up a more restrictive pharmacy network and use reduced cost-sharing to steer enrollees to in-network pharmacies. Any such reduced cost sharing cannot increase government subsidies to plans.

- The plan's network must include a sufficient number and range of retail pharmacies to provide enrollees with convenient access and emergency access. The network must be at least as comprehensive as the network required in the 2003 TRICARE retail pharmacy solicitation: 90 percent of urban Medicare beneficiaries must be within 2 miles of a network pharmacy, 90 percent of suburban Medicare beneficiaries must be within 5 miles, and 70 percent of rural Medicare beneficiaries must be within 15 miles. The access rules may also address residents of long-term-care facilities and Indian Health Service facilities.

- The Secretary has discretion to require PDPs to permit enrollees to receive 90-day supplies of drugs through a retail pharmacy, with the enrollee paying any difference in cost between retail and mail order.

Use of Standardized Technology

- The PDP sponsor must issue a card (or other technology) that may be used by an enrollee when purchasing prescription drugs under the plan.

- The Secretary will develop, adopt, or recognize standards for a card format in consultation with NCPDP and implement the standards in time for PDP sponsors to utilize them beginning January 1, 2006.

Requirements on Development and Application of Formularies

- PDP formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class.

- Any formulary used by a PDP must be developed and reviewed by a pharmacy and therapeutic committee, a majority of whose members must be physicians and pharmacists. The Committee also must include at least two independent experts, one of which is a practicing physician and one of which is a practicing pharmacist.

- The Secretary will request the organization United States Pharmacopoeia to develop and periodically revise a set of model guidelines for drug categories and classes. PDP sponsors may adopt these model guidelines or may create categories and classes of their own. PDP sponsors may only change their categories and classes at the beginning of a benefit year, except as the Secretary may permit to respond to changes in approved drugs and new therapeutic uses.

- Each PDP sponsor shall have procedures to educate health care providers and enrollees about its formulary.

- PDPs must give notice to the Secretary, enrollees, physicians, pharmacies and pharmacists before removing a drug from its formulary or changing its status on a tiered cost-sharing scale. This notice may consist of posting the changes to an Internet web.

Cost and Utilization Management; Quality Assurance; Medication Therapy Management Program

- The PDP sponsor shall have in place a cost-effective drug utilization management program, quality assurance measures, systems to reduce medication errors, and a program to control fraud, waste, and abuse.

- The PDP sponsor shall have a medication therapy management program, designed to pay pharmacists to counsel and otherwise assist enrollees with multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure), multiple medications, and high drug costs. The Secretary will determine what level of drug costs is to be used for purposes of targeting enrollees for the service. The therapy management programs will be coordinated with other chronic care improvement programs in Medicare.

Electronic Prescription Drug Program

- The Secretary shall promulgate final standards for electronic prescribing no later than April 1, 2008. The final standards will follow a set of initial standards (to be issued no later than September 1, 2005) and a 1-year pilot project for the initial standards that begins January 1, 2006. The National

Committee on Vital and Health Statistics--expanded to include representatives of physicians, pharmacists, and experts on e-prescribing, among others--will consult with standard-setting organizations and may recommend standards to the Secretary.

- Within 1 year of the promulgation of the final standards, any prescriptions for covered part D drugs prescribed for Medicare beneficiaries that are transmitted electronically must be transmitted according to those standards.

- The new e-prescribing standards should be designed to enable transmission of basic prescription data to and from doctors and pharmacists, as well as information about the patient's drug utilization history, possible drug interactions, the drug plan (including information about the formulary and cost-sharing), and information about lower-cost therapeutically appropriate alternatives. The standards must comply with HIPAA privacy rules. Messaging unrelated to appropriate prescribing (such as marketing) will not be allowed.

- The Secretary, in consultation with the Attorney General, will develop safe harbors under the anti-kickback and physician self-referral laws, allowing hospitals, group practices, PDPs, and MA plans to provide physicians with non-monetary remuneration, in the form of hardware, software, information technology services and training, which is necessary and used solely for electronic prescribing.

Grievance Mechanism, Coverage Determinations, Reconsiderations, and Appeals

- Similar to Medicare+Choice today, each PDP sponsor shall have procedures for hearing and resolving grievances between the sponsor and enrollees.

- Similar to Medicare+Choice today, a PDP sponsor shall have procedures to make and explain coverage determinations, to reconsider those determinations when challenged by an enrollee, and to handle expedited requests and appeals.

- A PDP sponsor must have an "exceptions" process whereby an enrollee may request to pay a preferred tier's cost-sharing for a lower tier drug. In such cases, the prescribing physician must determine that the formulary's preferred tier drug would not be as effective or would have adverse effects.

- The reconsideration and appeals process will also include cases where the enrollee is requesting that a PDP cover a drug that is not on its formulary. In such cases, the prescribing physician must determine that all drugs on the plan's formulary for that condition would not

be as effective or would have adverse effects. Enrollee cost sharing for non-formulary drugs provided following a successful reconsideration or appeal will count toward the enrollee's out-of-pocket limit.

- review procedures and appeals procedures similar to those of Medicare+Choice (Medicare Advantage) organizations.

Other provisions

- Similar to Medicare+Choice today, the PDP must have procedures to maintain privacy, confidentially, and accuracy of enrollee records.

- Similar to Medicare+Choice today, a PDP may be deemed to meet certain requirements if it is accredited by a private accrediting agency that the Secretary determines has standards that meet or exceed those that would otherwise apply. The "deemable" drug-related requirements are: access to covered drugs, quality assurance programs, and medication therapy management, as well as requirements about privacy, confidentiality and accuracy of enrollee records.

- PDPs will require pharmacies that dispense covered part D drugs to inform the enrollee at the point of purchase about cheaper generic equivalents and how much money the enrollee could save. The Secretary may waive this requirement in circumstances the Secretary specifies.

Effective Date:

- January 1, 2006, except as noted above for e-prescribing.

Subpart 2-Prescription Drug Plans; PDP Sponsors; Financing

Sec. 1860D—11. PDP Regions; Submission of Bids; Plan Approval

Current Law:

- None.

Provisions:

- Prescription drug plans will serve regional areas, with the regions determined by the Secretary. Service areas must consist of at least one entire PDP region or multiple PDP regions. To the extent practicable, the drug plan regions will be consistent with regions established for the new regional preferred provider organization (PPO) plans in Title II, though the Secretary may establish different regions for drug plans if it would improve access for eligible individuals. A drug plan may offer a benefit nationally by bidding on all regions. The Secretary will establish and may revise PDP regions for the Territories.

- Similar to Medicare Advantage, prescription drug plans will submit bids to serve eligible individuals in regions. For each plan it offers, the sponsor must, in addition to any other

information the Secretary requires, include information on the benefits provided and any cost sharing; the service area; the actuarial value of the coverage; information on the bid, including the actuarial basis for the bid, the portion of the bid attributable to basic and supplemental benefits; and assumptions regarding administrative expenses and expected reinsurance payments. The amount of expected reinsurance payments must be subtracted from the actuarial value to produce the bid amount. Medicare Advantage plans will use the same bidding process for the drug benefit portion of their bid in Title II.

- The plan bid will also describe what level of insurance risk it is willing to accept by making a proposal for a set of risk corridors. Plans that accept the standard risk corridors are considered "full risk" plans. Plans that bid for a more protective set of risk corridors are considered "limited risk" plans. Any modification of the risk corridors in a region for a PDP sponsor will apply to all the plans offered by that sponsor in that region. MA plans are not allowed to modify the standard risk corridors.

- The Secretary will establish processes for determining the actuarial value of the proposed drug plans and their components. Plans may use outside actuaries to make these determinations.

- The Secretary has authority to negotiate the terms and conditions of drug plan bids, including authority similar to that of the Office of Personnel Management for the Federal Employee Health Benefits Program.

- The Secretary may approve a drug plan bid if it meets all requirements and actuarial determinations. Plan bids must reasonably and equitably reflect the cost of providing the benefits.

- In approving plans, the Secretary must seek to maximize the amount of insurance risk that the plans bear. The Secretary may approve an unlimited number of full-risk plans, but may only approve as many limited risk plans as are necessary to avoid fallback. In selecting among limited risk plans to approve, the degree of risk has priority, but the Secretary may also take bid price into account.

- The Secretary will conduct a separate competitive bidding process for fallback plans. Plans will bid to serve one or more regions, but there cannot be a single national fallback plan. One fallback plan per region will be approved. The fallback service area may be an entire region, or the part of a region that does not have two at-risk plans available.

    - Fallback plans must meet all PDP requirements except for bearing risk.

- Fallback plans must be ready to serve the region on the same timetable as at-risk plans.

- Payments for fallback plans will cover the actual costs of providing covered Part D drugs to eligible individuals plus management fees. Performance measures will include how well the plan contains costs to the federal government, the plan's quality programs, its customer service system, and its efficiency in administering the benefit and adjudicating claims.

- The enrollee premium for fallback plan will be 25.5 percent of the Secretary's estimated cost of the drug benefit and administrative costs in that region. In making the cost estimate, the CMS Chief Actuary will use administrative load factors of at-risk plans.

- Fallback contracts are for three years.

- Fallback plans may not submit bids to be an at-risk PDP in any region for the first year of the fallback contract. Fallback plans also may not be subcontractors of at-risk PDPs in any region, though they may be subcontractors of Medicare Advantage plans.

- The Secretary will report annually about the use of limited-risk and fallback plans in Part D.

- The Secretary may not interfere in negotiations between drug manufacturers, pharmacies and PDP sponsors and may not require a particular formulary or institute a price structure for Part D drugs.

- PDP sponsors must coordinate benefits with State Pharmaceutical Assistance programs and may not impose on the state programs fees that are unrelated to coordination.

Effective Date:

- January 1, 2006

Sec. 1860D—12. Requirements for, and Contracts with, Prescription Drug Plan (PDP) Sponsors

Current Law:

- None

Provisions:

- Prescription drug plans must be licensed as insurers under state law throughout their service area. Organizations that have filed an application for state licensure may appeal to the Secretary for a temporary waiver of up to 36 months. The Secretary will establish solvency standards for plans to operate under during the waiver and until the plans receive state licensure.

- The Secretary may only enter into a contract with a drug plan if it meets all the requirements. An organization is ineligible for a PDP contract in a given region if 1) it bids to serve as a fallback plan in any region during the same year, 2) it serves as a fallback plan in any region during the same year, or 3) it served as a fallback plan in that region during the prior year. The restrictions on fallbacks apply even if a fallback is a subcontractor to a PDP sponsor (but not to a Medicare Advantage organization).

- Contract requirements will be the same or similar to contract requirements in Medicare+Choice today, including minimum enrollment, contract periods and terms, fraud protections, and sanctions.

- There is no government subsidy for supplemental drug coverage that a drug plan may offer over and above the standard Part D benefit, and the plan is at full insurance risk for the supplemental coverage. A drug plan may obtain private reinsurance.

- The Secretary may periodically revise standards, but may implement changes creating significant, new regulatory requirements under this section only at the beginning of a calendar year.

- As is the case for Medicare+Choice plans under current law, States may not apply premium taxes to PDPs for collected Medicare drug plan premiums.

Effective Date:

- The Secretary must promulgate solvency standards for drug plans by January 1, 2005.

Sec. 1860D—13. Premiums; Late Enrollment Penalty

Current Law:

- None

Provisions:

- A national weighted average drug bid will be constructed using all bids from drug plans and the drug portion of bids from Medicare Advantage plans. The weights will be average plan enrollment in the prior year. The Secretary will establish a mechanism for determining the weights in the first year. Bids from Medical Savings Account (MSA) plans, Private Fee-For-Service (PFFS) plans, specialized plans for special needs individuals, PACE plans, and cost contract plans are not included in the national weighted average bid.

- Part D premiums will vary by plan. The plan's premium for basic coverage will be set at approximately 25.5 percent of the national weighted average plan bid plus or minus the difference between the average (geographically adjusted) and the plan's bid. The plan premium will be uniform for all enrollees in a region, except that the premium will be increased by any late enrollment penalty that applies or decreased if the enrollee is eligible for low-income assistance. The plan may charge an additional premium for any supplemental coverage it offers.

- The late enrollment penalty applies to eligible individuals who either do not enroll in Part D by the last day of the period during which they are first eligible to enroll, or who fail to maintain other creditable coverage for more than a continuous period of 63 days. The penalty will be calculated as the greater of an actuarially sound amount for the uncovered period or, for each uncovered month, 1 percent of the average basic enrollee premium. Creditable coverage is defined as coverage provided through a group health plan and other specified coverage that meets or exceeds the actuarial value of standard Part D coverage. Entities that offer drug coverage are required to notify eligible individuals whether their coverage qualifies as creditable.

- Part D enrollees may pay plan premiums directly or through a Social Security check deduction. The Secretary will develop a mechanism to apportion any late enrollment penalties between the government and the plan.

Effective Date:

- January 1, 2006

Sec. 1860D—14. Premium and Cost-Sharing Subsidies for Low-Income Individuals

Current Law:

- No provision.

Provision:

This section provides premium and cost-sharing subsidies for three groups of Medicare eligible individuals. These low-income subsidy groups are:

- Group 1: full dual-eligibles with incomes below 100% federal poverty level (no asset test).

- Group 2: full dual eligibles with incomes at or above 100% FPL, as well as non-dual eligible Medicare eligible individuals with incomes less than 135% FPL who meet three times the SSI asset test of $6,000 for an individual and $9,000 for a couple in 2006 (increased by the CPI-U in subsequent years).

- Group 3: Medicare eligible individuals with incomes less than 150% FPL who meet the resource standard of $10,000 for an individual or $20,000 for a couple in 2006 (increased by the CPI-U in subsequent years).

The low-income subsidies are structured as follows:

- Eligible individuals in Group 1 receive the following:

  - » a full premium subsidy up to the benchmark premium amount;
  - » a full subsidy for the deductible;
  - » prescriptions with only a $1 copayment for each generic drug or multiple source preferred drug and a $3 copayment for any other drug, up to the out-of pocket limit of $3,600;
  - » prescriptions with $0 copayments after the out-of-pocket limit is reached; and
  - » limits on late enrollment penalties -- twenty percent of any applicable late enrollment penalties would apply for the first five years, after which no penalty would be imposed.

- Eligible individuals in Group 2 receive the following:

  - » a full premium subsidy up to the benchmark premium amount;
  - » a full subsidy for the deductible;
  - » prescriptions with only a $2 copayment for each generic drug or multiple source preferred drug and a $5 copayment for any other drug, up to the out-of pocket limit of $3,600;
  - » prescriptions with $0 copayments after the out-of-pocket limit is reached; and

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  - » limits on late enrollment penalties -- twenty percent of any applicable late enrollment penalties would apply for the first five years, after which no penalty would be imposed.

- Institutionalized persons who are full-benefit dual eligibles are exempt from cost sharing, regardless of whether they are in Group 1 or Group 2. They would not be required to use their personal needs allowance to pay cost sharing.

- Eligible individuals in Group 3 receive the following:

  - » a reduction of their monthly premium determined on a sliding scale based on income;
  - » a reduction of the deductible to $50;
  - » prescriptions with a 15% percent copayment, up to the out-of pocket limit of $3,600; and
  - » after the out-of-pocket limit is reached, prescriptions with only a $2 copayment for each generic drug or multiple source preferred drug and a $5 copayment for any other drug.

- Cost-sharing (other than for full benefit dual eligibles with incomes below 100% FPL), deductibles and coinsurance for these groups are indexed beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the U.S. for eligible beneficiaries as determined by the Secretary of HHS for a 12 month period ending in July of the previous year, using a methodology determined by the Secretary. Cost-sharing for full benefit dual eligibles with incomes below 100% FPL) would be indexed to the CPI-U.

- The premium subsidy amount for a full subsidy eligible beneficiary (Group 1 or Group 2) is the low-income benchmark premium for a PDP region. In a PDP region where all prescription drug plans are offered by the same PDP sponsor, the low-income benchmark premium is equal to the weighted average of premiums for all prescription drug plans offered by the PDP sponsor in the PDP region, excluding that portion of a premium attributable to any supplemental benefits. In a PDP region where prescription drug plans are offered by multiple PDP sponsors, the low-income benchmark premium is equal to the weighted average of premiums for all prescription drug plans and MA-PD plans offered in the PDP region, excluding that portion of a premium attributable to any supplemental benefits. A low-income subsidy may not be less than the lowest monthly eligible individual premium for a prescription drug plan that offers basic prescription drug coverage in a region.

- Eligibility for subsidy-eligible individuals is to be determined by State Medicaid agencies or by the Social Security Administration. Determinations will be effective beginning with the month that a subsidy-eligible beneficiary applied and the determination will remain effective for up to one year. Re-determinations and appeals for eligibility determinations by the state will follow existing re-determination and appeals set under each state's Medicaid Plan. The re-determinations and appeals for eligibility determinations by SSA will be determined by the Commissioner of SSA. The Commissioner will establish procedures for appeals similar to those in section 1631(c)(1)(A), which is the hearings and review process for disability.

- Full-benefit dual eligibles and recipients of supplemental security income (SSI) benefits are deemed to be eligible for the low-income subsidies applicable to eligible individuals with incomes less than 135% FPL (Group 2), except that full benefit dual eligibles with incomes below 100% FPL will be eligible for the low-income subsidies for Group 1. The Secretary may also deem QMB's, SLMB's, and QI-1's as low-income subsidy eligible individuals in these Groups.

- Income determinations will be conducted following SSI guidelines without regard to the application of 1902(r)(2) income disregards. With respect to resources, the Secretary may permit states to use the same asset or resource methodologies that are used with respect to determining eligibility for a QMB individual (section 1905 (p)) so long as the methodology does not result in any significant differences in the number of individuals determined to be subsidy eligible under Part D.

- The Secretary and the Commissioner of Social Security shall develop and disseminate to states a model, simplified application form and process for determination and verification of an eligible beneficiary's assets or resources. The application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources and their valuation. The form will contain copies of recent statements from financial institutions in support of the application. Matters attested to in the application shall be subject to verification.

- Residents of the Territories are not eligible for the low-income subsidies available to residents of states under Part D, but may be eligible for assistance under the special Territorial provisions of Part D in Section 103 (new section 1935(e)).

- The Secretary of HHS shall develop a process to provide notification of a PDP sponsor or a Medicare Advantage organization offering a drug plan that an enrolled eligible individual is eligible for a subsidy and the amount of the subsidy. The sponsor or plan, in turn, reduces the premiums or cost sharing that would otherwise apply and submits to the Secretary information on the reduced amount. The Secretary periodically and on a timely basis must reimburse the PDP sponsor or MA organization for the amount of the reduced premiums and cost sharing. Reimbursement may be computed on a capitated basis. The Secretary must ensure the confidentiality of any individually identifiable information.

Effective Date:

- January 1, 2006

Sec. 1860D—15. Subsidies for Part D Eligible Individuals for Qualified Prescription Drug Coverage

Current Law:

- None

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

Provisions:

- The government subsidy for Part D will total 74.5 percent of the cost of the benefit on average. It will be delivered through two mechanisms: a direct subsidy and reinsurance.
    - The direct subsidy for each plan will be calculated as the difference between the plan's bid (individually risk adjusted) and the plans' enrollee premium for basic coverage.
    - The reinsurance payments will cover the plan's allowable costs that are associated with 80 percent of drug costs in the catastrophic coverage range for each enrollee. Allowable costs do not include administrative costs and are net of any discounts or rebates the plan may receive for the drugs provided in the catastrophic range. The Secretary determines the method of payment to plans and may make interim payments based on projected costs. Plans must provide any information on claims experience and costs that the Secretary determines are necessary to administer the reinsurance payments.
    - The Secretary will establish a risk-adjustment mechanism for the drug bids. Drug plans and Medicare Advantage plans are required to submit claims data to the Secretary to aid in the development and improvement of the risk adjuster.
    - The Secretary will establish a geographic-adjustment mechanism for the drug plan bids, taking into account variations in drug prices by region. If the price variation is determined to be de minimis, the adjuster will not be used.
    - A system of risk corridors will also partially protect plans from unexpected losses and allow the government to share in any unexpected gains. For benefit years 2006 and 2007, the corridors will be specified as follows: the plan is fully at risk for expenses that fall within 2.5 percent of the plan's target amount; for amounts between 2.5 percent and 5 percent, the government pays (recoups) 75 percent

of the amount above (below) 2.5 percent; finally, for amounts above (below) 5 percent, the government pays (recoups) 80 percent. After 2007, the risk corridor thresholds rise from 2.5 percent to 5 percent in the first case and from 5 percent to 10 percent in the second case. Also after 2007, the risk sharing in the first threshold declines from 75 to 50 percent. A further protection mechanism retroactively makes the risk corridors more protective of plans in 2006 or 2007 if most plans have significant losses. Specifically, if more than 60 percent of plans, covering more than 60 percent of eligible individuals have costs that exceed the first threshold, the government will pick up 90 percent of those costs.

Effective Date:

- January 1, 2006

Sec. 1860D—16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund

Current Law:

- None.

Provision:

- A Medicare Prescription Drug Account is created within the Federal Supplementary Medical Insurance Trust Fund (Medicare Part B). The funds for the account shall be kept separate from other funds in part B and do not affect the computation of the Part B premium.

- The Managing Trustee of the account shall use the fund to make payments to drug plans (including direct subsidies, reinsurance payments and low-income subsidies), employer subsidies, payments for administrative expenses and certain payments for state administrative costs.

- The account shall generally consist of periodically appropriated general revenues, premiums from Part D enrollees, state contributions to Medicare drug costs, and any leftover balance from the temporary drug discount card's Transitional Assistance Account.

- A contingency reserve fund is established in order to assure prompt payment of benefits under part D and administrative expenses. The Secretary determines the level of the contingency reserve, up to 10 percent of estimated 2006 expenditures.

Effective Date:

- See above.

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

Sec. 1860D—21. Application to Medicare Advantage Program and Related Managed Care Programs

Current Law:

- None

Provisions:

- Beginning January 1, 2006, Medicare Advantage organizations must offer a plan with either basic prescription drug coverage or qualified prescription drug coverage that provides supplemental coverage for no premium. They may offer a plan without drug coverage in an area, but only if they also offer a plan with drug coverage in the same area.

- Enrollees in a Medicare Advantage plan on December 31, 2005 who fail to make a plan election for 2006 are deemed to continue in their Medicare Advantage plan as long as the plan had at least some drug coverage in 2005. If the Medicare Advantage Plan had no drug coverage in 2005 and the enrollee fails to make an election, then the enrollee is returned to the traditional fee-for-service program.

- An enrollee who exercises his or her option for a one-time switch out of a Medicare Advantage plan when first becoming eligible for Medicare will be allowed to then enroll in a

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prescription drug plan.

- If a Medicare Advantage plan that does not offer prescription drug coverage leaves the service area, then that plan's enrollees are deemed to return to traditional fee-for-service Medicare (unless he or she makes an election to another plan) and is guaranteed issue of a Medigap plan.

- All requirements for prescription drug plans apply to the drug benefit in Medicare Advantage plans. The Secretary may waive these requirements to the extent they duplicate or conflict with requirements already applicable for Medicare Advantage plans or to improve coordination of benefits provided under those plans.

- Private fee-for-service plans that offer prescription drug coverage are not required to negotiate prices, set up exclusive pharmacy networks, perform drug utilization management or medication therapy management. These plans receive the average reinsurance payments paid to other drug plans, rather than claim-by-claim reinsurance. They also do not receive risk corridors. The Secretary may not negotiate the terms and conditions of the plans' bids.

- Plans with cost contracts that offer prescription drug coverage must meet the requirements for Medicare Advantage plans. Only participants in such a plan may enroll in its Part D plan. The bids of such plans will not be taken into account in computing average benchmark bids and low-income benchmark premium amounts.

- If a PACE program chooses to provide Part D drug coverage to a Medicare beneficiary who participates in its program, the coverage will be treated as though the PACE program were an MA-PD local plan. Only participants in such a plan may enroll in its Part D plan. The bids of such plans will not be taken into account in computing average benchmark bids and low-income benchmark premium amounts.

Effective Date:

- January 1, 2006

Sec. 1860D—22. Special Rules for Employer-Sponsored Programs

Current Law:

- None

Provision:

- Employers and unions may receive subsidies for the purpose of maintaining prescription drug coverage for their retirees. To receive the subsidy, the employer or union must attest that the coverage is of equal or greater actuarial value to Part D. In 2006, the subsidy for each eligible individual equals 28% of allowable costs associated with enrollee drug costs between $250 and $5000 (indexed in later years to the growth in Medicare's per capita spending on Part D drugs). The allowable costs exclude administrative costs and any discounts or rebates the employer receives.

- Eligible individuals have the choice of whether to stay in employer-based coverage or to join Part D. Employers may offer coverage that exceeds Part D and have complete flexibility about how the benefit is designed.

Effective Date:

- None

Sec. 1860D—23. State Pharmaceutical Assistance Programs

Current Law:

- No provision.

Provision:

- States with pharmacy assistance programs will be permitted to participate in Part D by purchasing supplemental benefits through a Medicare Part D plan or by having their own supplemental benefit wrap around Part D. States must provide such assistance to individuals in all Part D plans and cannot discriminate based upon the Part D plan.

- The Secretary will establish a process to ensure the coordination between State Pharmaceutical Assistance Programs (SPAPs) and Part D, including enrollment file sharing; processing of claims, including electronic processing; claims payment; claims reconciliation reports; application of the out-of-pocket limit; and other administrative processes specified by the Secretary. Enrollees will be given a single plan benefit card to use for both programs

- States may pay cost sharing on behalf of enrollees. The costs incurred by the state may be counted toward the out-of-pocket limit for catastrophic coverage.

- The Secretary will provide payments through the Transitional Grant Program to SPAPs with approved applications to facilitate the transition of eligible individuals between SPAPs and Part D, as well as coordination between SPAPs and Part D. Funds can be used to: educate eligible individuals; provide technical assistance and counseling to enrollees; and other activities to promote effective coordination of enrollment, coverage, and payment between SPAPs and part D plans.

- Medicare is the primary payer with respect to state pharmacy assistance programs.

Effective Date:

- Before July 1, 2005

Sec. 1860D—24. Coordination Requirements for Plans Providing Prescription Drug Coverage

Current Law:

- None

Provisions:

- Coordination mechanisms established for state pharmaceutical assistance programs and Part D to exchange drug claims and track out-of-pocket expenses will be applied to other types of plans, including Medicaid plans, group health plans, FEHBP, military coverage and others. The Secretary may impose user fees to fund these coordination mechanisms. The Secretary may not impose these user fees on state pharmaceutical assistance programs unless the program does not meet the requirements established for state programs.

- The coordination mechanisms will not be allowed to impair Part D plans from utilizing their cost management tools.

Effective Date:

- None.

Subpart 4-Medicare Prescription Drug Discount Card and Transitional Assistance Program

Sec. 1860D—31. Medicare Prescription Drug Discount Card and Transitional Assistance Program.

Current Law:

- No provision in current law.

Provision:

- Medicare-endorsed drug cards would be available no later than 6 months after enactment and the program would end when the permanent prescription drug benefit becomes available to eligible individuals in 2006. There will be an appropriate transition for ending the discount card and beginning the drug benefit. Eligible individuals would have the choice of at least 2 cards in the 50 states and the District of Columbia. Cards would be available on at least a statewide basis; however, exclusive Medicare managed care sponsors (Medicare + Choice plans or Medicare cost plans) that limit card enrollment to their plan members could offer cards in their service area. All individuals with Medicare Part A or Part B would be eligible for the card, except those enrolled in Medicaid and entitled to Medicaid outpatient drug coverage (including under an 1115 waiver).

- Individuals can only enroll in one Medicare-endorsed card at a time. Individuals may switch to a different drug card for 2005. Card sponsors may charge no more than a $30 annual enrollment fee.

- Pharmacy Benefit Managers (PBMs), wholesalers, retail pharmacies, insurers, Medicare+Choice plans, or any other entity designated by the Secretary could be sponsors of a Medicare-endorsed drug card.

- Individuals who are eligible for the drug card, and with incomes at or under 135% of the federal poverty level, would be eligible for transitional assistance unless they have third

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party coverage for outpatient drugs from former employers, through an individual-purchased policy, TRICARE, Medicaid, or FEHBP (except if the coverage comes from a Medicare+Choice or Medigap plan, even if an employer pays the premium). Individuals would self-certify income, but HHS would verify eligibility through Medicaid, Social Security, or tax information, subject to strict confidentiality constraints. There would be no asset test (unlike the Medicaid programs). Up to $600 per year would be provided in conjunction with the discount card to purchase prescription drugs, but the amount may be prorated for eligible individuals who enroll for part of a year. Funds not used in one year may be rolled over to the next year. The annual enrollment fee would be paid by the Secretary for transitional assistance individuals. Individuals receiving transitional assistance with incomes below 100% of poverty would pay a 5% coinsurance on each discounted drug; those with incomes between 100-135% of poverty would pay 10% coinsurance on each discounted drug.

- The Secretary must establish procedures and may waive requirements of this section for purposes of providing transitional assistance so that sponsors of drug cards will make arrangements with pharmacies that support long-term care facilities; and so that pharmacies operated by IHS, Tribes, Tribal organizations, and urban Indian organizations have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 states and Washington DC where such a pharmacy operates.

- The Secretary may waive provisions of the discount card for the Territories. Those Territories that establish a plan will receive a portion of a $35 million special fund that may be used only to provide transitional assistance to some or all Medicare eligible individuals residing in the Territories with incomes below 135 percent of the Federal poverty level. Funds will be divided among the Territories based on their relative proportions of Medicare eligible individuals in all of the Territories.

Effective Date:

- No later than 6 months after enactment.

Subpart 5-Definitions and Miscellaneous Provisions

Sec. 1860D—41. Definitions; Treatment of References to Provisions in Part C

Current Law:

- None

Provision:

- The section includes a comprehensive list of the definitions that appear in other parts of Title I, as well as adding definitions of "insurance risk" and "PDP sponsor." It also states that, unless otherwise provided in Part D, references to Part C (Medicare+Choice/Medicare Advantage) provisions are to be applied as if references to M+C or MA plans, organizations, contracts, or election periods included references to parallel concepts under Part D, and as if any reference to Part C included a reference to Part D.

Effective Date:

- Enactment.

Sec. 1860D—42. Miscellaneous Provisions

Current Law:

- None

Provision:

- The Secretary may waive Part D requirements in the Territories if necessary to secure access to eligible individuals there.

- The Secretary will submit technical and conforming amendments to the Congress within 6 months of enactment.

- The Secretary will study the option of transitioning outpatient drug coverage in Part B to Part D and will report to Congress on the feasibility of that transition.

- The Secretary will report on the progress of Part D's implementation no later than January 1, 2005.

- Individual pharmacies may waive cost sharing for Part D enrollees qualifying for the low-income subsidies so long as they do not advertise the availability of these waivers.

Effective Date:

- January 1, 2005 for the Part B drugs study and implementation report to Congress

Sec. 102. Medicare Advantage Conforming Amendments

Current Law:

- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (P.L. 107-188) changed the annual coordinated election period from the month of November to November 15th through December 31st in 2003, 2004, and 2005. Once the temporary provision expires, the reporting dates and deadlines would return to the pre-P.L.107-188 dates.

- Medicare eligible individuals can make and change election to an M+C plan on an ongoing basis through 2004. Then beginning in 2005, individuals would only be able to make changes on a more limited basis.

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

Provision:

- Allows Medicare beneficiaries to continue to make and change elections to a Medicare+Choice plan on an ongoing basis through the end of 2005. The current law

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limitation on changing elections that begins in 2005 is delayed until 2006.

- Changes the annual, coordinated, election period to be November 15th to December 31st of the previous year for elections for 2004 and 2005 and to November 15, 2005 to May 15, 2006 for 2006. Beginning in 2007, the annual coordinated election period will permanently be from November 15th to December 31st.

- Establishes an educational and publicity campaign for MA plans and Medicare Advantage Prescription Drug (MA-PD) plans.

- If an individual's initial enrollment period for Part B ends after the end of the annual coordinated election period, then their initial enrollment period would be extended through the end of their Part B initial enrollment period.

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

- An MA-PD plan can provide for a separate payment for a participating physician who prescribes covered part D drugs under an electronic prescription program as long as the program meets Part D requirements.

Effective Date:

- Upon enactment.

Sec. 103. Medicaid Amendments Eligibility Determinations

Current Law:

- States must conduct eligibility determinations for low-income individuals who may qualify to receive Medicaid or to participate in the Medicare savings program. Most states (referred to as 1634 states) provide Medicaid coverage to SSI recipients; an individual's application for SSI at an SSA office entitles the individual for Medicaid benefits without any additional action required on the applicant's part. States, however, are not currently mandated in statute to do determinations as a condition of receiving FFP, other than as a compliance matter. States receive 50% FFP for administrative expenses they incur.

Provision:

- States are required as a condition of receiving any FFP to determine eligibility for premium and cost sharing subsidies for the new Medicare Part D prescription drug program and are required to provide the Secretary with information for verification of eligibility for the drug card as well as the

transitional assistance program. States shall also determine eligibility for and offer enrollment into a Medicare cost-sharing program (QMB, SLMB, and QI1) at the time they screen eligible individuals for low-income subsidies. States shall provide the Secretary with eligibility determination information as may be required to carry out the part D benefit. States will receive the regular Medicaid matching payment for administrative costs for these activities.

Effective Date:

- Upon enactment

Federal Assumption of Medicaid Premiums and Cost-sharing for Dually-eligible Individuals

Current Law:

- No provision.

Provision:

- Provides for a continued state contribution to the cost of providing benefits for full benefit dual eligibles through a monthly payment from the states to the Federal government. Payments are made in a manner similar to the mechanism through which states pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid.

- For each full benefit dual eligible in Part D, the state contribution is based on each state's own per capita drug spending on behalf of full benefit dual eligibles in 2003. By October 15, 2005, the Secretary will determine a per capita amount for each state. This amount will reflect the state share and is net of rebates. Starting January 1, 2006, each state will make a monthly payment to the Federal government for each full benefit dual eligible. The state contribution is reduced each subsequent year by equal amounts to 75% of the calculated per capita amount in 2015 where it remains thereafter.

- State contributions will be deposited in the prescription drug account of the SMI Trust Fund. Failure on the part of states to pay these amounts results in interest payments and a reduction of the amount due from the state's Federal Medicaid matching payment. New section 1935(c)(1)(D) requires the Secretary to perform periodic data matches to identify the full-benefit dual eligibles for purposes of computing state contributions. States would make contributions only on behalf of individuals who would otherwise be eligible for prescription drug benefits under Medicaid and who have full benefits under a state Medicaid plan. States would not make contributions on behalf of individuals such as QMBs and SLMBs for whom the state would pay only Part B premiums and Medicare cost sharing on their behalf.

- To assist states in their budget planning, the Secretary must notify states by October 15 each year of the per capita calculation for the next year. The per capita amount will be indexed by the change in Medicare drug spending.

- The ten-year phased-down state contribution factors are:

2006	90%
2007	88-1/3%
2008	86-2/3%
2009	85%
2010	83-1/3%
2011	81-2/3%
2012	80%
2013	78-1/3%
2014	76-2/3%
2015 and thereafter	75%

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Effective Dates:

- First estimate of State per capita payment amounts: October 15, 2005
- Accrual of State contributions: January 1, 2006

Medicaid Coordination with Medicare

Current Law:

- Medicaid is required to pay for services covered under the State Plan. To the extent that the State Plan covers prescription drugs, Medicaid is required to pay for these drugs. Medicaid is always the payer of last resort.

Provision:

- Federal Financial Participation (FFP) for Medicaid would not be available for prescription drugs, or any cost sharing respecting such drugs, for "full benefit" dual eligibles. Full benefit dual eligibles would receive prescription drug coverage through Part D. Full benefit dual eligibles are defined as individuals who have coverage through the Medicare drug benefit and are enrolled in Medicaid for full benefits either through categorical eligibility or Medically Needy eligibility, or as otherwise defined by the Secretary.
- There is one exception to this prohibition. FFP may be used to cover certain excludable drugs. These are drugs that are not covered in the Medicare drug benefit, such as certain mental health drugs. States may cover such drugs through Medicaid in the manner in which they would cover them for

individuals who are not full benefit dual eligibles or through an arrangement with the Medicare drug plan.

Effective Date:

- January 1, 2006

Treatment of Territories

Current Law:

- No provision.

Provision:

- Residents of the U.S. Territories are not eligible for the usual Part D low-income subsidies. They may be eligible instead for special assistance programs in their Territory, funded out of a separate pool of Federal money. This pool of funds totals $28.125 million for all of the Territories for the last three quarters of FY 2006 and $37.5 million per year for FY 2007 and future years. (The amount for later years will be adjusted by the percentage increase in Part D drug spending.) Funds in the pool will be divided among the Territories based on their relative proportions of residents entitled to Medicare Part A or enrolled under Medicare Part B. The funds can only be used by the Territories: (1) as medical assistance to help low-income Part D eligible individuals pay for covered Part D drugs and (2) for related administrative expenses (which cannot exceed ten percent of the funds received for any fiscal period). In order to receive a share of these funds, a Territory must establish and submit a plan meeting the conditions above and other criteria specified by the Secretary. The Secretary must submit a report to Congress on these provisions that may include recommendations (no date specified).

Effective Date:

- Second quarter FY 2006.

Best Price

Current Law:

- Manufacturers must pay state Medicaid programs a basic rebate for covered outpatient drugs. Basic rebates are due on single source and innovator drugs based on the greater of (1) the difference between the average manufacturer price for a drug (the average price paid by wholesalers) and bet price (the lowest price available from the manufacturer in the same period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States) or (2) 15.1% of the average manufacturer price. Rebates are due on non-innovator drugs based on 11% of the average manufacturer price. For purposes of determining Medicaid rebates, prices paid by a number of Federal and state entities are excluded from the definition of "best price."

Provision:

- The Best Price section of title XIX is amended to exclude from the best price calculation prices negotiated from manufacturers for covered discount card drugs under a Medicare endorsed discount drug card, prices negotiated for

covered Part D drugs by PDPs, prices negotiated for covered Part D drugs by MA-PD plans, and prices negotiated for such drugs by qualified retiree prescription drug plans on behalf of Medicare beneficiaries.

Effective Date:

- Effective with respect to drugs dispensed on or after January 1, 2006.

Extension of QI-1 Program

Current Law:

- 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

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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 March 31, 2004, by P.L. 108-89.

Provision:

- The QI-1 program is extended until September 30, 2004. The funding levels are consistent with current law and the extension is effective April 1, 2004.

Effective Date:

- April 1 2004 (Expires September 30, 2004)

SSA Outreach

Current Law:

- The Commissioner of SSA conducts outreach efforts in coordination with the states to identify individuals entitled to Medicare cost sharing.

Provision:

- Amends Section 1144 (Outreach efforts to increase awareness of the availability of Medicare cost sharing) to require SSA to provide awareness not only of Medicare cost sharing but of subsidies for low income individuals under Title XVIII and for the transitional drug card program through SSA outreach efforts.

Effective Date:

- Enactment.

Sec. 104. Medigap Amendments.

Medigap Amendments

Current Law:

- Three of the standardized Medicare Supplemental Health Insurance ("Medigap") benefit packages offer drug coverage - those classified as H, I and J, including the benefit package classified as J with a high deductible feature. Drug coverage is also available through pre-standardized Medigap policies. Finally, drug coverage is available through Medigap policies offered in three "waiver" states in which Medigap options differ from the national standard benefit packages (Wisconsin, Minnesota, and Massachusetts).

Provision:

- All of the provisions related toMedigap policies with drug coverage apply to the standardized policies (H, I, and J, including J with high deductible), as well as the pre-standardized Medigap policies with drug coverage and the Medigap policies with drug coverage in the waiver states.
    - o Sales of New Medigap Policies With Drug Coverage—No new Medigap policies with drug coverage can be sold or issued on or after January 1, 2006. Issuers can offer new H, I, and J policies with benefit packages modified to exclude drug coverage after January 1, 2006. Issuers offering Medigap policies with drug coverage in the three waiver states can

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offer these policies with the benefit package modified to exclude drug coverage. Failing to meet the requirements of this provision could result in a criminal penalty (e.g., a fine, or imprisonment of not more than 5 years, or both) and/or a civil money penalty not to exceed $25,000 (or $15,000 in the case of a person other than the issuer of the policy) for each such failure.

- o Renewal of Existing Medigap Policies With Drug Coverage—No existing Medigap policies with drug coverage can be renewed on or after January 1, 2006 for individuals who are part D enrollees. However, an existing Medigap policy with drug coverage that was issued before January 1, 2006 can be renewed for a non-part D enrollee.
- o Elimination of Duplicative Drug Coverage For Part D Enrollees—Individuals who enroll in a Part D plan who are covered under an existing Medigap policy with drug coverage will have the following options for eliminating the duplicative drug coverage:

+ If they enroll in Part D before the end of the initial Part D enrollment period, they can either: 1) continue with a modified version of their existing Medigap policy that excludes coverage for prescription drug expenses incurred after the effective date of the individual's coverage under a Part D plan and adjusts their Medigap premiums to reflect the elimination of drug coverage (as with previous coverage, the modified policy would be guaranteed renewable); or 2) enroll on a guarantee issue basis in a Medigap policy with a different benefit package (A, B, C, or F, including F with high deductible, the two proposed new benefit packages (described below), or comparable benefit packages in the three waiver states) through their current insurer if they seek to do so not later than 63 days after the effective date of their coverage under a Part D plan and if that benefit package is offered and available for issuance to new enrollees by such insurer. Any issuer that fails to meet the requirements related to guaranteed renewability and guaranteed issue of a substitute policy will be subject to a civil money penalty not to exceed $5,000 for each such failure.

+ If they enroll in Part D after the initial Part D enrollment period, they only have the option for modified coverage described above.

o Notification of Current Policyholders With Drug Coverage—Requires issuers to provide written notice to each individual who holds a Medigap policy with drug coverage during the 60-day period immediately preceding the initial Part D enrollment period. The written notice must be in accordance with standards that the Secretary establishes in consultation with the National Association of Insurance Commissioners, and must:

+ Notify individual policyholders of their Medigap options if they do or do not enroll in a Part D plan during the initial enrollment period.
+ Notify policyholders whose current Medigap plan does not provide creditable prescription drug coverage of that fact, and that if they do not enroll in Part D during the initial enrollment period, there will be limitations on when they can

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enroll in Part D during a given year, and that any such enrollment will be subject to a late enrollment penalty.

+ Provide other information that the Secretary may specify, including information about the potential impact of their decision on their Medigap premiums.

- Guaranteed Issue For Eligible individuals Who Try Medicare Advantage—The current law provision providing certain return rights for individuals who leave Medigap coverage to try M+C is modified to address the situation where the Medigap coverage included drug coverage. These individuals would have guaranteed issue rights to their previous Medigap policy, modified to exclude drug coverage.
- Creation of Two New Standard Medigap Benefit Packages and Revisions to Existing Standards—Requires that the standards for Medigap benefit packages be revised to reflect changes made by this statute, and requires that two new standard benefit packages be created. If the National Association of Insurance Commissioners makes the necessary revisions to its Model Regulation within nine months, those revisions will apply. Otherwise, the Secretary must make the revisions. To the extent practicable, these revisions should provide for implementation of the revised standards by January 1, 2006. The two new benefit packages consist of:
  - except as provided below, coverage of 50% (first new package) or 75% (second new package) of the cost-sharing otherwise applicable under parts A and B, except for the part B deductible;
  - coverage of 100% of hospital inpatient coinsurance and 365 extra lifetime days of coverage of inpatient hospital services;
  - coverage of 100% of any cost-sharing otherwise applicable for preventive benefits; and
  - limits annual out-of-pocket spending under parts A and B to $4,000 (first new package) or $2,000 (second new package) in 2006 (to be adjusted for inflation by the Secretary).
- Prohibition on State Mandate to Issue Part D Coverage—States cannot require Medigap insurers to issue Part D coverage.

Effective Date:

- Upon enactment.

Sec. 105. Additional Provisions Relating to Medicare Prescription Drug Discount Card and Transitional Assistance Program

Current Law:

- No provision in current law.

Provision:

- In general, provides for conforming amendments to the statute as outlined in Section 1860D-31 such as, establishes an exclusion of costs related to the drug discount card from determination of the Part B monthly premium. Also, applies confidentiality to certain, non-aggregated drug pricing data, i.e. non-aggregated pricing data reported to determine the extent of negotiated price concessions passed through to drug card enrollees, pharmacies, or otherwise.
- Provides that there shall be no judicial review of a decision not to endorse a card sponsor.
- If an order is issued to enjoin any provision of the drug card, such order cannot affect any other provision of the drug card.
- Provides conforming amendments to the Internal Revenue Code of 1986 for disclosing tax return information for purposes of providing the $600 subsidy under the drug card.

Effective Date:

- Enactment.

Sec. 106. State Pharmaceutical Assistance Transition Commission

Current Law:

- No provision.

Provision:

- A State Pharmaceutical Assistance Transition Commission will be established to develop a proposal for addressing the unique transitional issues facing State Pharmaceutical Assistance Programs (SPAPs), and program participants due to the implementation of the new Medicare prescription drug benefit.
- A SPAP is defined, for purposed of establishing this Commission, as a non-Medicaid program operated by a state (or under contract with a state) that provided, as of the date of enactment of this legislation, financial assistance to Medicare beneficiaries for the purchase of prescription drugs. A program participant is a low-income Medicare beneficiary who is a participant in a SPAP.
- The Commission will include a representative of the Governors from each SPAP state that the Secretary identifies as having a statewide program offering coverage at least comparable to the low income assistance offered under the Part D benefit; representatives from states with other state pharmaceutical assistance programs, as appointed by the Secretary; representatives of organizations with an interest in SPAP programs and/or participants as appointed by the Secretary, but not to exceed the number of state representatives; representatives of Pharmacy Benefit Managers, Medicare Advantage organizations, and other private health insurance plans as appointed by the Secretary; the Secretary and other members he or she may specify. The Commission will develop a proposal that protects specified interests of states and program participants, and that is consistent with the principles of Medicare modernization. The Commission will produce a report to Congress with recommendations and a detailed proposal, and will receive

administrative support from the Secretary. The Commission will terminate after the report is submitted.

Effective Date:

- The Commission is established the first day of the third month beginning after the date of enactment. The report is due January 1, 2005.

Sec. 107. Studies and Reports

Current Law:

- None.

Provision:

- The Secretary shall conduct a study that examines variations in per capita spending under the Part D prescription drug benefit among PDP regions and report to Congress by January 1, 2009.
- The Secretary shall conduct a thorough review of the current standards of practice for pharmacy services provided to patients in nursing facilities no later than 12 months after the date of the enactment of this Act. The Secretary shall submit a report to Congress on the study no later than 18 months after the date of enactment.
- The Secretary shall enter into a contract with the Institutes of Medicine of the National Academies of Science (IOM) to carry out a comprehensive study of drug safety and quality issues in order to provide a blueprint for a system-wide change. The IOM shall convene a committee of leading experts and key stakeholders in pharmaceutical management and drug safety in conducting the study. Appropriations are authorized to carry out such a study. The study shall be completed within an 18-month period, and the report to Congress shall be submitted upon completion of the study.
- The Secretary shall provide a study on the feasibility and advisability of multi-year contracts for PDP sponsors and MA organizations. The Secretary shall submit a report to Congress on this study no later than January 1, 2007.
- The Comptroller General of the General Accounting Office shall conduct a study to determine the extent to which asset tests for the Part D low-income subsidy affect utilization and access for beneficiaries. The Comptroller General shall submit a report to Congress by September 30, 2007.
- The Secretary shall undertake a study on providing drug labeling and usage information to blind and visually impaired individuals and report to Congress not later than 18 months after enactment.

Effective Date:

- See above for different report dates.

Sec. 108. Grants to Physicians to Implement Electronic Prescription Drug Programs

Current Law:

- None.

Provision:

- The Secretary is authorized to make grants to physicians to assist them in implementing electronic prescribing, with preference given to rural physicians and those who disproportionately serve Medicare beneficiaries. The grants may be used to procure relevant computer software and hardware, to upgrade existing computer systems, or for education and training. Each physician or practice may receive only one grant, and the applicant must put up (either directly or through a non-Federal donation) at least 50 percent of the cost of implementing electronic prescribing.
- $50,000,000 for fiscal year 2007 is authorized to carry out this provision and such sums as may be necessary for fiscal years 2008 and 2009.

Effective Date:

- See above.

Sec. 109. Expanding the Work of Medicare Quality Improvement Organizations to Include Parts C and D

Current law:

- Requires peer review organizations (also referred to as quality improvement organizations or QIOs) to review the professional activities of entities and individuals that provide health care services under the Medicare program.

Provision:

- Specifies that the requirement for QIOs to review professional activities includes Medicare Advantage organizations under Part C and prescription drug sponsors under Part D.
- Specifies that the organization is to offer providers, practitioners, Medicare Advantage organizations and prescription drug sponsors quality improvement assistance related to prescription drug therapy. Also specifies that these functions will be treated as a review function.
- Requires the Secretary to ask the Institute of Medicine (IOM) to conduct an evaluation of the peer review program. This evaluation is to include, among

other things, a review of the extent to which QIOs improve quality of care for Medicare beneficiaries, the extent to which other entities could perform QIO functions as well as or better than QIOs, funding of QIOs, and oversight of QIOs. The Secretary is to report to Congress on the results of this evaluation by June 1, 2006.

- If the Secretary finds, based on the IOM evaluation, that other entities could improve quality in the Medicare program as well as or better than QIOs, the Secretary is to provide for increased competition by adding new types of entities that can perform QIO functions.

Effective Date:

- On or after January 1, 2004.

Sec. 110. Conflict of Interest Study

Current Law:

- None.

Provision:

- Requires the Federal Trade Commission to conduct a study of differences in payment amounts for pharmacy services to enrollees in group health plans that utilize pharmacy benefit managers.
- The study shall include information on the assessment of the differences in costs incurred by enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmacy benefit managers and community pharmacies. The study shall include information on whether the group health plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

Effective Date:

- The Federal Trade Commission shall submit a report to Congress no later than 18 months after the date of the enactment of this Act.

Sec. 111. Study on Employment-Based Retiree Health Coverage

Current Law:

- None.

Provision:

- Requires the Comptroller General of the General Accounting Office to conduct an initial and final study to examine trends in employment-based retiree health coverage (as defined in section 1860D-22(c)(1) of the Social Security Act), including coverage under the Federal Employee Health Benefits Program, and the options and incentives available under this Act which may have an effect on the voluntary provision on part D drug coverage.

Effective Date:

- The Comptroller General shall submit a report to Congress on the initial study no later than 1 year after the date of the enactment of this Act and on the final study no later than January 1, 2007.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage Program

Current law:

- Part C of current law is the "Medicare+Choice" program.

Provision:

- Establishes the Medicare Advantage program under Part C.
- Indicates that references to Medicare+Choice and to Part C are deemed to be references to the Medicare Advantage program.
- In order to avoid confusion, authorizes the Secretary to provide for an orderly transition to the use of the terms "Medicare+Choice" and "Medicare Advantage," to be completed by January 1, 2006.

Effective Date:

- Enactment.

Subtitle B—Immediate Improvements

Sec. 211. Immediate Improvements

Current Law:

- M+C plans are paid based on monthly capitation rates that are the largest of three amounts: (1) a blend amount, (2) a floor amount, or (3) a minimum 2 percent increase over the prior year's rate.

Provision:

- For 2004, adds to the current 3 amounts in the "largest of" methodology a fourth amount of 100% of projected fee-for-service Medicare costs (excluding direct medical education and including a VA/DOD adjustment).
- For years after 2004, the Secretary is required to recalculate 100% of fee-for-service Medicare costs at least every 3 years.
- For 2004 and succeeding years, modifies the minimum increase rate to be the larger of 102% of the previous year's rate or the prior year's rate increased by the Medicare growth percentage, with no adjustment to this rate for over- or under-projection for years before 2004.
- For 2004, eliminates the budget neutrality requirement for the blend capitation rate.

- The Secretary is to announce new rates for 2004 within 6 weeks of enactment. [Rates for 2004 that were announced in May 2003 apply for January-February 2004, but the Secretary will ensure that total 2004 payments are what plans would have been paid if the revised rates had been in effect all year.]
- Applies the provisions of section 604 of BIPA of 2001 related to submission of revised ACR proposals, return to the program, and use of additional payment amounts. Under these provisions:
- Existing organizations that experience rate increases because of the 2004 revised rates are required to submit a revised ACR proposal for 2004 within 2 weeks of the announcement of revised rates. When submitting an ACR proposal, an organization may use additional payment amounts only to reduce premiums, reduce cost sharing, enhance benefits, utilize benefit stabilization funds, or stabilize and enhance access to providers. Organizations choosing to use additional payment amounts to stabilize and enhance access to providers may do so only if it does not result in increased premiums, increased cost-sharing, or reduced benefits. Any regulations that limit the amounts withheld in a benefit stabilization fund are waived, with respect to ACR proposals for March to December 2004.
- Organizations that previously had provided notice of termination or service area reductions may return to the program or their service area if they provide an ACR proposal within 2 weeks after the Secretary announces the revised 2004 rates.
- Notwithstanding the issuance of revised rates, organizations will continue to be paid on a fee-for-service basis for 2004 for costs associated with certain new national coverage determinations and legislative changes in benefits that are made mid-year.

- Organizations that are required to submit revised ACR proposals must provide written notice to enrollees of changes in eligible individual premiums, eligible individual cost-sharing, or benefits under the plan not more than 3 weeks after the Secretary approves their revised ACR proposals.
- Provides that private FFS plans with sufficient providers or professionals under contract (for a category of provider or health care professional) can charge eligible individuals higher co-payments when they obtain care from non-contract providers or professionals.
- The Secretary is required to study the impact of additional funding for Medicare Advantage plans on the availability of such plans and on the benefits and premiums of such plans. The report is due by July 1, 2006.
- MedPAC is required to study the method for calculating 100% of fee-for-service costs, including the bases for variation in costs between different geographic areas and the accuracy of risk adjustment methods, within 18 months of enactment.

- MedPAC is required to study the extent to which Medicare Advantage plan cost-sharing structures affect access to services or influence the health status of individuals who enroll in such plans. The report is due by December 31, 2004.

Effective Date:

- Upon enactment.

Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

Sec. 221. Establishment of MA Regional Plans

Current law:

- None.

Provisions:

- A new regional plan offering is established for Medicare Advantage on a preferred provider organization (PPO) model. A regional PPO is defined as a plan that has a network of providers who contractually agree on reimbursement for covered services, but that also pays some reimbursement if the enrollee sees a provider outside the network.
- The Secretary cannot approve local MA PPOs in 2006 and 2007 unless they were already operating in an area in 2005.

- Following a market survey, the Secretary will establish 10 to 50 Medicare Advantage regions, designed to maximize plan participation. A regional PPO plan must serve the entire region. Plans may offer a PPO in more than one region or in all regions.
- If a regional MA plans feature a deductible, it must have a unified deductible (unlike the separate Part A and Part B deductibles in traditional Medicare). Plans may waive the deductible for preventive services or other services. Regional MA plans must also feature a catastrophic limit on out-of-pocket expenditures for in-network services and a limit for all covered services.
- A set of risk corridors will protect plans from unexpected losses in 2006 and 2007.
    - The plan's target spending amount for the year includes total payments to plans from the government and enrollee premiums, minus the plan's administrative costs assumed in its bid.
    - The risk corridors are symmetrical in that the government pays plans if costs are above the target and recoups its share of the savings when costs are below the target.
    - The plan is fully at risk for the first 3 percent of costs above or below a target amount.
    - The plan and the government share 50 percent of costs/savings that are 3 to 8 percent off the target.
    - The government pays/keeps 80 percent of the costs/savings when costs are more than 8 percent off the target.

    - Plans' costs are subject to audit by the Secretary, and the Secretary must hold the plans' financial information confidential.
- MA regional plans must be licensed in at least one state in the MA region and must file applications to be licensed in the remaining states. The Secretary may temporarily waive the licensure requirement for any states in which the application has not yet been approved. In the case of a waiver, the MA plan will select one state's licensure rules, and the Secretary will require the plan to meet that state's standards throughout the service area.
- A stabilization fund will be established to provide plans with incentives to enter and remain in MA regions.
    - The fund will have an initial capitalization of $10 billion on January 1, 2007 and the money will be available until December 31, 2013.

- The stabilization fund will also receive one half of the government's 25 percent share of any rebates that result when regional MA plans bid below the regional MA benchmarks.
- Subject to the budget constraint, the stabilization fund can be used in several ways:
    + NATIONAL BONUS -- For organizations that offer a national plan by bidding on all regions, CMS increases the benchmark payment by 3 percent for each of the organization's regional plans.
    + REGIONAL PLAN ENTRY BONUS -- If a region had no MA regional plans offered in the prior year, the Secretary may increase the benchmark amount for the region. The amount and duration of the increase are at the Secretary's discretion, and the increase will be available to all plans that enter.
    + REGIONAL PLAN RETENTION BONUS -- If plans notify the Secretary that they intend to exit, and the Secretary determines that fewer than two MA regional plans would be available, and the enrollment in regional MA plans in that region is below the national average, then the Secretary may increase the benchmark payment for plans in that region. The maximum increase is the greater of either 3 percent of the regular benchmark or an amount that would bring the region's benchmark up to the average benchmark relative to average adjusted per capita costs in traditional Medicare. This plan retention funding cannot be used in more than two consecutive years in a region. It also cannot be used in a region that received a plan entry bonus payment in the prior year.
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- Increases in the benchmark apply to that year only; the following year's benchmarks are calculated without regard to any prior increases due to use of the stabilization fund.
- The Secretary and the CMS Actuary must determine in advance of a year that the use of the stabilization fund will not exceed the funds available. The Secretary may impose enrollment limits on plans receiving increases in order to keep from exceeding the fund limit.

- Starting in 2008, the Secretary must report annually to Congress and to the Comptroller General on the use of the stabilization fund, the amounts available, and cost containment steps taken.

    - The General Accounting Office will report every two years, starting in 2009 about the use of the stabilization fund, costs to the program, and any effects on enrollee satisfaction and the quality of care in MA regional plans.
- For their non-drug benefits, MA regional plan bids will be compared to an MA regional benchmark (described further in Sec. 222). The regional MA benchmark will be a blend consisting of a statutory component and component based on plan bids.
    - The statutory component of the MA regional benchmark will consist of a weighted average of the county Medicare Advantage rates for all counties in the region. The weights will be the number of Medicare beneficiaries in each county.
    - The bid-based component will consist of a weighted average of plan bids in the region. The weights will be each plan's enrollment in the region during the prior year. The Secretary has two options for determining the weight in the first year. Plans are either weighted equally or by the projected enrollment estimates included in their bids, as verified and/or adjusted by the Chief Actuary.
    - The MA regional benchmark will consist of a weighted average of the two components. The weight on the statutory component will be the share of Medicare beneficiaries nationally who are enrolled in traditional Medicare during the prior year. The weight on the plan-bid component will be one minus the statutory component weight.
- MA regional plans may choose to apply a single local coverage determination throughout the region.
- Regional MA plans must meet network adequacy standards throughout the region. The Secretary is authorized to spend up to $25 million per year (in 2006 -- indexed by hospital market basket increases for later years) for bonus payments to hospitals in areas where regional PPO plans are unable to agree to contracts with those hospitals. The payment is the difference between what the plan pays and what the hospital would have been paid if the patient were in traditional Medicare and the hospital were a critical access hospital. In these cases, the MA regional plan must pay hospitals at least the Medicare fee schedule, and hospitals must demonstrate that the cost of providing the service exceeds the Medicare fee rate.

Effective Dates:

- January 1, 2006.
- PPO regions to be established by January 1, 2005.
- The stabilization fund will be capitalized on January 1, 2007.

Sec. 222. Competition Program Beginning in 2006

Current law:

- Private plans (currently referred to as Medicare+Choice plans and referred to as Medicare Advantage plans under this legislation) are paid based on capitated rates. The rates are

based on a complex formula in the statute that sets each county rate at the largest of three amounts: a floor amount, a local/national blend amount, or a minimum increase over the prior year's rate. To the extent that the rate calculated under this formula is greater than the plan's estimate of the cost of providing the Medicare benefit, the plan is required to provide additional benefits or may reduce the enrollee's Part B premium.

Provision:

NOTE: See summary of Sec. 221 for provisions on (1) MA regions, (2) risk corridors and stabilization fund (with entry and retention bonuses) for regional MA plans, (3) computation of region-specific benchmark amounts for Part A and B benefits, (4) network adequacy requirements, and (5) requirement for a single deductible and catastrophic limit for regional MA plans.

- In general, this section sets forth a structure that applies to most MA plans (but not to MSAs or ESRD enrollees in MA plans). The essentials of this structure are:
    - benchmark amounts for Part A and B benefits, determined by the Secretary,
    - bids submitted by MA organizations, for Part A and B and other benefits, and
    - a comparison of bids and benchmarks for Part A and B benefits for purposes of determining (1) eligible individual rebates (if bid is lower) or premiums for those benefits (if bid is higher) and (2) plan payment amounts for those benefits.
- For local plans, the Secretary determines benchmark amounts for benefits covered by Parts A and B for geographic areas. These are based on the capitation rates determined under current law as amended by Section 211, summarized above. Per section 221, calculation of benchmark amounts for regional plans is based on a blend of capitation rates and plan bids.
- The Secretary announces benchmark amounts and risk adjustment factors and related information by the first Monday in April.
- Plans submit a 3-part bid by the first Monday in June addressing (1) Medicare Part A and B benefits (with cost sharing required for Part A and B services or an actuarially equivalent amount), (2) Part D (basic prescription drug) benefits, and (3) supplemental benefits (i.e., reduction in cost sharing for Part A and B benefits, enhancement to the basic drug package, and additional health care benefits). Bids must also include information on the actuarial bases for bids.

- With respect to bids, the Secretary may accept only bid amounts that are supported by the actuarial bases provided by the MA organization. The Secretary has negotiating authority similar to the authority of the Director of the Office of Personnel Management under the Federal Employees Health Benefits Program (this authority does not apply to bids from private FFS plans).

- In order to determine beneficiary rebate amounts (if any), the Secretary compares the plan's bid for Part A and B benefits to the benchmark (which is for Part A and B). If the risk-adjusted bid is lower than the risk-adjusted benchmark, a rebate of 75% of the difference is available to the plan to provide supplemental benefits (described above) or a reduction in the prescription drug, supplemental, or Part B premium.
- The determination of a plan's basic premium (if any) also involves a comparison of the bid to the benchmark. If the plan's unadjusted bid for Part A and B benefits is higher than the unadjusted benchmark, the plan's basic premium is the difference between the unadjusted bid and the unadjusted benchmark.
- Eligible individuals may choose to have plan premiums withheld from their Social Security check, through an electronic funds transfer mechanism, or other means the Secretary may specify including payment by an employer.
- With respect to payments to the plan,
    - If the bid is lower than the benchmark, the payment amount for Part A and B benefits is the portion of the 3-part bid for Medicare Part A and B benefits (subject to risk adjustment for individual enrollee demographic and health status factors) plus the rebate amount (except rebates related to the Part B premium).
    - If the bid is equal to or higher than the benchmark, the payment is the benchmark amount, also subject to risk adjustment. If the bid is higher than the benchmark, the plan must charge a basic premium (described above). If it charges a basic premium, the plan also receives an additional payment related to the plan's risk profile.
    - Payments to plans are also adjusted based on the variation in capitation rates among the different local areas included in the region or service area.
- The competitive bidding provisions do not apply to MSAs. MSAs will be paid under the methodology in effect before enactment of this statute, with payments based on MA benchmark amounts.
- The Secretary can decide when to implement bid-based payment for ESRD enrollees. Until that time, plans will be paid for their ESRD enrollees under the

methodology in effect before enactment of this Act. ESRD enrollees will pay the same premium and receive the same rebates provided to other plan enrollees.

- The Secretary may not require an MA organization to contract with any specific entity or individual nor can he or she require any particular price structure for payment by plans to entities or individuals.
- There will be a separate payment for MA-PD plans consisting of subsidies under 1860D-15.

Also under 1860D-15 there is a provision for risk corridors for prescription drug payment. Finally, payment will also be made for premium and cost-sharing reductions for low-income individuals under 1860D-14. (See discussion of Title I drug benefit for additional detail.)

- Premiums for Part A and B benefits (if any), prescription drug benefits, and supplemental benefits must be the same for all enrollees in a plan, except if an employer/union negotiates a different benefit package, in which case premiums for those retirees would be uniform.
- Repeals the ACR process for years after the 2005 contract year.
- Allows the Secretary to waive or modify provisions that hinder the design of, offering of, or enrollment in MA plans offered by employers, labor organizations or the trustees of funds established by employers or labor organizations.
- The Secretary may not approve a plan if he or she determines that the plan's design is likely to substantially discourage enrollment by certain eligible individuals.
- Revises funding for eligible individual education and information activities, authorizing $200 million beginning with fiscal year 2006.

Effective Date:

See Sec. 223 below.

Sec. 223. Effective Date; Issuance of Regulation

Current law:

- Not applicable.

Provision:

- Provisions of subtitle C (sections 221 and 222) are effective for plan years beginning on or after January 1, 2006.

- The Secretary is to revise regulations for Part C to carry out the provisions of this statute (no date specified).

Effective Date:

- See text on "Provision" above.

Subtitle D—Additional Reforms

Sec. 231. Specialized MA plans for Special Needs Individuals

Current law:

- MA plans may not limit enrollment to subgroups of the Medicare population. Rather, they must enroll any eligible individual if they are open for enrollment (which they must be at least once a year) and do not have a capacity waiver.

Provision:

- Establishes a MedicareAdvantage option for private plans that exclusively or disproportionately enroll "special needs" individuals. Two groups of special needs Medicare individuals are specified, the institutionalized and those who also have Medicaid coverage.
- The Secretary can also establish standards for other "special needs" groups, i.e., those with severe or disabling chronic conditions that would benefit from enrollment in a specialized MA plan. The Secretary may include ESRD eligible individuals as special needs individuals. (ESRD eligible individuals are otherwise prohibited from enrolling in an MA plan, but they may remain in a plan in which they were enrolled if they develop ESRD after enrollment).
- These Specialized MA plans will be paid on the same basis as other MA plans.
- This option is available for periods before January 1, 2009.
- Requires a report to Congress due December 31, 2007 on the quality of services and costs and savings under this option.

Effective Dates:

- In general, upon enactment (i.e., for the institutionalized and those with Medicaid coverage).
- A final regulation establishing requirements for special needs eligible individuals with severe or disabling chronic conditions is to be issued no later than 1 year after enactment.

Sec. 232. Avoiding Duplicative State Regulation

Current law:

- Preempts application to MA organizations of State law or regulations related to benefit requirements, requirements relating to inclusion or treatment by providers, coverage determinations (including related appeals and grievance processes), cost-sharing requirements, and requirements relating to marketing materials, summaries and schedules of benefits.

Provision:

- Expands federal preemption to all state laws and regulations except for licensure laws and laws related to plan solvency.

Effective Date:

- Upon enactment.

Sec. 233. Medicare MSAs

Current law:

- There was an M+C MSA demonstration, authorized by BBA. No plans ever joined the demonstration.

Provision:

- The MSA program becomes a permanent option, the capacity limit is removed, and the deadline for enrollment is eliminated. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of MA coordinated care plans.

Effective Date:

- Upon enactment.

Sec. 234. Extension of Reasonable Cost Contracts

Current law:

- Reasonable cost contracts cannot be extended or renewed after December 31, 2004.

Provision:

- Extends current law through December 31, 2007.
- Beginning January 2008, cost contracts cannot continue in any area that has at least 2 MA regional plans or at least 2 MA local plans that meet minimum enrollment requirements of at least 5,000 enrollees in most urban areas and at least 1,500 enrollees in other areas.

Effective Date:

- Upon enactment

Sec. 235. 2-Year Extension of Municipal Health Service Demonstration Projects

Current law:

- This demonstration has operated since 1978 in Baltimore, San Jose, Milwaukee, and Cincinnati. Participating clinics provide Medicare-covered primary and preventive care as well as non-covered services including prescription drugs, dental and vision care, and transportation. The demonstration was originally scheduled to end in 1984 but has been extended six times by Congress. Under the most recent extension (in BIPA 2000), the demonstration will end December 31, 2004. In BBA 1997, Congress limited participation in the demonstration to eligible individuals who were already enrolled and had received at least one project service between Jan. 1, 1996, and enactment of the BBA (August 5, 1997). The BBA also required the four sites to develop transition plans (which began in 2000) to phase?in cost?sharing for non?covered services, and provide counseling on managed care options available in the area.

Provision:

- The provision extends the MHSP demonstration through December 31, 2006.

Effective Date:

- Upon enactment.

Sec. 236. Payment by PACE Providers for Medicare and Medicaid Services Furnished by Non-Contract Providers

Current law:

- Programs of all-inclusive care for the elderly (PACE) provide to frail elderly eligible individuals of Medicare and/or Medicaid a comprehensive package of community-based services covered by both programs under a capitated payment system. PACE programs enter into contracts (specifying payments and other conditions) with various types of providers, physicians, and other entities to furnish this care. Sometimes, a PACE participant needs to use a non-contract provider, physician, or other entity, which can then charge the PACE program high amounts for that care. Such high charges make it more difficult for a PACE program to operate within its capitation payments.

Provision:

- Extends Medicare Advantage limits on balance billing to cover PACE programs. Medicare-participating providers, physicians, and other entities must accept these limits when they furnish Medicare-covered services to a

participant of a PACE program with which they do not have a contract or other agreement establishing payment amounts. Providers participating under a State Medicaid program must accept payments of no more than those they would receive under the State plan when they furnish services covered under Medicaid but not under Medicare to a participant of a PACE program with which they do not have a contract or other agreement establishing payment amounts.

Effective Date:

- Effective for services furnished on or after January 1, 2004.

Sec. 237. Reimbursement for Federally Qualified Health Centers Providing Services Under MA Plans

Current law:

- Ensures that payments are sufficient for patients enrolled in fee-for-service Medicare by providing cost-based reimbursement that is subject to an administrative cap for FQHCs. Current law also ensures that in both Medicaid fee-for-service and Medicaid managed care, FQHC payments are sufficient to cover the costs of caring for Medicaid patients.

Provision:

- Establishes a wrap-around payment in Medicare to make up for the shortfall between what a Medicare Advantage care plan pays an FQHC, and the reasonable cost payments the FQHC otherwise would receive under Medicare fee-for-service.
- Medicare Advantage plans must pay FQHCs the same levels and amounts they pay other providers for similar services.

Effective Date:

- Effective for services provided on or after January 1, 2006 and contract years beginning on or after January 1, 2006.

Sec. 238. Institute of Medicine Evaluation and Report on Health Care Performance Measures

Current law:

- None.

Provision:

- Requires the Secretary to enter into an arrangement under which the Institute of Medicine (IOM) and the National Academy of Sciences will conduct an evaluation of leading health care performance measures in the public and

private sectors and options to implement policies that align performance with payment under the Medicare program.

- IOM shall consult with MedPAC in conducting this evaluation and submit a report on the evaluation describing the findings and recommendations for an overall strategy and approach for aligning payment with performance, including options for updating performance measures in the original Medicare fee-for-service, Medicare Advantage, and any other programs under Title XVIII.

Effective Date:

- Effective not later than 18 months after enactment.

Subtitle E—Comparative Cost Adjustment (CCA) Program

Sec. 241. Comparative Cost Adjustment (CCA) Program

Current law:

- Current law does not require bids from private plans nor does it vary the Part B premium based on projected costs for eligible individuals in traditional fee-for-service Medicare or private plan bids.

Provision:

- Beginning in 2010, the comparative cost adjustment (CCA) program will be implemented in up to 6 Metropolitan Statistical Areas (MSAs) for 6 years. Eligible MSAs will have at least 2 local Medicare Advantage plans with at least 25% of area Medicare eligible individuals enrolled in such plans. (Eligible individuals in counties within a targeted MSA that lack at least 2 private plans would not be affected).
- Criteria for designating sites include requirements that at least one site will be from the largest 4 eligible MSAs (defined by total MA eligibles) and at least one site from the 4 eligible sites with the lowest population density. Preference is to be given to areas that are not in a PPO demonstration.
- The benchmark in CCA areas will be calculated using a formula that weights a fee-for-service (FFS) portion (based on the greater of the national or local enrollment percentage) and a local plan portion (based on 1.0 minus the FFS percentage). The portion for FFS beneficiaries is based on a projected fee-for-service amount for the area (with adjustments,

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including an adjustment for the demographics and health status of the FFS beneficiaries to reflect the average costs for a typical beneficiary in the CCA area). The local plan portion is based on the weighted average of bids for

plans in the area (with adjustments for plan service area and CCA area differences and the distribution of plan enrollees).

- Part B premiums for eligible individuals in CCA areas with incomes and assets above a specified level who remain in the FFS program would be adjusted, based on whether the FFS amount is more or less than the CCA benchmark amount.
    - If the FFS amount is more than the benchmark, the Part B premium would be increased by 100% of the difference, subject to the 5% limit described below.
    - If the FFS amount is less than the benchmark, the Part B premium would be reduced by 75% of the difference, also subject to the 5% limit described below.

      Any reduction or increase in the Part B premium (that results from the CCA program) for eligible individuals in the FFS Medicare program could not exceed 5% of the national Part B premium.
- Eligible individuals with incomes below 150% of poverty, and assets as under Title I, would not be subject to any Part B premium change as a result of the benchmark.
- For the MA local plans in the CCA program area, the CCA benchmark will be used rather than the benchmark established under Section 222. It is phased-in over a 4-year period.
- The program does not change the entitlement to defined benefits for all eligible individuals.
- Upon completion of the program, the Secretary will report to the Congress on the financial impact of the CCA program, beneficiary satisfaction, changes in access to physicians and other health care providers, and recommendations regarding extension or expansion of the CCA program.

Effective Date:

- Effective for plan years beginning in 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Sec. 301. Medicare Secondary Payor (MSP) Provisions

Current law:

- Generally, the law requires that Medicare be the secondary payer whenever another health plan, as defined under the Act, also provides coverage for the

beneficiary's services. In these cases, any payments made by Medicare are considered to be conditional and Medicare has a right to seek recovery.

- The amendments address three issues that have been the subject of recent and on-going litigation in cases in which Medicare has sought recovery of conditional payments. The first amendment, §301(a), makes clear that the interpretation of the conditional payment language popularized by the Fifth Circuit in Thompson v. Goetzmann, 315 F.3d 457, 467-469 (5th Cir. 2002), - in which the Court opined that Medicare cannot recover conditional payments if the primary plan would not have been expected to pay for services "promptly" - is incorrect.
- The second amendment, §301(b)(1), clarifies the term "self-insured plan," making clear that Medicare may recover conditional payments from monetary settlements made by tortfeasors when the settlement is not funded by an insurance policy.
- The third amendment, §301(B)(3), clarifies that CMS can recover payments from employers which have sponsored or contributed to an employee group health plan.

Provision:

- The amendment at §301(a) clarifies that conditional payments can be recovered because primary responsibility does not turn on whether a plan can pay "promptly." The amendment eliminates the word "promptly" from the operative section of the statute and adds language which makes it clear that any payment made by the Secretary when a plan is not expected to make payment promptly is conditioned upon reimbursement to the appropriate Trust fund.
- The second amendment at §301(b)(1) clarifies that a business, trade or professional entity is deemed to have a "self-insured plan" if it carries its own risk, whether by failing to obtain insurance or otherwise.
- The third amendment, §301(b)(3) adds language clarifying that the United States may bring an action against "all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) . . . ."

Effective Date:

- All §301(a) amendments are effective as of 1984 and all §301(b) amendments are effective as of 1980.

Sec. 302 Payment for Durable Medical Equipment; Competitive Acquisition of Certain Items and Services

Current law:

- The Balanced Budget Act of 1997 gave CMS the authority to conduct competitive bidding demonstrations for Medicare Part B items and services, excluding physician services. This authority expired on December 31, 2002.
- The competitive bidding demonstrations have been successful in reducing costs for the Medicare program. Bidding demonstrations were implemented in Polk County, Florida, and San Antonio, Texas. Savings differed by demonstration site, but averaged 20% in the latest bids at both sites, resulting in savings for both the program and eligible individuals. CMS maintained high quality of products and services throughout the demonstrations and protected beneficiary access to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items and services within the selected demonstration sites.
- Currently, DMEPOS items and services are paid according to the DMEPOS 2003 fee schedule.

Provision:

- This provision establishes a competitive bidding process for durable medical equipment (DME), enteral nutrition, and off-the-shelf orthotics (those requiring minimal adjustment) as a nationwide permanent part of Medicare by phasing-in the program as follows: in 10 of the largest metropolitan statistical areas in 2007; 80 of the largest metropolitan statistical areas in 2009; and additional areas after 2009. In areas where competitive acquisition is not conducted after 2009, the Secretary may either apply competitive bidding payment amounts (from areas where competitive bidding is conducted) or may set payment amounts through inherent reasonableness (IR) authority. Class III devices, as defined in the Food, Drug, and Cosmetic Act, that are categorized as DME, would be exempt from this provision. Inhalation drugs are not included under this provision.
- Clinical laboratory tests are included as a demonstration project but only for tests furnished without a face-to-face encounter between the patient and the entity furnishing the test (i.e., reference labs). The Secretary must submit an initial report to Congress on the demonstration project by December 31, 2005 and progress and final reports to Congress as appropriate. There is no initial start date for the demonstration.
- Establishes a freeze on payments for all durable medical equipment (DME), excluding Class III devices, from 2004 to 2008; however the freeze may end prior to 2008 as the freeze shall not apply in competitive acquisition areas after competitive bidding has been implemented in those areas. Payments for prosthetic devices, prosthetics, and orthotics are frozen from 2004 to 2006. GAO is required to report by March 1, 2006, (and the Secretary is required to take GAO's recommendations into account) on the appropriate payment update for Class III devices for 2007 and 2008.
- For 2005 and subsequent years, or until competitive bidding is implemented for each of these items, the Secretary will establish a payment amount for oxygen, oxygen equipment, standard

wheelchairs including standard power wheelchairs, nebulizers, diabetic supplies including lancets and test strips, hospital beds, and air mattresses by applying an update factor that is based on findings of the OIG on differences between Medicare and FEHP regarding payments.

- This section also requires the Secretary to establish and implement quality standards that independent accreditation organizations will apply to certain DME; prosthetic devices; orthotics; prosthetics; parenteral and enteral nutrients, equipment and supplies; medical supplies, home dialysis supplies and equipment; therapeutic shoes; electromyogram devices; salivation devices; blood products; and transfusion medicine, as the Secretary deems appropriate. Quality standards shall include consumer service standards.
- This section requires that an eligible individual receive a face-to-face examination and a written prescription from a physician or certain practitioners other than a physician before Medicare pays for a power wheelchair. In addition, this section requires the Secretary to establish standards for clinical conditions for payment for all DME. The standards shall specify the types of equipment that require a face-to-face examination as a condition for payment. In addition, the Secretary is directed to first establish standards for those DME items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation for payment.

Effective Date:

- Upon enactment.

Sec. 303. Payment Reform for Covered Outpatient Drugs and Biologicals

Current law:

- Currently, payments for covered drugs and biologicals are 95 percent of average wholesale price (AWP).
- Currently, Medicare makes separate payments to physicians for administration of drugs and biologicals. Changes in the relative values for such services are subject to the normal budget-neutrality requirement that applies to changes in RVUs under the physician fee schedule.

Provision:

- Most drugs and biologicals furnished during 2004 would be paid 85 percent of the April 1, 2003, AWP, except for specified drugs for which an alternative percent of not less than 80 percent is substituted for 85 percent. The drugs for which an alternative percent would be substituted are those identified in table 3 of the NPRM (68 Fed. Reg. 50,445 (Aug. 20, 2003)) and are based on an average of the percent of the AWP at which the drugs and biologicals are widely available in the market based on IG and GAO studies. The percent would also be different where manufacturers had submitted data to the

Secretary by the close of the comment period on the NPRM (i.e., by October 15, 2003) that an alternative percent reflect the market price.

- The following drugs and biologicals would be paid 95 percent of AWP during 2004 and in some cases after 2004: vaccines furnished on or after January 1, 2004; blood clotting factors furnished during 2004; new drugs furnished during 2004 which were not available for payment as of April 1, 2003; drugs and biologicals furnished in connection with the furnishing of renal dialysis service if separately billed by renal dialysis facilities during 2004 and 2005.
- Infusion drugs furnished through an item of covered durable medical equipment would be paid at 95 percent of the October 1, 2003 AWP until such drugs were under the competitive bidding system for durable medical equipment. Blood and blood products would continue to be paid in the same manner as such payment amount was determined on October 1, 2003.
- Beginning with 2005, payment would be based on 106 percent of the average sales price for drugs and biologicals. In order to have payment made under both Medicare and Medicaid, a manufacturer would have to submit quarterly information on the manufacturer's average sales price (MASP) and the total number of units, wholesale acquisition cost, if required to make payment, and nominal sales price. Such data are subject to audit by the HHS Inspector General. The Secretary takes the MASPs and determines the average sales price (ASP) using a method specified in statute for single and multiple source drugs. The manufacturer's average sales price includes sales to all purchasers other than sales exempt from best price (as such term is used by Medicaid) and sales at nominal charges. Such price is net of volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under section 1927).
- Requires the IG to conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals. Requires the IG to compare the ASP to the widely available market price and to the average manufacturer's price (AMP). If the ASP exceeds 105 percent of the widely available market price or the AMP (in 2005 and a percent specified by the Secretary in 2006 and thereafter) , the IG is required to inform the Secretary and the Secretary is required to substitute for the ASP, the lesser of the widely available market price or 103 percent of the AMP. The Secretary may apply civil money penalties if the manufacturer made a misrepresentation in the reporting of the average sales price. Several elements of the ASP payment system are exempt from judicial and administrative review. The Secretary is required to conduct a study on sales of drugs and biologicals to large volume purchasers such as pharmacy benefit managers and health maintenance organizations for purposes of determining whether the price at

which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to physicians. A report to Congress on such study is required by January 1, 2006.

- Requires the Secretary to establish and implement a competitive acquisition program where physicians are given the opportunity annually to make a choice to have drugs and biologicals furnished to them by competitively selected contractors upon submission of a prescription for a particular eligible individual. The program begins on January 1, 2006. The competitively selected contractors would collect applicable deductibles and coinsurance. Medicare payment would only be made for drugs and biologicals actually administered to an eligible

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individual, not to those dispensed to a physician. The Secretary could not award a contract to a competitive contractor unless the contractor had sufficient arrangements to acquire and deliver the drugs and biologicals and meet certain quality, service, financial performance and solvency standards. Multiple contractors would be selected for an area. Contracts would apply for 3 years. The Secretary would be required to conduct the competition for a single drug within a multiple source HCPCS code.

- In order to maintain the integrity of the drug and biological distribution system, contractors would be required to acquire all drug and biological products they distribute directly from the manufacturer or from a distributor that has acquired the products directly from a manufacturer and comply with any product integrity safeguards determined to be appropriate by the Secretary. Contractors would be required to comply with a code of conduct specified by the Secretary that includes standards relating to conflicts of interest and comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the HHS IG. Contractors would be required to furnish drugs and biologicals only to physicians and not to eligible individuals. The Secretary is required to establish rules whereby drugs and biologicals acquired through a contractor may be used to resupply inventories of such drugs and biologicals if they are required immediately, the physician could not have obtained them from the contractor and they were administered in an emergency situation.
- Contractors are required to disclose to the Secretary not more often than quarterly their net acquisition costs. The Secretary is required to make appropriate price adjustments to reflect significant increases or decreases in a contractor's reasonable net acquisition costs.
- Several elements of the bidding process are specified. Costs of delivery and dispensing are to be included in the bid but costs related to administration, wastage, spillage and spoilage are not to be included. The Secretary is

required to determine a single payment amount for each drugs and biologicals based on the bids submitted. The contractor would collect applicable coinsurance and deductibles. Several features of the competitive contractor system are exempt from judicial and administrative review. The Secretary is required to submit a report to Congress by July 1, 2008 on the competitive contractor program.

- The Secretary is required, beginning with January 1, 2005, to establish a separate payment amount for furnishing blood clotting factors. In establishing such fee, the Secretary is authorized to take into account the mixing (if appropriate) and delivery of clotting factors to an eligible individual, including special inventory management and storage requirements, and ancillary supplies and patient training necessary for the self-administration of clotting factors. The Secretary is required to establish a pharmacy supplying fee in the case of oral immunosuppressive drugs, oral cancer and oral anti-emetic drugs furnished by a retail pharmacy. The current payment methodology for radiopharmaceuticals is continued.
- Requires changes in the data and methodology used to determine practice expense RVUs for drug administration services beginning with 2004. Requires use of survey data on practice expenses to the Secretary by oncologists. Requires use of data on compensation of clinical nurses from the oncologist survey in the methodology for determining practice expense

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RVUs for drug administration services. Requires adding to drug administration services work relative value units equal to the work RVUs for the lowest level office visit. Also requires the Secretary to review and modify policy regarding payment for each administration of multiple chemotherapeutic agents in a single day to a single patient. All these changes are exempt from the normal budget-neutrality requirement that applies for adjustments to relative value units under the Medicare physician fee schedule.

- As a transition, requires payments for drug administration services to be increased by an additional 32 percent in 2004 and 3 percent in 2005.
- Requires the Secretary to further adjust RVUs for 2005 and 2006, without application of the budget-neutrality requirement, based on timely submission of surveys by other specialties as long as 40 percent of the specialty's Medicare revenues are from drug administration services. Any changes would be exempt from the budget-neutrality requirement.
- Requires the Secretary to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for such services taking into account levels of complexity of the administration and resource consumption. Requires the Secretary to use existing processes for consideration of coding changes and changes in RVUs. Requires consultation with relevant physician specialties. Any resulting changes in RVUs would be exempt from the budget-neutrality requirement.

- Requires the Secretary to make adjustments of the non-physician work pool methodology so that services whose practice expense RVUs are determined by such methodology are not affected relative to services whose practice expense RVUs are determined by the basic practice expense RVU method.
- Requires MedPAC to review the changes made under this section with respect to drug administration and submit reports on the changes to payment for items and services furnished by oncologists and those furnished by other specialties. The former is due by January 1, 2006 and the latter by January 1, 2007. The Secretary may use the reports= conclusions as a basis for adjustments in payment rates for items and services furnished by oncologists.
- For drugs and biologicals and drug administration services furnished by physicians, the provisions apply to physicians in the specialties of medical oncology, hematology and hematology/oncology.

Effective Date:

- Drugs and biologicals furnished beginning January 1, 2004.

Sec. 304. Extension of Application of Payment Reforms for Covered Outpatient Drugs and Biologicals to Other Physician Specialties

Current Law:

- Medicare pays for certain covered outpatient drugs and biologicals furnished by physicians in all physician specialties.

Provision:

- Eliminates the limitation, applied in section 303 of the Act, so that the payment provisions of section 303 apply to physicians of all specialties.

Effective Date:

- January 1, 2004.

Sec. 305. Payment for Inhalation Drugs

Current law:

- Inhalation drugs furnished through covered durable medical equipment are paid for at 95 percent of AWP. GAO is not required to conduct a study of inhalation therapy.

Provision:

- Requires payment for inhalation drugs furnished during 2004 at 80 percent of the April 1, 2003 AWP. Beginning with 2005, sets payment for inhalation drugs at ASP plus 6 percent. Requires GAO to conduct a study to examine the adequacy of current reimbursements for inhalation therapy.

Effective Dates:

- Drugs and biologicals furnished beginning with 2004.
- The GAO report is due 1 year from enactment.

Sec. 306. Demonstration Project for Use of Recovery Audit Contractors

Current law:

- Current law does not require the use of recovery audit contractors. However, CMS has conducted a limited demonstration project using such contractors. Two companies participated in the demonstration project. They conducted credit balance audits and were paid a capped maximum contingency fee.

Provision:

- The Secretary shall conduct a demonstration of recovery audit contractors in at least 2 states for not longer than 3 years to identify under or overpayments and collect the overpayments. The Secretary shall determine the percentage of recovered funds to be retained in the CMS program management account. The contractor will retain the remainder.

Effective Date:

- Upon enactment

Sec. 307. Pilot Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities or Providers

Current law:

- There is no Federal requirement to conduct background checks on long-term care workers. Some states mandate background checks through state law.

Provision:

- This provision would authorize $25 million in funds from the Treasury for a 3-year pilot program for national and state background checks on employees of long-term care facilities or providers. No more than 10 states would be selected for the pilot. The Secretary of the Department of Health & Human Services, in consultation with the Attorney General, would evaluate the pilot.
- The pilot program would identify efficient, effective and economical processes for long term care facilities or providers to conduct background checks on employees with direct access to residents and patients. The pilot would only apply to long-term care facilities and providers that participate in the Medicare and/or Medicaid programs. The facilities and providers included in the pilot are: nursing homes; home health agencies, providers of hospice care, providers of personal care services, residential long-term care

providers; and intermediate care facilities for the mentally retarded. Pilot states may expand the program, during the first year of the pilot, to other long-term care providers, as they deem appropriate. Self-directed care arrangements are excluded from the pilot.

- States would develop procedures for conducting the background checks. These procedures should include certain elements. Facilities and providers would notify potential employees of the requirement to conduct a background check, obtain their authorization to conduct the check, and collect information such as a statement disclosing any disqualifying information and a rolled set of fingerprints. Then, facilities and providers would start the background check process by checking available registries such as the Federal Healthcare Integrity Practitioner Data Bank (HIPDB) and the state Nurse Aide Registry. If no disqualifying information were found through these checks, then the facility or provider would request the state to conduct state and national level checks (FBI records).
- Disqualifying information would be information about a conviction for a relevant crime or a finding of abuse, neglect or misappropriation of resident or patient property. A conviction for a relevant crime includes crimes that would be reported to the HIPDB (i.e., health care fraud, felony relating to controlled substances), and other offenses as defined by the pilot states. At any point in the background check process, if disqualifying information were found, the process would stop, and the employee would be discharged. A long-term care facility or provider may not knowingly employ any direct patient access employee who has any disqualifying information.
- Participating states may permit long-term care facilities or providers to provide for a period of provisional employment while a new employee is undergoing a background check. During that period, the facility or provider would provide supervision of the provisional employee. In determining the appropriate level of supervision, participating states must take into account costs or burdens that would be imposed on small rural long-term care facilities or providers, as well as the nature of care delivered by such providers that are home health agencies or providers of hospice care.
- The provision outlines certain selection criteria for the pilot states, such as: geographic diversity; the inclusion of a variety of long-term care facilities or providers; evaluation of a

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variety of payment mechanisms for covering the costs of the background checks; and the evaluation of a variety of penalties used by participating states to enforce the requirements. In addition, the Secretary shall, to the greatest extent practicable, select at least: one state that provides for a period of provisional employment and one state that does not; one state that establishes procedures under which employment agencies may contact the state directly to conduct background checks on prospective direct patient access employees; and one state that includes patient abuse prevention

training for managers and employees of long-term care facilities and providers as part of its pilot.

- The evaluation would cover a number of topics, including: the procedures implemented by pilot states to conduct the checks; the costs and how they should be allocated across Medicare, Medicaid, providers and workers; the effectiveness of checks conducted by employment agencies; and the extent to which the checks lead to any unintended consequences such as a reduction in the available workforce.

Effective Date:

- October 1, 2003

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

Sec. 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 care 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. Public Law 108-7 and 108-89 provided that between April 1, 2003 and March 31, 2004, all hospitals would be paid on the basis of the large urban standardized amount.
- Under Medicare's hospital inpatient prospective payment system (PPS), in Puerto Rico, separate standardized amounts were also used for hospitals located in large urban areas and hospitals located in other areas.

Provision:

- This provision would permanently equalize urban and rural hospital standardized amounts under the hospital inpatient PPS as of April 1, 2004 (payments have already been equalized from April 1, 2003 to March 31, 2004).
- For hospitals in Puerto Rico, for discharges beginning in FY 2004 (allowing CMS to adjust systems in April 1, 2004), the standardized amount in Puerto Rico shall equal the standardized amount for urban hospitals, updated in each year.

Effective Date:

- October 1, 2003 (CMS has already equalized the standardized amounts through April 1, 2004. For Puerto Rico hospitals, CMS can make prospective adjustments as of April 1, 2004).

Sec. 402. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds

Current law:

- Disproportionate share payment adjustment percentages can vary among hospitals based upon the particular hospital's location, bed size, designation as a rural referral center or sole community hospital, and disproportionate patient percentage. The statutory disproportionate share adjustment percentages for rural and small urban hospitals cannot exceed 5.25 % and typically result in substantially lower DSH payments to those hospitals than to large urban hospitals.

Provision:

- For discharges occurring on or after April 1, 2004, for rural hospitals (including rural referral centers and sole community hospitals) and small urban hospitals, the provision substitutes the disproportionate share payment adjustment percentage applicable to large urban hospitals for

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the otherwise applicable percentages, and, except for hospitals classified as rural referral centers, caps the DSH adjustment percentage at 12%.

- The new DSH adjustment is not applicable to Pickle Hospitals (as defined at §1886(d)(5)(F)(i)(II) of the Social Security Act.

Effective Date:

- April 1, 2004

Sec. 403. Adjustment to the Medicare Inpatient Hospital Prospective Payment System Wage Index to Revise the Labor-Related Share of Such Index

Current law:

- Hospital inpatient PPS payments are adjusted by the hospital wage index of the area where the hospital is located or the area in which it is classified. Presently, 71% of the standardized amount is adjusted by the area wage index. This represents the "labor-related share" of the standardized amount.

Provision:

- Beginning October 1, 2004, 62% of the standardized amount will be adjusted by the area wage index. This reduction is applicable only if such change would result in higher total payments to the hospital.

Effective Date:

- October 1, 2004

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

Current law:

- Hospital inpatient PPS standardized amounts are increased annually using an update factor that is determined in part by the projected increase in the hospital market basket (the factor used to estimate the change in the price of goods and services used to furnish inpatient hospital care). Currently, CMS revises the category weights, reevaluates the price priorities for such categories and rebases the market basket once every 5 years.

Provision:

- Requires the Secretary to establish a frequency for revising the weights used in the hospital market basket more frequently than once every 5 years. The Secretary will publish the reasons for the frequency established in the final payment rule for inpatient hospital services for FY 2006.

Effective Date:

- October 1, 2005

Sec. 405. Improvements to Critical Access Hospital Program

Increase in Payment Amounts

Current law:

- Payment to Critical Access Hospitals (CAHs) for inpatient CAH, outpatient CAH, and covered skilled nursing facility services furnished in a CAH are paid at 100% of reasonable costs.

Provision:

- This provision increases the CAH payment amount to 101% of reasonable costs.

Effective Date:

- For cost reporting periods beginning on or after January 1, 2004.

Coverage of Costs for Certain Emergency Room On-Call Providers

Current law:

- The Benefits Improvement and Protection Act of 2000 (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.

Provision:

- The provision expands on-call payments to physician-assistants, nurse practitioners, and clinical nurse specialists.

Effective Date:

- For services furnished on or after January 1, 2005.

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. A CAH is not eligible for PIP payments.

Provision:

- This provision authorizes periodic interim payments for inpatient CAH services and requires the Secretary to develop alternative timing methods for PIP.

Effective Date:

- Payments made on or after July 1, 2004.

Condition for Application of Special Professional Service Payment Adjustment

Current law:

- CAHs can elect to be paid for their outpatient CAH services at a rate equal to the sum of its facility fee paid on a reasonable cost basis and at 115% of the fee schedule for professional services otherwise included within outpatient critical access hospital services- the "Method 2" billing option.

Provision:

- Prohibits CMS from requiring that all physicians providing services in a CAH assign their billing rights to the CAH as a condition for electing the "Method 2" billing option.

Effective Dates:

- For CAHs that made an election before November 1, 2003, the provision is effective for cost reporting periods beginning on or after July 1, 2001. For CAHs that make an election after November 1, 2003, the provision is effective for cost reporting periods beginning on or after July 1, 2004.

Revision of Bed Limitation for Hospitals

Current law:

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

Provision:

- Allows CAHs to operate up to 25 beds as either acute care or swing beds.

Effective Date:

- January 1, 2004, but any implementing regulations shall only apply prospectively.

Provisions Relating to FLEX 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. Funding for the Rural Hospital Flexibility Grant Program was $25 million in each of fiscal years 1998 through 2002. Authorization to award grants expired in FY 2002.

Provision:

- Authorizes existing FLEX grant funding for all States of $35,000,000 in each of fiscal years 2005 through 2008.

Effective Date:

- October 1, 2004.

Authority to Establish Psychiatric and Rehabilitation Distinct Part Units

Current law:

- Beds in distinct-part skilled nursing facility units do not count toward the CAH bed limit. Beds in distinct-part psychiatric or rehabilitation units operated by an entity seeking to become a CAH count toward the bed limit.

Provision:

- Allows CAHs to establish psychiatric and rehabilitation distinct part units. However, such distinct part units must meet the requirements (including

conditions of participation) that would apply if they were established in an acute care hospital. Beds in these distinct part units are excluded from the bed count. Services provided in these distinct part units will be under the applicable payment system for those units.

Effective Date:

- For cost reporting periods beginning on or after October 1, 2004.

Waiver Authority

Current law:

- To be designated a critical access hospital, a facility must meet one of the following criteria: (1) be located in a county or equivalent unit of a local government in a rural area, (2) be located more than a 35-mile drive from a hospital or another facility, or (3) be certified by the State as being a necessary provider of health care services to residents in the area.

Provision:

- This provision allows the State to continue to certify facilities as necessary providers in order for them to be designated as critical access hospitals until January 1, 2006.

Effective Date:

- Upon enactment.

Sec. 406. Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals

Current law:

- There is no current designation for hospitals to be "low volume hospitals." Medicare pays for inpatient hospital services without regard for the number of eligible individuals discharged from any hospital.

Provision:

- Beginning with FY 2005, the Secretary would calculate an additional payment as appropriate to be made to low volume hospitals. Low volume hospitals are defined as hospitals that have less than 800 discharges during the fiscal year and are located more than 25 road miles from another acute care hospital. The additional percentage increase (which is capped at 25%) would be based on the relationship, as determined by the Secretary, between the standardized cost-per-case and the number of discharges for acute inpatient hospitals.

Effective Date:

- October 1, 2004

Sec. 407. Treatment of Missing Cost Reporting Periods for Sole Community Hospitals

Current law:

- Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole

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source of inpatient services reasonably available in a geographic area, or are located more than 34 road miles from another hospital. A SCH receives the higher of the following payment rates: the current hospital inpatient PPS base payment rate, or its hospital-specific per discharge costs from either FY1982, 1987 or 1996 updated to the current year. The FY1996 base year option will be fully implemented beginning FY2004.

Provision:

- Prohibits CMS from denying a SCH application based on unavailable cost report data due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, as long as data are available for at least one base cost reporting period.

Effective Date:

- For cost reporting periods beginning on or after January 1, 2004.

Sec. 408. Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients

Current law:

- Currently only a doctor of medicine or osteopathy (MD or DO) can serve as the attending physician for an eligible individual who elects hospice.

Provision:

- Allows a nurse practitioner to serve as the attending physician for a patient who elects the hospice benefit. The nurse practitioner acting as the attending would be prohibited from certifying the terminal diagnosis.

Effective Date:

- Upon enactment

Sec. 409. Rural Hospice Demonstration Project

Current law:

- Hospice care is generally provided in a patient's home. Under current law, the aggregate number of inpatient care days provided to hospice eligible individuals in a 12-month period is limited to 20 percent of total days of hospice care.

Provision:

- Establishes a demonstration project to test delivery of hospice care in rural areas under which Medicare eligible individuals without a caregiver at home may receive care in a facility of 20 or fewer beds. Such facility will not have to offer hospice services in the community or comply with the 20 percent limit on inpatient days.

Effective Date:

- Upon enactment.

Sec. 410. Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities

Current law:

- Certain services are specifically excluded from the SNF prospective payment system (PPS), including physician services; physician services provided by nurse practitioners (NP), physician assistants (PA) and clinical nurse specialists; certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist. Rural health clinic (RHC) services include physicians, NP/PAs, clinical psychologists and clinical social workers. Federally qualified health centers (FQHC) provide the same services as RHCs, in addition to preventive primary health services, when furnished to an individual as an outpatient.

Provision:

- Clarifies that certain services provided by individuals affiliated with RHCs and FQHCs are excluded from the SNF PPS, in the same manner as they would be excluded if provided by an individual who is not affiliated with RHCs or FQHCs.

Effective Date:

- For services furnished on or after January 1, 2005.

Sec. 410A. Rural Community Hospital Demonstration Program

Current law:

- No provision.

Provision:

- The provision establishes a 5-year demonstration program to test the advisability and feasibility of establishing rural community hospitals (RCHs). A RCH is a hospital located in a rural area (or reclassified as such), with fewer than 51 acute care beds, is not currently designated or eligible for designation

as a critical access hospital, and that makes available 24-hour emergency care services. Distinct part psychiatric and rehabilitation beds do not count toward the bed limit.

Effective Date:

- Implementation is not to occur later than January 1, 2005, but the demonstration program may not be implemented before October 1, 2004.

Subtitle B—Provisions Relating to Part B Only

Sec. 411. 2-year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services

Current law:

- The PPS for services provided by hospital outpatient departments (OPD) was implemented in August 2000. Under the hold-harmless provision, rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have been paid under the prior

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reimbursement system for covered OPD services provided before January 1, 2004.

Provision:

- The hold harmless provisions governing OPD reimbursement for hospital outpatient services performed at small rural hospitals would be extended for 2 years under the hospital outpatient prospective payment system beginning with cost reporting periods on or after January 1, 2004. Section 411 also provides hold harmless protections to sole community hospitals located in a rural area are for 2 years beginning with cost reporting periods on or after January 1, 2004. The Secretary must further increase payments to these hospitals by January 1, 2006 if, under a study mandated by this section, the Secretary finds rural costs of providing outpatient services is greater than urban costs.

Effective Dates:

- Hold harmless extension begins with cost reporting periods on and after January 1, 2004.
- Payment increases by January 1, 2006, if necessary, based on results of the study.

Sec. 412. Establishment of Floor on Work Geographic Adjustment

Current law:

- The Secretary is required to establish a separate geographic adjustment factor for each of the three relative value components of each physician's service that measures the relative costs of physician work, practice expense and malpractice in one area compared to the national average. Only one-quarter of the work component has a geographic adjustment and three-quarters is the same in all areas of the country.

Provision:

- Requires the Secretary to raise the work geographic index to 1.0 in any physician payment locality where the index is less than 1.0 for 2004, 2005 and 2006.

Effective Date:

- Services furnished during 2004, 2005 and 2006.

Sec. 413. Medicare Incentive Payment Program Improvements for Physician Scarcity

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.

Provision:

- This provision sets up a new 5% incentive payment program designed for primary and specialty physicians in areas that have few physicians available. The provision requires that counties be identified based separately on the ratio of primary care physicians to Medicare eligible individuals residing in the county, and on the ratio of specialist care physicians to Medicare eligible individuals residing in the county. As with the current HPSA bonus program, the 5% bonus would be added to the amount that Medicare pays after deducting beneficiary cost sharing so that eligible individuals did not pay cost sharing on the incentive

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payment. The provision requires, to the extent feasible, counting a rural census tract of a metropolitan statistical area, commonly known as Goldsmith Modification areas, as a scarcity area. Effective for services furnished on or after January 1, 2005 and before January 1, 2008.

- The provision also requires the Secretary to pay the current law 10 percent HPSA incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify that the services were furnished in such area. In addition, the provision requires the Secretary to develop a user-friendly web site page for

physicians to obtain information on partial county HPSAs and facilitate reporting of the modifier to identify the applicability of the incentive payment. The provision requires that before the beginning of a calendar year the Secretary identify the HPSAs for which the incentive payments will be made for such calendar year. Effective January 1, 2005.

- The provision calls for a GAO study of differences in payment amounts under the physician fee schedule for physicians' services in different geographic areas. The study is to include an assessment of the validity of the geographic adjustment factors, an evaluation of measures used for adjustment, an evaluation of methods used to determine professional liability insurance costs used in computing the malpractice component, and an evaluation of the effect of the adjustment to the physician work geographic index with respect to physician location and retention in areas affected by such an adjustment. A final report is to be submitted to Congress with recommendations no later than 1 year after enactment.

Effective Dates:

- Physician Scarcity Incentive Payment services furnished on or after January 1, 2005, and before January 1, 2008; HPSA Incentive Payment: January 1, 2005; Report of study to Congress no later than 1 year after enactment.

Sec. 414. Payment for Rural and Urban Ambulance Services

Current law:

- Historically, ambulance payment was based on "reasonable charges" (for independent suppliers) or "reasonable cost" (for hospital-based entities). BBA 1997 required the Secretary to develop (through negotiated rulemaking) a national fee schedule for ambulance services, to replace these prior methodologies. Phased-in implementation of the fee schedule began April 1, 2002, with 100 percent fee schedule payment to begin in 2006. During the transition period, payment is based on a blend of a provider's or supplier's old methodology and the fee schedule rates, with a gradually decreasing portion based on the prior payment methods. The fee schedule amount includes a geographically adjusted base rate (for each level of ambulance service) plus a mileage payment (with an extra 50 percent added to the first 17 miles for ground transports originating in a rural area, and to total payment for rural air transports). The BBA stipulated that aggregate payment during the fee schedule's first year could not exceed the aggregate payment that would have been made under the former methodologies.

Provision:

- This provision establishes an alternate fee schedule phase-in formula for certain providers and suppliers, in which the fee schedule portion of the blended rate is based on a specified blend of a regional fee schedule and the

regular (national) fee schedule. To establish the regional fee schedules, CMS will calculate rates for each level of ground ambulance service for each of nine census regions, using the same methodology as used to calculate the original fee schedule. If the alternate phase-in formula for a region would result in higher payment, then all providers and suppliers in that region would be paid under that formula (and their phase-in would last four additional years, through 2010).

- The provision increases mileage payments for ground ambulance trips over 50 miles by one-quarter of the payment per mile otherwise applicable to the trip, through 2008.
- The provision directs the Secretary to provide a percentage increase in the base payment rate for ambulance trips that originate in a rural area with a population density in the lowest quartile of all rural county populations, through 2009. To establish the percentage increase, the Secretary will estimate the average cost per trip (not including mileage) in the lowest quartile as compared to the average cost in the highest quartile of all rural county populations.
- The provision increases payment by 2 percent for rural ground ambulance services, and by 1 percent for non-rural ground ambulance services, through 2006. Such increases will not be taken into account in calculating payments in subsequent years.
- The provision requires a GAO report on how costs differ among different types of ambulance providers, and on accessibility, supply, and quality of ambulance services in areas in which payment is reduced under the ambulance fee schedule.

Effective Dates:

- Ambulance fee schedule provisions: July 1, 2004.
- Initial GAO report is due December 31, 2005; final report is due December 31, 2007.

Sec. 415. Providing Appropriate Coverage of Rural Air Ambulance Services

Current law:

- Medicare covers ambulance services only when other forms of transportation are medically contraindicated. Payment may be made for an air ambulance (either fixed wing or helicopter) when transport by ground is infeasible or would pose a risk to the patient's health. Claims for air ambulance services that are not found to meet these standards may be denied or downgraded to the ground ambulance payment rate.

Provision:

- This provision requires regulations to provide that, if any ambulance service would be covered by Medicare, a rural air ambulance service will be reimbursed at the air ambulance rate if the service (1) is reasonable and necessary based on the patient's condition at or immediately prior to transport, and (2) meets equipment and crew requirements established

by the Secretary. A rural air ambulance service is deemed medically necessary when (1) requested by a physician or other qualified person (as specified by the Secretary) who reasonably determines that land transport would threaten the patient's survival or health, or (2) furnished pursuant to a State or regional EMS agency protocol recognized by the Secretary under which use of an air ambulance is recommended (unless such agency has an ownership interest in the entity furnishing the service).

- In most cases, the presumption of medical necessity does not apply if there is a financial or employment relationship between the person requesting the air ambulance (or an immediate family member of such person) and the entity furnishing the service, or an entity under common ownership with the entity furnishing the service.

Effective Date:

- January 1, 2005.

Sec. 416. Treatment of Certain Clinical Diagnostic Laboratory Tests Furnished to Hospital Outpatients in Certain Rural Areas

Current law:

- Generally, hospitals that provide clinical diagnostic laboratory tests under Medicare Part B are reimbursed using a fee schedule. However, tests furnished by critical access hospitals as part of their outpatient services are exempted from the fee schedule and paid "reasonable cost". Medicare pays 100 percent of the fee schedule rate or cost reimbursement for clinical laboratory tests, with no beneficiary cost sharing.

Provision:

- This provision requires reasonable cost reimbursement of Medicare Part B covered clinical diagnostic laboratory tests furnished by certain rural hospitals with fewer than 50 beds as part of outpatient services of the hospital, for a two-year period. Qualifying hospitals are located in a rural area with a population density in the lowest quartile of all rural county populations.

Effective Date:

- The date on or after July 1, 2004 upon which a new cost reporting period begins.

Sec. 417. Extension of Telemedicine Demonstration Project

Current law:

- The Balanced Budget Act of 1997 (BBA) established a 4-year demonstration project where an eligible health care provider telemedicine network would use high-capacity computer systems and medical informatics to improve primary

care and prevent health complications in Medicare eligible individuals with diabetes mellitus.

Provision:

- This provision extends the current telemedicine demonstration project by 4 additional years, and authorizes an additional $30 million in funding.

Effective Date:

- October 1, 2004.

Sec. 418. Report on Demonstration Project Permitting Skilled Nursing Facilities to be Originating Telehealth Sites; Authority to Implement

Current law:

- Under current law, the list of originating telehealth sites is limited to the following sites: the office of a physician or practitioner, a critical access hospital, a rural health clinic, a Federally Qualified Health Center, and a hospital.

Provision:

- Requires the Health Resources and Services Administration (HRSA) to conduct its evaluation in consultation with CMS, and includes authority for the Secretary to deem a SNF to be included in the list of permissible originating telehealth sites beginning on January 1, 2006.

Effective Date:

- Report to Congress is required to be submitted no later than January 1, 2005.

Subtitle C—Provisions Relating to Parts A and B

Sec. 421. 1-Year Increase for Home Health Services Furnished in a Rural Area

Current law:

- There is currently no adjustment increase in payments for home health services provided in rural areas. BIPA 2000 established a temporary 10 percent increase in home health payments for home health services furnished in rural areas. This temporary increase expired on April 1, 2003.

Provision:

- Increases payments to home health agencies for services provided in a rural area by 5 percent for one year, beginning April 1, 2004. Standard home health prospective payment amounts will not be reduced to offset this increase.

Effective Date:

- For episodes and visits ending on or after April 1, 2004 and before April 1, 2005.

Sec. 422. Redistribution of Unused Resident Positions

Current law:

- Currently any resident slots that are within the FTE cap but not filled by a hospital, remain available to that hospital to be filled at a later date.

Provision:

- Redistributes resident positions from hospitals that have not met their resident FTE cap for the most recently settled or submitted (subject to audit) cost reporting period (with certain exceptions).
- Resident slots available for redistribution are based on the difference between the hospitals otherwise applicable FTE cap (termed the "otherwise applicable resident limit") and the number of resident slots filled in the most recently settled or submitted cost reporting period (the "reference resident level"). Additionally, there are two exceptions regarding expansions of existing programs or previously approved new residency programs that may apply to the calculation of the "reference resident level".
- Resident positions that are available for redistribution would be returned to HHS. These unused residency positions would be distributed by the Secretary based on location, with priority given to rural hospitals, then to small urban hospitals, and then to hospitals that are the only one with that particular residency training program in the state. Additionally the Secretary must take into consideration whether the hospital is likely to fill such positions with the first three cost reporting periods after the distribution is made.
- No hospital would be allowed more than 25 new FTEs.

Effective Date:

- July 1, 2005

Subtitle D—Other Provisions

Sec. 431. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations

Current law:

- Section 1128B(b)(3) of the Social Security Act provides safe harbors to the anti-kickback statute, which prohibits kickbacks involving federal health care programs.

Provision:

- Creates a new safe harbor to the anti-kickback statute for certain agreements with federally qualified health centers (FQHCs). Under the new safe harbor, the prohibition against kickbacks does not apply to remuneration under a contract, lease, grant, loan, or other agreement between certain FQHCs and any individual or entity providing items, services, donations, or loans to the FQHC if the arrangement would contribute to the FQHC's ability to maintain or increase the availability or quality of services provided to a medically underserved population.
- The Secretary is required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) results in savings of Federal grant funds or increased revenues to the health center; (2) expands or limits a patient's freedom of choice; and (3) protects a health care professional's independent medical judgment regarding

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the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception.

Effective Date:

- Upon enactment. The Secretary would be required to publish a final regulation establishing these standards no later than 1 year from the date of enactment.

Sec. 432. Office of Rural Health Policy Improvement

Current law:

- The Office of Rural Health Policy (ORHP) advises the Secretary on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in the Medicare and Medicaid programs on the financial viability of small rural hospitals, the ability of rural areas to attract and retain physicians and other health professionals, and access to and the quality of health care in rural areas. In addition to advising the Secretary, the Office has other responsibilities including coordinating the activities within HHS that relate to rural health care.

Provision:

- This provision expands the list of explicit responsibilities of the Office to include administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.

Effective Date:

- Upon enactment.

Sec. 433. MedPAC Study on Rural Hospital Payment Adjustments

Current law:

- None.

Provision:

- This provision directs the Medicare Payment Advisory Commission (MedPAC) to conduct a study analyzing the effect on total payments, growth in costs, capital spending, and such other payment effects of certain rural sections of the bill. The sections of the bill MedPAC is directed to study include the following: equalizing the urban and rural standardized amount (Sec. 401); establishing enhanced DSH payments for hospitals with fewer than 100 beds (Sec. 402); adjusting the labor-related share of the hospital wage index (Sec. 403); more frequently updating the weights used in the hospital market basket (Sec. 404); making improvements to the critical access hospital (CAH) program (Sec. 405); adding an adjustment for low-volume hospitals (Sec. 406); providing a 2-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services (Sec. 411); establishing cost-based reimbursement for certain clinical diagnostic laboratory tests to hospital outpatients in certain rural areas (Sec. 416), and creating an out-bound commuting wage adjustment reclassification for hospitals (Sec. 505).

Effective Date:

- Interim report with respect to changes to the critical access hospital provisions under section 405 is due no later than 18 months after enactment; final report on all matters studied under this section is due no more than 3 years after enactment.

Sec. 434. Frontier Extended Stay Clinic Demonstration Project

Current Law:

- No provision.

Provision:

- The provision authorizes a new demonstration project under which frontier extended stay clinics in isolated rural areas are treated as providers of items and services under the Medicare program. A frontier extended stay clinic (FESC) is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road and is designed to address the needs of seriously or critically ill

or injured patients who, due to adverse weather conditions or for other reasons, need monitoring and observation for a limited period of time.

Effective Date:

- Upon enactment.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Sec. 501. Revision of Acute Care Hospital Payment Updates

Current law:

- Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket. Congress establishes the update for Medicare's hospital inpatient PPS. Acute care hospitals were scheduled to receive the full market basket as an update for FY 2004 and subsequently.

Provision:

- For fiscal years 2005 through 2007, hospitals would receive the full market basket update only if they submit the 10 hospital quality measures the Secretary has established as of November 1, 2003. If hospitals do not submit the 10 quality measures, then they receive an update of market basket minus 0.4 percentage points. Hospitals have a 30-day grace period to submit data with respect to the FY 2005 update.
- GAO is required to conduct a study to determine (1) the appropriate level and distribution of Medicare payments in relation to costs to hospitals under the IPPS and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs across geographic areas, kinds of hospitals, and types of cases. The study, including recommendations for necessary legislative and administrative action is due within 24 months of the enactment of MMA.

Effective Date:

- October 1, 2004

Sec. 502. Revision of the Indirect Medical Education (IME) Adjustment Percentage

Current law:

- The Balanced Budget Act of 1997 (BBA) reduced the Medicare indirect medical education (IME) add-on payment from a 7.7% increase in payment for every 10% increase in teaching intensity, to a 6.0% payment increase for FY2000, and to 5.5% beginning with FY2001. The Balanced Budget Refinement Act of

1999 (BBRA) adjusted the schedule established in the BBA by setting the add-on payments at 6.5% for FY2000, 6.25% for FY2001 and 5.5% for FY2002 and thereafter. The Benefits Improvement Act of 2000 (BIPA) further modified the IME adjustment schedule by maintaining 6.5% for FY2001 and 2002, and by reducing the payment add-on to 5.5% for FY 2003 and thereafter.

Provision:

- This provision raises the IME add-on percentage for discharges occurring between April 1, 2004 and October 1, 2004 to 5.98%, and for discharges occurring during FY 2005 to 5.79%, during FY 2006 to 5.58%, during FY 2007 to 5.38%, and during FY 2008 and future years to 5.5%.

Effective Date:

- April 1, 2004

Sec. 503. Recognition of New Medical Technologies Under Inpatient Hospital Prospective Payment System

Current law:

- The Benefits Improvement and Protection Act of 2000 (BIPA) established that hospital inpatient PPS should recognize the cost of new medical services and technologies starting October 1, 2001. CMS established that a technology that provided a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for an eligible new technology would occur when the standard diagnosis related group (DRG) payment was inadequate. This threshold was established as one standard deviation above the mean standardized DRG; the add-on payment for new technology would be the lesser of the following: 1) 50% of the costs of the new technology or 2) 50% of the amount by which the costs exceeded the standard DRG payment.

Provision:

- This section (1) requires the Secretary to add new diagnosis codes in April 1 of each year (but not adjust payments or DRG classifications mid-year); (2) adjusts the threshold for new technology to the lesser of 75% of the standardized amount or 75% of one standard deviation for the DRG involved; (3) requires the Secretary to have more public input when determining whether a new technology represents a substantial improvement (i.e., make public the list of services applying for new technology payments; accept comments, data and recommendations; and hold a meeting for interested parties to present data to CMS); (4) directs the Secretary to demonstrate a preference for assigning an eligible technology into a DRG before establishing an add-on payment for the new technology, taking into account similar

clinical or anatomical characteristics and the relative cost of the technology; (5) requires that any applications submitted for FY 2004 that were denied are to automatically be reconsidered for 2005; and (6) waives budget neutrality.

Effective Date:

- The Secretary is required to take the necessary steps to ensure that the amendments contained in this provision are reflected in the IPPS final rule for fiscal year 2005.

Sec. 504. Increase in Federal Rate for Hospitals in Puerto Rico

Current law:

- Under Medicare's hospital inpatient PPS, separate standardized amounts are used to establish payments for discharges from short-term general hospitals in Puerto Rico. The Balanced Budget Act of 1997 (BBA) provided for an adjustment of the Puerto Rico rates from blended amounts based on 25% of the federal national amounts and 75% of the local amounts to blended amounts based on a 50/50 split between national and local amounts.

Provision:

- The PPS rate for hospitals in Puerto Rico would be permanently increased to 75% of the national rate in FY 2005. From April 1, 2004 through October 1, 2004, the payment amount for Puerto Rico hospitals is changed to 62.5% federal rate and 37.5% local Puerto Rico rate.

The payment amount changes to 75% federal rate and 25% local Puerto Rico rate in FY 2005 and subsequent fiscal years.

Effective Date:

- April 1, 2004

Sec. 505. Wage Index Adjustment Reclassification Reform.

Current law:

- Under current law, hospitals paid under the inpatient hospital PPS may apply to the Medicare Geographic Classification Review Board (MGCRB) for reassignment to another geographic area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity on the basis of distance or commuting for purposes of using the other area's wage index. The regulations permit a hospital to establish proximity to the new area by documenting that at least 50 of its employees reside there or that it is at least 15 miles from the area (if urban) or 35 miles from the area (if rural). Other cost criteria must be met before a hospital will be reclassified. If reclassification is granted, the wage index for

the new area will be used to calculate Medicare's payment for inpatient and outpatient services provided by the hospital.

Provision:

- The Secretary would establish a new process, similar to the current wage index reclassification process, to make payment adjustments (beginning FY2005) based on commuting patterns of hospital employees. Some of the requirements are: a specified percentage (determined by the Secretary and not to exceed 10%) of hospital employees residing in a qualifying county are commuting to hospitals in an area or areas that have higher wage index values, and the average hourly wage of the hospitals in the qualifying county exceeds the average hourly wage of all hospitals in the qualifying area. Hospitals that qualify for the payment adjustment would receive a blended wage index amount based on the percent of hospital employees residing in the county who commute to higher wage-index areas. The wage index increase is effective for 3 years unless a hospital requests to terminate the payment.

Effective Date:

- The Secretary is required to take the necessary steps to ensure that the actual reclassifications are in place for fiscal year 2005.

Sec. 506. Limitation on Charges for Inpatient Hospital Contract Health Services Provided to Indians by Medicare Participating Hospitals

Current law:

- Since 1985-86, Medicare participating hospitals have been required to participate in medical care programs operated by the Departments of Veterans Affairs and Defense, which purchase specialty care they cannot provide directly, and to accept Medicare-like rates as payment in full for non-Medicare patients. The Indian Health Service (IHS) and Tribal and urban Indian health programs also purchase specialty care they cannot provide directly for their eligible individuals. There is no provision in current law that requires Medicare participating hospitals to participate in IHS, tribal or urban Indian health programs. Indian health

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programs lack sufficient market share to negotiate reasonable payment rates from many of these other providers, depleting more rapidly the limited funds available to buy this care. Funding for IHS and Tribal programs is estimated to pay for only about 60 percent of medically necessary care; the rest must be deferred.

Provision:

- Medicare-participating hospitals that furnish inpatient hospital services must also participate in the contract health services program funded by IHS and operated by IHS, Indian Tribes or Tribal organizations and in any program funded by IHS and operated by an urban Indian organization for the purchase of items and services covered under those programs and furnished to an individual eligible for those programs. The Medicare-participating hospitals must comply with regulations that are required to be promulgated by the Secretary on admission practices, payment methods and rates, and must accept no more than such payment rates as payment in full.

Effective Date:

- As of a date specified by the Secretary, no later than one year after enactment, for Medicare participation agreements in effect or entered into on or after such date.

Sec. 507. Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals

Current law:

- The physician self-referral law (often referred to as the "Stark law") prohibits a physician from making referrals for designated health services to an entity with which he or she has a financial relationship, unless an exception applies. Entities furnishing such services are also prohibited from billing Medicare for those services. Current law includes an exception that permits a referring physician to have an ownership or investment interest in a hospital if (1) the physician is authorized to perform services at the hospital, and (2) the ownership/investment interest is in the hospital overall (not merely a subdivision of the hospital). Current law also allows ownership or investment interests in an entity furnishing designated health services in a rural area if substantially all such services furnished by the entity are furnished to residents of the rural area.

Provision:

- This provision specifies that, for the 18-month period beginning on December 8, 2003 and ending on June 8, 2005, physician ownership and investment interests in "specialty hospitals" do not qualify for the Stark hospital ownership exception. In addition, section 507 further specifies that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers does not apply in the case of specialty hospitals located in a rural area. In other words, for this 18-month period only, a physician may not refer a Medicare patient to a hospital in which he or she has an ownership or investment interest if the hospital is a specialty hospital, even if the specialty hospital is in a rural area.

- For purposes of this provision, the term "specialty hospital" does not include psychiatric, rehabilitation, children's, or long-term care hospitals, certain cancer hospitals, and existing specialty hospitals that satisfy certain criteria outlined in section 507. Physician ownership interests in and referrals to a specialty hospital are permitted if all of the following criteria are satisfied: (1) the Secretary determines that the hospital was in operation or under development before November 18, 2003; (2) the number of physician investors does not increase after that date; (3) the types of specialized services furnished by the hospital do not change after that date; and (4) any increase in the number of beds at the hospital occurs only on the main campus of the hospital and does not exceed the greater of 5 beds or 50 percent of the beds in the hospital as of November 18, 2003.
- The provision directs MedPAC to study any differences in the cost of services furnished by physician-owned specialty hospitals compared to local full-service community hospitals within specific diagnosis-related groups, the extent to which each type of hospital treats patients with certain diagnoses, the financial impact of physician-owned specialty hospitals on local full-service hospitals, how the current diagnosis-related group system should be updated to better reflect hospital costs, and the proportions of payments received, by type of payer, between specialty hospitals and local full-service hospitals.
- The provision directs the Secretary to study the percentage of patients admitted to specialty hospitals who are referred by physicians with an ownership interest, the referral patterns of physician owners, the quality of care and patient satisfaction in physician-owned specialty hospitals compared to local full-service hospitals, the differences in uncompensated care between specialty and full-service hospitals, and the relative value of tax exemptions available to such hospitals.

Effective Dates:

- The prohibition against physician referrals to specialty hospitals is effective for the 18-month period beginning on the date of enactment.
- Studies due 15 months after enactment.

Sec. 508. 1-Time Appeals Process for Hospital Wage Index Classification

Current law:

- Under current law, hospitals paid under the inpatient hospital PPS may apply to the Medicare Geographic Classification Review Board (MGCRB) for reassignment to another geographic area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity for purposes of using the other area's wage index. The regulations specify that a hospital can establish proximity to the new area by documenting that at least 50% of its employees reside there. Other cost criteria must be met before a hospital will be reclassified. If reclassification is granted, the wage index for the new area will be used to calculate Medicare's payment for inpatient and outpatient services provided by the hospital.

Provision:

- Directs the Secretary to establish a process for hospitals to appeal the wage index classification and be reclassified to another area within the State, or to

an area in a contiguous State. The appeals are heard by the MGCRB. To qualify under this provision, a hospital must be one that does not qualify for reclassification based on the regulatory

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requirements related to distance. The hospital must also meet additional criteria set by the Secretary. The Secretary can also modify the wage comparison criteria guidelines outlined in regulation. The reclassification applies for 3 years, beginning April 1, 2004. Expenditures for this section are limited to $900 million.

- Additionally, subsection (f) deems hospitals that were reclassified by an act of Congress that expired on September 30, 2003 to be reclassified from January 1, 2004 through September 30, 2004. Section 152 of BBRA reclassified hospitals in the following areas:
    - Iredell County, North Carolina, is deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina-South Carolina Metropolitan Statistical Area;
    - Orange County, New York, the large urban area of New York, New York is deemed to include such county;
    - Lake County, Indiana, and Lee County, Illinois, are deemed to be located in the Chicago, Illinois Metropolitan Statistical Area;
    - Hamilton-Middletown, Ohio, is deemed to be located in the Cincinnati, Ohio-Kentucky-Indiana Metropolitan Statistical Area;
    - Brazoria County, Texas, is deemed to be located in the Houston, Texas Metropolitan Statistical Area; and
    - Chittenden County, Vermont, is deemed to be located in the Boston-Worcester-Lawrence-Lowell-Brockton, Massachusetts-New Hampshire Metropolitan Statistical Area.

Hospitals in these areas will be deemed to be reclassified for the purposes of the wage index from January 1, 2004 through September 1, 2004.

Effective Dates:

- January 1, 2004—the Secretary has to establish the process; February15, 2004—deadline for hospitals to file the appeal; April 1, 2004—date of reclassification.

Subtitle B—Other Provisions

Sec. 511. Payment for Covered Skilled Nursing Facility Services

Current law:

- Under current law, there is no additional SNF payment for residents with AIDS. Under PPS, SNFs are paid a daily rate that is adjusted based upon the relative resource utilization of the eligible individual. There are 44 resource utilization groups (RUGs) used to adjust payment for care needs; each group reflects the intensity of services, such as skilled nursing care and/or various therapy and other services, needed by an eligible individual.

Provision:

- Increases the per diem payment amount for a SNF resident with AIDS by 128%. The 128% increase will not apply on or after such date as the Secretary implements SNF case mix refinements to reflect the increased costs associated with caring for residents with AIDS.

Effective Date:

- For services furnished on or after October 1, 2004.

Sec. 512. Coverage of Hospice Consultation Services

Current law:

- There is currently no coverage for hospice consultation services provided by a physician who is the hospice medical director, or a hospice employee, or who has an arrangement with the hospice, to an individual who has not yet elected the hospice benefit. An independent attending physician may bill Medicare directly for advanced care planning services.

Provision:

- Creates coverage of hospice consultation services (one time only) for a terminally ill individual who has not yet elected the hospice benefit. The amount paid to the hospice shall be equal to the payment under the physician fee schedule for an evaluation and management visit for problems of moderate severity and requiring medical decision making of low complexity.

Effective Date:

- January 1, 2005.

Sec. 513. Study on Portable Diagnostic Ultrasound Services for Beneficiaries in Skilled Nursing Facilities

Current law:

- Medicare does not pay for the transportation of or technician services relating to portable diagnostic ultrasound equipment when such service is furnished to Medicare eligible individuals in skilled nursing facilities.

Provision:

- The Comptroller General is required to study and report to Congress on various aspects of portable diagnostic ultrasound services furnished to Medicare eligible individuals in skilled nursing facilities. The study is to consider: the types of portable ultrasound services furnished to such beneficiaries, the types of portable equipment used to furnish such services, the technical skills and training required for technicians to furnish such services; the clinical appropriateness of transporting portable ultrasound equipment and technicians to patients in SNFs as opposed to transporting such patients to a hospital or other facility; the financial impact if Medicare were to make separate payment for portable ultrasound diagnostic services; and whether the Secretary should establish credentialing or other requirements for technicians that furnish diagnostic ultrasound services.

Effective Date:

- Report due 24 months after enactment

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

Sec. 601. Revision of Updates for Physicians' Services

Current law:

- The physician update is determined by a statutory formula that compares actual expenditures to sustainable growth rate (SGR) target expenditures. The application of the statutory formula will result in a -4.5 percent update for 2004 and another negative update for 2005.

Provision:

- Requires that the update for 2004 and 2005 not be less than 1.5 percent. Prohibits an adjustment to SGR target expenditures as a result of this amendment. Requires use of the 10-year rolling average GDP in the SGR formula, beginning with SGRs for 2003.

Effective Date:

- Services furnished during 2004 and 2005.

Sec. 602. Treatment of Physicians' Services Furnished in Alaska

Current law:

- The fee schedule is determined for each service based on the relative value of the procedure, the conversion factor and the geographic adjustment (for each of the physician work, practice expense and malpractice components).

Provision:

- Sets each of the geographic indices for Alaska at 1.67 for 2004 and 2005.

Effective Date:

- Services furnished during 2004 and 2005

Sec. 603. Inclusion of Podiatrists, Dentists, and Optometrists Under Private Contracting Authority

Current law:

- The private contract provision of current law applies to allopathic and osteopathic physicians and non-physician practitioners.

Provision:

- Expands the private contract provision to apply to podiatrists, dentists, and optometrists.

Effective Date:

- Upon enactment.

Sec. 604. GAO Study on Access to Physician Services

Current law:

- None.

Provision:

- Requires GAO to conduct a study on Medicare eligible individual access to physicians' services, including examination and assessment of specified items. A report to Congress is required within 18 months of enactment, including a determination of whether data from claims submitted by physicians indicate potential access problems, and whether Medicare eligible individual access may have improved, remained constant or deteriorated over time.

Effective Date:

- Upon enactment.

Sec. 605. Collaborative Demonstration-Based Review of Physician Practice Expense Geographic Adjustment Data

Current law:

- The Secretary is required to review geographic adjustment factors under the physician fee schedule not less often than every three years.

Provision:

- Requires the Secretary, by January 1, 2005, in collaboration with State and other appropriate organizations representing physicians and other appropriate persons, to review and consider alternative data sources than those currently used in establishing the geographic adjustment for practice expenses. Requires the Secretary to carry out the study in two physician payment localities, one rural and at least one statewide locality. Requires the Secretary to report to Congress by January 1, 2006 on the review, including information on the alternative data sources considered, including the accuracy and validity of the data as measures of the elements of the practice expense geographic adjustment as well as the feasibility of using such alternative data nationwide in lieu of current proxy data, and the estimated impacts of using such alternative data.

Effective Date:

- Study by January 1, 2005 and report to Congress by January 1, 2006.

Sec. 606. MedPAC Report on Payment for Physicians' Services

Current law:

- None.

Provision:

- Requires MedPAC to submit two reports to Congress by 1 year from enactment. The first study is on several aspects of the practice expense component of the physician fee schedule. The second study is on several aspects of the volume of physicians' services.

Effective Date:

- One year from enactment.

Subtitle B—Preventive Services

Sec. 611. Coverage of an Initial Preventive Physical Examination

Current law:

- Medicare coverage is precluded for routine screening or preventive services except when such services are specifically authorized by law. The Medicare statute also explicitly excludes coverage of "routine physical checkups."

Provision:

- This provision establishes coverage of a one-time initial preventive physical exam within 6 months of an eligible individual's first coverage under Part B, with the goal of health promotion and disease detection. The benefit covers a physical exam (including measurement of height, weight and blood pressure,

and an electrocardiogram), as well as education, counseling and referral related to other preventive services covered by Medicare for some or all eligible individuals (including vaccinations, screening mammography, screening pap smear and pelvic exam, prostate cancer screening, colorectal cancer screening, diabetes self-management, bone mass measurement, glaucoma screening, medical nutrition therapy, cardiovascular screening, and diabetes screening). Such services may be furnished by physicians, physician assistants, nurse practitioners, and clinical nurse specialists, and are paid under the physician fee schedule.

Effective Date:

- January 1, 2005, but only for eligible individuals whose Part B coverage begins on or after such date.

Sec. 612. Coverage of Cardiovascular Screening Blood Tests

Current law:

- Medicare coverage is precluded for routine screening tests unless specifically authorized by law. Tests to detect cardiovascular disease or abnormalities associated with cardiovascular disease (such as high cholesterol) are covered only for diagnostic purposes (for an individual exhibiting signs or symptoms of a potential medical problem).

Provision:

- This provision establishes coverage of screening blood tests for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease). The covered tests include those for (1) cholesterol levels and other lipid or triglyceride levels and (2) other indications associated with the presence of or elevated risk for cardiovascular disease, as the Secretary may approve for all individuals or for some individuals determined by the Secretary to be at risk for cardiovascular disease. Such indications may include those measured by noninvasive testing. The Secretary may only approve such indications associated with the presence or elevated risk of cardiovascular disease if the blood test for such indication has been recommended by the United States Preventive Services Task Force. The Secretary must establish, in consultation with appropriate organizations, standards for the frequency of each type of cardiovascular screening blood test with a frequency not to exceed once every two years.

Effective Date:

- Effective for tests furnished on or after January 1, 2005.

Sec. 613. Coverage of Diabetes Screening Tests

Current law:

- Medicare coverage is precluded for routine screening tests unless specifically authorized by law. Tests to detect diabetes are covered only for diagnostic purposes (for an individual exhibiting signs or symptoms of a potential medical problem).

Provision:

- This provision establishes coverage for diabetes screening tests for individuals who satisfy the eligibility requirements of being at risk for diabetes. Such tests include a fasting plasma glucose test and such other tests as the Secretary determines appropriate in consultation with appropriate organizations. In order to be considered at risk for diabetes, an individual must have any of the following risk factors: hypertension, dyslipidemia, obesity, prior identification of elevated impaired fasting glucose or prior identification of impaired glucose tolerance. In addition, individuals at risk include those who have at least two of the following characteristics: overweight, family history of diabetes, history of gestational diabetes or delivery of a baby weighing more than 9 pounds, and age of 65 or older. The Secretary must establish, in consultation with appropriate organizations, standards for the frequency of diabetes screening tests with a frequency not to exceed twice within a twelve-month period following the most recent diabetes screening test for that individual.

Effective Date:

- Effective for tests furnished on or after January 1, 2005.

Sec. 614. Improved Payment for Certain Mammography Services

Current law:

- Medicare covers an annual screening mammogram for all women age 40 and over, and one baseline mammogram for women age 35-39. Medicare also covers medically necessary diagnostic mammograms. Screening mammography (in all settings) is paid under the physician fee schedule, but diagnostic mammography performed in a hospital outpatient department is paid under the OPD prospective payment system.

Provision:

- This provision establishes payment for both screening and diagnostic mammography under the physician fee schedule.

Effective Dates:

- For screening mammography: upon enactment.
- For diagnostic mammography: January 1, 2005.

Subtitle C—Other Provisions

Sec. 621. Hospital Outpatient Department (HOPD) Payment Reform

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 at least 2, but not more than 3 years, after which 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 medical devices, drugs and biologicals. 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.

Provision:

- Requires use of Medicaid definitions for drugs. In 2004, payment for a sole source drug must be between 88 and 95 percent of the reference average wholesale price (AWP) of the drug. In 2005, payment for a sole source drug must be between 83 and 95 percent of the reference AWP. In 2004 and 2005, payment for an innovator multiple source drug may not exceed 68 percent of the reference AWP. In 2004 and 2005, payment for a noninnovator multiple source drug may not exceed 46 percent of the reference AWP. These payments will apply to radiopharmaceuticals and to drugs for which pass-through payments were made on or before December 31, 2002. Payment for orphan drugs will be as designated by the Secretary. Payment for new drugs and biologicals with no HCPCS code assigned will be 95 percent of AWP.
- In 2004 and again in 2005, GAO will be required to survey hospital acquisition costs for each specified, covered outpatient drug. The Secretary must be provided data resulting from such surveys for use in setting the payment rates for 2006. No later than July 1, 2005, MedPAC must report to the Secretary on adjustment in APC payment rates for overhead costs and related expenses. Payment for brachytherapy devices furnished between January 1, 2004 and before January 1, 2007 will be set at charges adjusted to cost. The Secretary must create separate APC groups based on the number, isotope, and radioactive intensity of these devices. By January 1, 2005, GAO must submit a report to the Congress and the Secretary including specific recommendations for appropriate payments for brachytherapy devices.

Effective Dates:

- Update drug payments January 1, 2004
- GAO report due in 2004, and another in 2005

- The Secretary must be provided data resulting from GAO surveys for use in setting the payment rates for 2006
- MedPAC report due July 1, 2005
- Set brachytherapy payments January 1, 2004

  *GAO brachytherapy report due January 1, 2005

Sec. 622. Limitation of Application of Functional Equivalence Standard

Current law:

- In the November 1, 2002 final rule that established the 2003 HOPD PPS rates, a new anemia treatment for cancer patients with transitional pass-through status was found to be functionally equivalent (although not structurally identical) to an existing treatment. Therefore, the transitional pass-through rate for the drug was reduced to zero starting for services in 2003.

Provision:

- The Secretary would be prohibited from publishing regulations that apply a functional equivalence standard to drugs or biologicals for purposes of OPD transitional pass-through payments on or after the date of enactment, unless such a standard was applied prior to enactment for the purpose of determining eligibility of a drug or biological for pass-through payments in OPDs. The provision does not affect the Secretary's authority to deem drugs identical for the purpose of pass-through payments if two drugs are pharmaceutically equivalent and biologically equivalent as determined by the FDA.

Effective Date:

- Upon enactment

Sec. 623. Payment For Renal Dialysis Services

Current law:

- Payment for dialysis services for beneficiaries with end stage renal disease (ESRD) is based on prospective payment amounts (composite rates) under the authority of a provision added by OBRA 1986. OBRA 1990 provided for a $1.00 payment increase in the composite rates; the statutory language, however, has constrained CMS's authority to change the payment rates or methodology, including updating the wage index.
- BBRA contained a provision so that the locked in composite rate was no longer effective as of January 1, 2000 and increased the composite rate payment in the year 2000 by 1.2 percent above 1999 payment rates and in the year 2001, by 1.2 percent above 2000 rates. BIPA subsequently increased the mandated 2001 update to 2.4%, effective January 1, 2002. There is no rate increase scheduled for ESRD composite payment rates in 2004.

- BIPA directed the Secretary to conduct a study and develop a system that creates a more comprehensive composite rate, bundling-in drugs and diagnostic laboratory services that are currently billed separately. This provision did not authorize or require implementation of such a bundled system. BIPA required the Secretary to report to Congress by July 1, 2002 on the results.

Provision:

- The composite rate will be increased by 1.6% for services provided on or after January 1, 2005.
- The prohibition on dialysis facility exceptions to the composite rate (BIPA 422) is made inapplicable to pediatric facilities (those with 50% of patients under age 18).
- The Inspector General (IG) is required to do two reports: (1) on existing drugs (drugs for which a billing code exists prior to January 1, 2004), due by April 1, 2004; and (2) on new drugs (drugs for which a billing code does not exist prior to January 1, 2004). Both IG reports are required to: compare the payments made to facilities for the drugs to the acquisition costs by such facilities for the drugs; and estimate the rates of growth for expenditures on such drugs and biologicals by facilities.
- Beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system, for a limited number of patient characteristics and adjusted by a geographic index. The new system includes the services in the composite rate, as increased by 1.6 percent, and the spread on separately billable drugs (including erythropoietin) as determined by the IG reports. Beginning with 2006, the Secretary will annually increase the basic case-mix adjusted payment amounts by estimated growth in drug expenditures applied only to the spread component. In 2004, separately billable drugs will be paid the same as current law. In 2005, they will be paid acquisition costs. In 2006 and beyond, the Secretary will determine whether payment is acquisition cost or under the ASP. Drugs and biologicals (including erythropoietin) that were separately billable before the date of enactment will continue to be separately billable.
- By October 1, 2005, the Secretary must submit a report to Congress detailing the elements and features for the design of a bundled prospective payment system for services furnished by ESRD facilities. (i.e., bundle, case mix, wage index, rural area payment adjustments, etc).
- For three years, beginning on January 1, 2006, the Secretary must establish a demonstration project of the use of a fully case-mix adjusted payment system for ESRD services for certain patient characteristics. Drugs and biologicals that are separately billed by ESRD facilities and clinical lab tests related to those drugs will be bundled into the payment. No more than 500 providers

may participate. $5,000,000 is authorized to be appropriated in FY2006 to conduct this demonstration. Additionally, the Secretary must create an Advisory Board to provide advice and recommendations with respect to its establishment and operation.

Effective Dates:

- Upon enactment—
    - Composite rate increase for services on or after January 1, 2005
    - First IG report due April 1, 2004, second due April 1, 2006
    - Basic case-mix adjusted PPS beginning with services furnished on or after January 1, 2005
    - Increase the basic case-mix adjusted payment amounts beginning with 2006
    - Report to Congress due October 1, 2005 designing bundled PPS
    - Demonstration project established beginning on January 1, 2006, for three years

Sec. 624. 2-Year Moratorium on Therapy Caps; Provisions Relating to Reports

Current law:

- Prior to BBA 1997, Medicare paid "reasonable cost" for outpatient therapy services (physical therapy, occupational therapy, speech/language therapy) furnished by facilities. Physicians and therapists in independent practice were paid under the physician fee schedule. In addition, therapists in independent practice were subject to an annual cap on the amount of services covered (set at $900 prior to the BBA).
- The BBA moved payment for outpatient therapy furnished by facilities to the physician fee schedule. It also increased the caps on services provided by therapists in independent practice to $1,500 and expanded the application of the caps to all outpatient therapy services except those provided by a hospital outpatient department. Initially, eligible individuals could receive up to $1,500 of physical therapy (including speech/language therapy) and $1,500 of occupational therapy services each year. The amount of the cap is updated annually by the MEI (under current law, the cap would be $1,640 for 2004).
- BBRA 1999 placed a moratorium on the coverage caps in 2000 and 2001. BIPA 2000 extended the moratorium through 2002. Implementation of the annual caps ($1,590 for 2003) began on September 1, 2003.

Provision:

- This provision sets a new moratorium on implementation of therapy caps for two years (2004 and 2005).
- It also directs the Secretary not to apply the therapy caps to expenses incurred with respect to therapy services from the date of enactment through December 31, 2003.
- The provision sets a deadline for the submission of reports relating to therapy caps and therapy utilization, which were mandated by BBA 1997 and BBRA 1999.
- The provision requires GAO to identify conditions or diseases that may justify waiver of the therapy caps and to recommend criteria for such waivers.

Effective Dates:

- Moratorium: January 1, 2004.
- Inapplicability of current year caps: date of enactment.

- HHS report deadlines: March 31, 2004.
- GAO report deadline: October 1, 2004.

Sec. 625. Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period

Current law:

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

Provision:

- The provision would waive the late enrollment penalty in the case of certain military retirees who enrolled in Part B during 2001, 2002, 2003, or 2004. The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004.

Effective Dates:

- Applies to premiums for months beginning with January 2004.
- The Secretary is required to establish method for providing rebates of premium penalties for months on or after January 2004 if they had been collected.

Sec. 626. Payment for Services Furnished in Ambulatory Surgical Centers

Current law:

- The current payment system for services furnished in ambulatory surgical centers (ASCs) is determined by the Secretary in accordance with a survey of costs in such facilities. Payments are updated annually by the CPI.

Provision:

- For FY 2004, beginning April 1 reduces the update to CPI minus 3 percentage points. The update is 0 percent for FY 2005, the last quarter of CY 2005 and CY's 2006 through 2009 (the update cycle is switch to a calendar year basis beginning with 2005). Eliminates the requirement for basing payment rates on a survey of costs of ASCs. Requires implementation of a revised payment system taking into account recommendations in a GAO study. The revised system is required to be budget neutral in the first year of implementation, which can be between January 1, 2006 and January 1, 2008. Administrative and judicial review is precluded for key elements of the revised payment system.
- GAO is required to study the relative costs of procedures furnished in ASCs compared to hospital OPDs and how accurately ambulatory payment categories reflect procedures furnished in ASCs.

Effective Date:

- Services furnished beginning April 1, 2004.

Sec. 627. Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics

Current law:

- The payment limits for therapeutic/diabetic shoes and inserts are based on original limits set in the statute for 1988, updated each year by the durable medical equipment (DME) update. The statute establishes one single payment ceiling, rather than separate payment limits, for custom and pre-fabricated inserts.

Provision:

- Moves the payment methodology for therapeutic/diabetic shoes and inserts under the fee schedule for orthotics and prosthetics. The Secretary may establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary is required to establish a payment amount for an individual substituting modifications to the covered shoe (rather than obtaining one or more pairs of inserts) that would assure that there is no net increase in Medicare expenditures.

Effective Date:

- January 1, 2005

Sec. 628. Payment for Clinical Diagnostic Laboratory Tests

Current law:

- Payment for clinical laboratory tests is made at the lowest of the actual charge, the local fee schedule amount, or a national limitation amount (NLA) based on 74 percent of the median of the local fee schedule amounts, or 100 of the median for a new test for which no NLA has previously been set. Payment amounts are updated each year based on the percentage change in the CPI-U. However, Congress eliminated the annual payment update in 1988, restricted the update to 2 percent of CPI?U each year from 1991 through 1993, and again eliminated the update for 1994, 1995 and 1998 through 2002.

Provision:

- This provision eliminates payment updates for clinical laboratory tests for 5 years (2004-2008).

Effective Date:

- January 1, 2004.

Sec. 629. 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 eligible individual pays an annual deductible of $100. The Part B deductible has been set at $100 since 1991.

Provision:

- The Part B deductible remains $100 through 2004, becomes $110 for 2005, and beginning in 2006, will be updated by the annual percentage increase in the monthly actuarial rate under section 1839(a), which is essentially the growth rate in Medicare program expenditures.

Effective Date:

- The deductible increases in 2005.

Sec. 630. 5-Year Authorization of Reimbursement for All Medicare Part B Services Furnished by Certain Indian Hospitals and Clinics

Current law:

- Sections 1814(c) and 1835(d) of the Social Security Act generally prohibit payments to Federal providers. Section 1880 provides limited exceptions to allow payments for certain items or services to Indian Health Service (IHS) facilities operated by IHS or by Indian Tribes or Tribal organizations.

Provision:

- This section would expand the scope of items or services for which payment may be made to IHS facilities to include all other Part B covered items and services, but only for items and services furnished during the five-year period beginning on January 1, 2005.

Effective Date:

- January 1, 2005 - December 31, 2009.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

Sec. 641. Demonstration Project for Coverage of Certain Prescription Drugs and Biologicals

Current law:

- Currently, Medicare has a limited prescription drug benefit. Medicare part B covers injectible drugs that are furnished incident to a physician's service, and which "are not usually self-administered by the patient." Medicare also covers certain FDA-approved oral anticancer drugs if they have the same indication and active ingredient as a drug that is injectible and would be covered if furnished incident to a physician's service.

Provision:

- This provision establishes a 2-year demonstration to pay for prescription drugs and biologicals prescribed as replacements for drugs or biologicals otherwise covered under two part B provisions. The demonstration will be conducted at sites selected by the Secretary, may include up to 50,000 patients, and may receive up to $500 million in funding.
- The provision requires a report to Congress evaluating patient access and outcomes under the demonstration, as well as its cost-effectiveness.

Effective Dates:

- Demonstration: 90 days after enactment but in no case may the project extend beyond December 31, 2005.
- Report is due July 1, 2006.

Sec. 642. Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home

Current law:

Medicare covers intravenous immune globulin for the treatment of primary immune deficiency diseases when it is furnished as a component of inpatient or outpatient facility services, or "incident to" a physician's service. It is not currently covered in the eligible individual's place of residence.

Provision:

- Requires Medicare to pay for intravenous immune globulin for the treatment of primary immune deficiency diseases in the eligible individual's place of residence for items furnished beginning January 1, 2004.

Effective Date:

- Items furnished beginning January 1, 2004.

Sec. 643. MedPAC Study of Coverage of Surgical First Assisting Services of Certified Registered Nurse First Assistants

Current law:

- No provision.

Provision:

- Requires MedPAC to conduct a study on the feasibility and advisability of providing Medicare Part B payment for surgical first assisting services furnished to Medicare eligible individuals by certified registered nurse first assistants.

Effective Date:

- Report due by January 1, 2005.

Sec. 644. MedPAC Study of Payment for Cardio-Thoracic Surgeons

Current law:

- No provision.

Provision:

- Requires MedPAC to conduct a study on the practice expense relative values under the physician fee schedule for thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical patient care staff in hospitals.

Effective Date:

- Report due by January 1, 2005.

Sec. 645. Studies Relating to Vision Impairments

Current law:

- Medicare does not cover routine eye care or related services and will not pay for eyeglasses; most contact lens; eye exams for the purposes of prescribing or changing eyeglasses or contact lenses; and most routine procedures to determine the refractive state of the eyes. The law provides for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

Provision:

- The Secretary is required to study the feasibility and advisability of: 1) providing payment of vision rehabilitation services furnished by vision rehabilitation professionals, and 2) implementing a demonstration project for vision care PPO networks to furnish and pay for eyeglasses following cataract surgery and should include recommendations for legislative or administrative action.

Effective Dates:

- Secretary's report and recommendations on payment for vision rehabilitation services is due to Congress by January 1, 2005.
- Secretary's report on feasibility of a vision care PPO demonstration project is due 1 year from enactment.

Sec. 646. Medicare Health Care Quality Demonstration Programs

Current law:

- CMS is undertaking a series of disease management demonstration projects that provide eligible individuals with greater choices, enhance quality of care, and offer better value for the dollars spent on healthcare.

Provision:

- Establishes a 5-year demonstration program that expands the current physician group practice demonstration and evaluates the effect of various factors on quality of patient care. Expands the definition of health care groups to include regional coalitions and integrated delivery systems in addition to physician groups. Allows "health care groups" to incorporate approved alternative payment systems and modifications to the traditional fee-for-service and Medicare Advantage benefit package.
- Demonstration covers both FFS and Medicare Advantage eligible individuals.
- The demonstration must be budget neutral.

Effective Date:

- Upon enactment.

Sec. 647. MedPAC Study on Direct Access to Physical Therapy Services

Current law:

- Outpatient physical therapy services and comprehensive outpatient rehabilitation facility (CORF) services are covered if (1) a physician certifies that such services are medically necessary, (2) the services are provided pursuant to a treatment plan established by a physician (or for physical therapy, by a qualified physical therapist), which is periodically reviewed by a physician, and (3) the services are furnished while the individual is under the care of a physician.

Provision:

- This provision directs MedPAC to study the feasibility and advisability of allowing fee-for-service eligible individuals direct access to outpatient physical therapy services and physical therapy services furnished as CORF services without requiring that the patient be under the care of (or referred by) a physician or supervised by a physician, and allowing a physician or qualified therapist to satisfy any requirements for certification and the establishment and periodic review of a treatment plan.

Effective Date:

- Report to Congress due January 1, 2005.

Sec. 648. Demonstration Project for Consumer-Directed Chronic Outpatient Services

Current law:

- No current Medicare demonstration.

Provision:

- Requires the Secretary to establish a demonstration project to test methods that improve quality of care provided to Medicare beneficiaries with chronic conditions. An evaluation of best practices of methods that permit individuals to self-direct the provision of personal care services is required prior to implementation of the demonstration. The demonstration project is required to be budget neutral.

Effective Date:

- Upon enactment.

Sec. 649. Medicare Care Management Performance Demonstration

Current law:

- No current Medicare demonstration.

Provision:

- Establishes a pay-for-performance 3-year demonstration program with physicians to meet the needs of eligible individuals by using health information technology (such as email communication, clinical alerts and reminders, and other information technology that meets standards prescribed by the Secretary) and evidence-based outcomes measures.
- The Secretary shall designate no more than 4 sites for this demonstration of which 2 will be

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in urban areas, 1 will in be in a rural area, and 1 will be in a state with a medical school with a geriatrics department that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia.

- Eligible individuals are those enrolled in Parts A and B, but not Part C, who have one or more chronic medical conditions specified by the Secretary (one of which may be a cognitive impairment).
- Physicians who meet or exceed performance standards established by the Secretary related to clinical quality and outcome measures will receive a per beneficiary payment. This payment amount can vary based on different levels of performance.
- The demonstration must be budget neutral.

Effective Date:

- Upon enactment.

Sec. 650. GAO Study and Report on the Propagation of Concierge Care

Current law:

- None.

Provision:

- Requires GAO to study and report on the propagation of concierge care where physicians seek a membership or other incidental fee from patients as a condition of seeing patients or accepting them into their practice, or under which physicians require patients to purchase an item or service in order to receive a health care item or service from a physician.

Effective Date:

- Report to be submitted by 12 months after enactment.

Sec. 651. Demonstration of Coverage of Chiropractic Services Under Medicare

Current law:

- By statute, Medicare currently covers chiropractor services with respect to treatment by means of manual manipulation of the spine (to correct a subluxation). There is no limit on the number of visits. The BBA removed the prior statutory requirement that an x-ray show a problem with the spine before chiropractor services would be covered. States vary in what services they license chiropractors to perform.

Provision:

- Establishes a 3-year demonstration project to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. The demonstration will evaluate whether participating eligible individuals used fewer Medicare covered services than those who did not participate; the cost of providing chiropractic services under Medicare; beneficiary satisfaction with services; and other matters as determined appropriate by the Secretary.

- The demonstration must be budget neutral.

Effective Date:

- Not before October 1, 2004.

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Sec. 701. Update in Home Health Services

Current law:

- Under current law, the annual update for home health is on a fiscal year basis and home health agencies receive the full market basket percentage update.

Provision:

- Changes the home health prospective payment system (PPS) update from a fiscal year to a calendar year basis and sets the update at market basket minus 0.8 percent for each of years 2004 (last 3 calendar quarters), 2005 and 2006, returning to full market basket in 2007.

Effective Date:

- Upon enactment.

Sec. 702. Demonstration Project to Clarify the Definition of Homebound

Current law:

- No current demonstration. An individual must be homebound in order to qualify for home health services. The current definition of homebound requires absences from the home to be infrequent, of short duration, and require considerable and taxing effort.

Provision:

- Establishes a 2-year demonstration where certain Medicare beneficiaries with chronic conditions are deemed to be homebound and eligible for receipt of home health services.

Effective Date:

- Not later than 180 days after enactment.

Sec. 703. Demonstration Project for Medical Adult Day Care Services

Current law:

- No current Medicare demonstrations in this area. Under current law, a homebound individual may attend adult day care and still be considered homebound; however, home health services generally must be provided in the individual's home.

Provision:

- Requires the Secretary to establish a 3-year demonstration to test the provision of home health services to home health eligible individuals in an adult day care setting.

Effective Date:

- Upon enactment.

Sec. 704. Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and non-Medicaid Patients

Current law:

- The OASIS instrument is used by home health agencies to measure patient outcomes and allow home health agencies to compare outcomes against the care provided. Current conditions of participation require the collection of this data for all patients served by the home health agency.

Provision:

- Suspends collection of OASIS information on non-Medicare and non-Medicaid patients until final regulations are published regarding use and collection of OASIS for non-Medicare and non-Medicaid patients. Requires a study and report on the benefits/value and burden of collecting such information from both large and small home health agencies.

Effective Dates:

- Suspension—Upon enactment
- Report—Not later than 18 months after enactment

Sec. 705. MedPAC Study on Medicare Margins of Home Health Agencies

Current law:

- None.

Provision:

- Requires MedPAC to examine payment margins under the home health PPS and report to Congress.

Effective Date:

- Within 2 years after enactment.

Sec. 706. Coverage of Religious Nonmedical Health Care Institution Services Furnished in the Home

Current law:

- Religious nonmedical health care institutions (RNHCIs) are defined in current law under 1861(ss) of the Social Security Act as institutions providing nonmedical items and services to inpatients on a 24-hour basis.

Provision:

- Allows a RNHCI to provide home health services but only with respect to items and services ordinarily furnished by home health agencies in the home, and that are comparable to items and services furnished by home health agencies that are not RNHCIs. Payment may not be made in any year in which such payments exceed $700,000 and the provision expires December 31, 2006.

Effective Date:

- Upon enactment.

Subtitle B—Graduate Medical Education

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

Current law:

- Medicare direct graduate medical education (GME) payments are based on the Medicare share of a hospital's base year per resident training costs (the "per resident amount") and the hospital's number of full-time equivalent residents. Since the enactment of the Benefits Improvement and Protection Act of 2000 (BIPA), hospital per resident amounts below 85 percent of the geographically adjusted national average per resident amount have been raised to the 85 percent "floor" amount. Hospital per resident amounts that exceed 140 percent of the geographically adjusted national average are frozen at the current level, and are not updated annually for inflation as are per resident amounts that are below the 140 percent "ceiling," until the cost reporting period beginning during FY 2003. After that, hospital per resident amounts that exceed the ceiling receive a reduced update (the CPI minus 2 percentage points).

Provision:

- Reinstates the freeze on further updates to hospital per resident amounts that exceed the 140 percent ceiling. This freeze applies to cost reporting periods beginning during FY 2004 through 2013.

Effective Date:

- October 1, 2004.

Sec. 712. Exception to the Initial Residency Period for Geriatric Residency or Fellowship Programs

Current law:

- In general, for purposes of direct graduate medical education payments, residents are weighted at 100 percent during their initial residency period, and at 50 percent if they are beyond their initial residency period. The initial residency period is limited to the minimum number of years of training required to become initially board certified in the specialty in which the resident is training. There is a statutory exception that can extend the 100 percent weighting for up to two additional years for residents training in geriatric residency or fellowship programs beyond the otherwise applicable initial residency period.
- Historically, the medical boards for geriatricians required two years of training to become initially board eligible in geriatrics. Recently, the boards have reduced the minimum training requirement to one year. The agency could apply its policies regarding the initial residency period, weighting factors and the exception for geriatric residents to reduce the possible extension on the 100 percent weighting factor for geriatric residents from two years to one year.

Provision:

- Clarifies that Congress intended the geriatric exception to allow up to two years of additional training in a geriatrics program to be considered part of the initial residency period, and weighted at 100 percent, regardless of the reduction in the initial period of board eligibility by the relevant medical boards. Effective for cost reporting periods beginning on or after October 1, 2003.

Effective Date:

- October 1, 2003

Sec. 713. Treatment of Volunteer Supervision

Current law:

- Currently, hospitals must incur "all or substantially all of the costs" attributable to a residency training program in a non-hospital site in order for the hospital to count the time spent by residents in the non-hospital site for purposes of direct and indirect GME payments. Among other things, "all or substantially all of the costs" of the training program includes costs attributable to supervisory teaching physicians at the non-hospital site.

Provision:

- Requires the Secretary to allow hospitals to count FTE residents in osteopathic and allopathic family practice programs that were in existence as of January 1, 2002, who are training in non-hospital sites regardless of the financial arrangements between the hospital and the supervisory teaching physician in the non-hospital site.
- Requires an OIG study.

Effective Dates:

- Upon enactment for the provision.
- IG report due one year after enactment.

Subtitle C—Chronic Care Improvement

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

Current law:

- No current chronic care programs under traditional fee-for-service Medicare.

Provision:

- Requires the Secretary to phase in chronic care improvement programs in traditional fee-for-service. Chronic care improvement programs shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures for targeted eligible individuals with one or more threshold conditions (such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or

conditions selected by the Secretary to be appropriate for a chronic care improvement program).

- Chronic care improvement programs are required to (1) have a process to screen each targeted eligible individual for conditions other than the specified chronic conditions, such as impaired cognitive ability and co-morbidities, in order to develop an individualized, goal-oriented care management plan; (2) provide each targeted eligible individual participating in the program with the care management plan; and (3) carry out the plan and other chronic care improvement activities. The care management plan is required to be developed with the eligible individual and, to the extent appropriate, include: (1) a designated point of contact responsible for communications with the eligible individual and for facilitating communications with other health care providers; (2) self-care education for the eligible individual (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members; (3) education for physicians and other providers and collaboration to enhance communication of relevant clinical information; (4) the use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment; and (5) the provision of information about hospice care, pain and palliative care, and end-of-life care.
- The Secretary will enter into agreements with chronic care improvement organizations, such as disease management organizations, health insurers, integrated delivery systems, physician group practices, a consortium of such entities, or any other entity the Secretary determines to be appropriate to carry out such programs. In Phase I of this program, the Secretary shall develop, test, and evaluate chronic care improvement programs using randomized clinical trials in specific geographic areas. In Phase II, the Secretary shall expand the program to additional geographic areas, or even nationwide, if specific conditions of success have been met during Phase I. The Secretary will identify eligible individuals who may benefit from these programs, but participation will be voluntary.
- Organizations must meet performance standards and will be required to refund fees the Secretary paid to them if such fees exceed estimated savings. Chronic care improvement programs must be budget neutral.
- Funds will be appropriated as is necessary, from the Medicare Trust Funds, to establish agreements with chronic care improvement programs. Funding may not exceed $100 million in aggregate increased expenditures (after taking into account savings attributable to these programs) over the 3-year period beginning October 1, 2003.

Effective Date:

- 12 months after enactment.

Sec. 722. Medicare Advantage Quality Improvement Programs

Current law:

- The Medicare+Choice program has a quality assurance program to ensure that organizations monitor and measure health care data. The program includes monitoring and evaluating high

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volume and high-risk services and the care of acute and chronic conditions. The organizations are required to evaluate the effectiveness of these efforts.

Provision:

- Requires each Medicare Advantage (MA) organization to have an on-going quality improvement program to improve the quality of care provided to enrollees in each MA plan, with the exception of private fee-for service and MSA plans. As part of the quality improvement program, each MA organization shall have a chronic care improvement program to identify and monitor enrollees with multiple or sufficiently severe chronic conditions, as defined by the MA organization.
- An MA organization can be accredited (and periodically reaccredited) by a private accrediting organization as long as the private accrediting organization has been deemed by the Secretary to apply and enforce quality standards that meet/exceed quality standards that the Secretary has established.
- Each MA organization must collect, analyze, and report data that measure health outcomes and other indices of quality. The Secretary is not permitted to collect data on quality, outcomes, and beneficiary satisfaction for purposes of consumer choice and program administration if the data were not already collected as of November 1, 2003. If the Secretary wishes to change the types of quality data that MA organizations must submit, the Secretary must consult with MA plans, and accrediting organizations and submit a report to Congress on the reasons for such changes.

Effective Date:

- Contract years beginning on or after January 1, 2006.

Sec. 723 Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy

Current law:

- None.

Provision:

- Within 6 months of enactment, the Secretary must develop a research and data plan to improve the quality of care and reduce the cost of care for chronically ill Medicare eligible individuals. The plan is required to integrate

existing datasets, identify new data needs and a methodology to address them, plan for the collection of this new data in a data warehouse, and develop a research agenda using such data. Not later than two years after enactment, the plan must be implemented. Appropriations are authorized (such sums as may be necessary in FYs 2004 and 2005).

Effective Dates:

- Plan developed within 6 months of enactment.
- Plan implemented within 2 years of enactment.

Subtitle D—Other Provisions

Sec. 731. Improvements in National and Local Coverage Determination Process to Respond to Changes in Technology

Current law:

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Coverage Advisory Committee (MCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD).

Provision:

- This provision requires the Secretary to develop guidance documents concerning the factors considered in making national coverage determinations (NCDs), and sets timeframes for completing NCDs (6 months for NCDs not requiring outside technology assessment or deliberation by the MCAC; 9 months for NCDs requiring such assessment or deliberation, when a clinical trial is not involved).
- The provision establishes processes and timeframes for public comment on draft NCDs, and the issuance of final NCDs, including responses to public comments., The provision requires public disclosure of the clinical evidence and data considered if the decision differs from that recommended by the MCAC. If an NCD request is granted, the Secretary will assign and implement a temporary or permanent billing code. The Secretary must also implement revised procedures for issuance of temporary national HCPCS codes for Part B services.
- The provision requires the Secretary to develop plans to evaluate whether local coverage determinations (LCDs) should be adopted nationally, and to promote greater consistency among LCDs.

- The provision establishes coverage of routine costs associated with clinical trials of Category A (experimental/investigational) medical devices. In the case of a trial initiated before January 1, 2010, the device involved in the trial must be determined by the Secretary to be intended for use in diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

Effective Dates:

- NCD provisions: January 1, 2004.
- LCD provisions: July 1, 2004.
- Procedures for temporary HCPCS codes: July 1, 2004.
- Coverage of Category A clinical trials: January 1, 2005.

Sec. 732. Extension of Treatment of Certain Physician Pathology Services Under Medicare

Current law:

- Section 542 of BIPA required separate payment for the technical component of certain pathology services furnished by an independent laboratory for an inpatient or outpatient of a "covered hospital." The BIPA provision was effective for a two year period beginning January 1, 2001.
- Despite expiration of the BIPA moratorium after 2002, CMS (in a Program Memorandum dated January 17, 2003) directed the carriers to continue the moratorium until they received further instructions from CMS.

Provision:

- This provision continues direct payment for the technical component of certain pathology services for 2005 and 2006.

Effective Date:

- Effective for services furnished on or after January 1, 2005.

Sec. 733. Payment for Pancreatic Islet Cell Investigational Transplants for Medicare Beneficiaries In Clinical Trials

Current law:

- Pancreatic islet cell transplants are an investigational therapy and Medicare has a national non-coverage determination for them. Medicare does not pay for pancreatic islet cell transplants.

Provision:

- Requires the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation, which includes Medicare eligible individuals (under either Part A, Part B, or both). Requires Medicare to pay for both the routine costs, including immunosuppressive drugs, as well as for the transplantation and appropriate related items and services for eligible individuals in clinical trials.

Effective Date:

- Payments begin not earlier than October 1, 2004.

Sec. 734. Restoration of Medicare Trust Funds

Current law:

- The Secretary of the Treasury and the Secretary of Health and Human Services must ask for a legislative fix from Congress to correct clerical errors in order to restore the appropriate level of funding to the Medicare Trust Funds.

Provision:

- This provision gives the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, legal authority to transfer money from the general fund to the

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Medicare Trust Funds (HI and SMI) in order to restore interest income lost by the Trust Funds because of the clerical error that occurred on April 15, 2001.

- The Secretary of the Treasury must take certain actions with respect to the Trust Funds with the goal of correcting Trust Fund holdings to replicate, to the extent practicable, the holdings that would have been held by the Trust Funds if the clerical error had not occurred. To fulfill this goal, the Secretary of the Treasury must issue to the Trust Funds certain obligations and redeem others in addition to restoring interest income.
- This provision also gives the Secretary of the Treasury legal authority to transfer money from the general fund to the Medicare Trust Funds (HI and SMI) to correct clerical errors that occur after April 15, 2001, provided that the Secretary of the Treasury notifies the appropriate committees of Congress of the error and the actions to be taken, before such action is taken.

Effective Dates:

- For the clerical error that occurred on April 15, 2001, effective upon enactment and transfer of money required not later that 120 days after enactment.
- For clerical errors occurring after April 15, 2001, effective upon enactment.

Sec. 735. Modifications to Medicare Payment Advisory Commission (MedPAC)

Current law:

- At present, MedPAC does not have to consider the budgetary implications of its recommendations. Additionally, MedPAC members are currently required to publicly disclose financial and other conflicts of interest through a system established by the Comptroller General. Current law does not require MedPAC to include a member with pharmaceutical expertise.

Provision:

- This provision requires that MedPAC examine budgetary consequences, whether directly or through consultation with outside experts, before making any recommendations.
- This provision (Sec. 735(c)) also requires that MedPAC members be treated as employees of Congress and therefore must adhere to the Ethics in Government Act of 1978 with respect to disclosure.
- The provision (Sec. 735(d)) also requires MedPAC to produce two new reports, one detailing the need for current data and sources to determine the financial circumstances of Medicare providers, and a second reporting on investments, endowments and other financing endeavors of Medicare-participating hospitals as well as access to capital financing for private and for not-for-profit hospitals.
- The provision also requires MedPAC to include an expert in "pharmaco-economics" or prescription drug benefit programs on the Commission.

Effective Dates:

- Sec. 735(c), personal disclosure: January 1, 2004
- Sec. 735(d), the new reports: Not later than June 1, 2004.

Sec. 736 Technical Amendments

Current law:

- Provisions exist in current law, but with technical errors in the text.

Provision:

- Corrects current law with technical amendments.

Effective Date:

- Upon enactment.

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

Sec. 801. Inclusion in Annual Report of Medicare Trustees of Information on Status of Medicare Trust Funds

Current law:

- The Medicare Trustees for both the Medicare Part A and Part B Trust Funds must report to Congress by April 1 of each year on the operation and status of each of the Trust Funds during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years. The reports do not include information about whether Medicare outlays exceed any particular percentage of general revenues.

Provision:

- The provision requires that the Medicare Trustees include as part of their annual report a new section reviewing the impact on general revenues for both the Medicare Part A and Part B Trust Funds (this includes the new Part D drug account), beginning with the report in 2005. The report will include a determination of trust fund balances, and whether the projected general revenue Medicare funding exceeds 45% for that fiscal year or for any of the succeeding six fiscal years. A Medicare funding warning is made if 2 years in a row, general revenues are expected to exceed 45% of total Medicare spending in any of the 7 fiscal years in the reporting period.

Effective Date:

- Beginning with reports to Congress by April 1, 2005.

Sec. 802. Presidential Submission of Legislation

Current law:

- None.

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

Provision:

- If there is a Medicare funding warning under section 801(a)(2) of this Act (concerning a determination by the Medicare Trustees that there is projected

to be excess general revenue funding in a given fiscal year), the President is required to submit to Congress proposed legislation to respond to such warning.

- Such proposed legislation should be designed to eliminate excess general revenue Medicare funding for the 7 fiscal year period that begins in a given fiscal year.
- The President is not required to submit the proposed legislation if legislation is enacted during the year in which the warning is made which eliminates excess general revenue Medicare funding.

Effective Date:

- Upon Enactment

Sec. 803. Procedures in the House of Representatives

Current law:

- None

Provision:

- Requires the Majority Leader and the Minority Leader of the House of Representatives, or their designees, to introduce legislative proposals submitted by the President in response to the warning by the Medicare Trustees of excess general revenue Medicare funding (as specified in section 801 of this Act)
- Requires the Chairman of the Committee on the Budget of the House to certify whether or not the proposed legislation eliminates excess general revenue Medicare funding for each fiscal year in the 7 fiscal year reporting period.

Effective Date:

- Upon Enactment

Sec. 804. Procedures in the Senate

Current law:

- None.

Provision:

- If the Presidents submits a legislative proposal pursuant to section 801 of this Act, then the Majority Leader and Minority Leader of the Senate (or their designees) shall introduce this proposal.
- The proposed legislation shall be referred to the Committee on Finance. If the Committee on Finance has not reported Medicare funding legislation by June 30 of a year in which the President is required under section 801 of this Act to submit a Medicare funding warning

proposal, then any Senator may move to discharge the Committee of any single Medicare funding legislation measure.

Effective Date:

- Upon Enactment

Subtitle B—Income-Related Reduction in Part B Premium Subsidy

Sec. 811. Income-Related Reduction in Part B Premium Subsidy

Current law:

- The Medicare Part B premium is set at 25% of estimated program spending in a given year. The income of the beneficiary is not a criterion for determining the premium of the beneficiary.

Provision:

- Generally, this provision increases Part B premiums for certain eligible individuals who meet certain income thresholds.
- The income thresholds, where an eligible individual's modified adjusted gross income exceeds the threshold, are: $80,000 for an individual's tax return and $160,000 for a joint tax return (both amounts updated by an inflation adjustment).
- Data for the modified adjusted gross income of the eligible individual for purposes of this threshold are generally determined using income from two taxable years prior to the year involved. The Secretary of the Treasury supplies these data to the Commissioner of Social Security. If the eligible individual is a non-filer, the Commissioner of Social Security, in consultation with the Secretary, must prescribe regulations for the treatment of such eligible individuals. Income from the tax return would include interest for the eligible individual that had been tax exempt in the taxable year.
- The Commissioner of Social Security, in consultation with the Secretary of the Treasury, must establish procedures under which an eligible individual's modified adjusted gross income shall, at the eligible individual's request, be determined using a more recent taxable year than the taxable year otherwise applicable. The Commissioner and the Secretary of the Treasury must establish a methodology for making the request, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.
- A request to use a more recent taxable year may only be granted when: (1) the eligible individual furnishes to the Commissioner documentation for the recent taxable year, such as a copy of a filed Federal tax return or an equivalent document; and (2) the eligible individual's modified adjusted gross income for the more recent taxable year is significantly less than such income determined under the rules described above by reason of the death of the eligible individual's spouse, the marriage or divorce of such eligible individual,

or other major life changing events specified in regulations prescribed by the Commissioner, in

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consultation with the Secretary.

Reducing the Government Subsidy

- If the eligible individual meets the income threshold, the government's subsidy will be less than the current 75%.
- If the modified adjusted gross income for an eligible individual is:
  Greater than $80,000 and less than $100,000, the government subsidy is 65%;
  Greater than $100,000 and less than $150,000, the government subsidy is 50%;
  Greater than $150,000 and less than $200,000, the government subsidy is 35%;
  Greater than $200,000, the government subsidy is 20%.
- The smaller federal subsidies are phased-in over 5 years. The phase-in percentages are:
  For 2007, 20% of the reduced federal subsidy;
  For 2008, 40% of the reduced federal subsidy;
  For 2009, 60% of the reduced federal subsidy;
  For 2010, 80% of the reduced federal subsidy;
  For 2011 and each subsequent year, 100% of the reduced federal subsidy.

Effective Date:

- The increase in premiums for eligible individuals is effective January 2007.

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

TITLE IX—Administrative Improvements, Regulatory Reduction, and Contracting Reform

Sec. 900. Administrative Improvements Within the Centers for Medicare & Medicaid Services (CMS)

Current law:

- The Secretary of Health and Human Services has authority for administering the Medicare program. The Secretary originally created the Agency that administers the Medicare and Medicaid programs in 1977 under his

administrative authority. Title 5 of the U. S. Codes sets the Administrator's salary at level IV of the Executive Schedule. The Secretary has delegated the responsibility for the Medicare and Medicaid programs to the Administrator of the Centers for Medicare & Medicaid Services (CMS).

Provision:

- The Secretary must ensure that no later than January 1, 2008, CMS will have a Center administering the Medicare Advantage (Part C) and Voluntary Prescription Drug Benefit (Part D) programs. The Center's director will report to the Administrator.
- The Secretary may employ for the purposes of administering Parts C and D, such management staff as appropriate and these individuals should have private sector expertise in negotiations with health benefits plans. The management staff should have superior expertise from either the public or private sector in at least one of the following areas:
    - Review, negotiation, and administration of health care contracts;
    - Design of health care benefit plans;
    - Actuarial sciences;
    - Compliance with health plan contracts;
    - Consumer education and decision making; and,
    - Other areas to be specified by the Secretary.
- The management staff should be paid based on their expertise, experience and performance but in no case will the rate of compensation exceed the highest rate of basic pay for the Senior Executive Service under section 5382 (b) of title 5, United States Code.
- The Chief Actuary's office should have an actuary dedicated to Parts C and D.
- The grade level of the Administrator of CMS will increase to an Executive Level III.

Effective Dates:

- Not later than January 1, 2008, implementation for the Center and the flexibilities in the Center's management staff
- January 1, 2004, the grade level of the Administrator of CMS will increase to an Executive Level III

Subtitle A—Regulatory Reform

Sec. 901. Construction; Definition of Supplier

Current law:

- No provision.

Provision:

- Clarifies the relation of this Title to current law and legal remedies; defines supplier.

Effective Date:

- Upon enactment.

Sec. 902. Issuance of Regulations

Current law:

- Section 1871 of the Social Security Act codifies several requirements and procedures for issuing regulations for the Medicare program. The statute also incorporates some of the rulemaking procedures and exceptions permitted under the Administrative Procedure Act, 5 U.S.C. §553. There is no specific statutory provision concerning "logical outgrowth."

Provision:

- The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish a regular timeline for the publication of final regulations based on the publication of a proposed regulation or an interim final regulation.
- If the timeline established for an interim final regulation expires before a final regulation is issued, the interim final regulation will not remain in effect unless the Secretary publishes a notice of continuation (for a 1-year extension) that includes an explanation for not complying with the deadlines.
- The Secretary is required to submit a report to Congress that describes and explains the instances when a final regulation was not published within the applicable timeline.
- This provision requires that final regulations be the logical outgrowth of a notice of proposed rulemaking or interim final rule. If it is not a logical outgrowth, the rule can be treated as a proposed regulation and shall not take effect until there is a further opportunity for public comment.

Effective Date:

- With respect to the timeline for issuing regulations, effective on enactment. The Secretary shall provide for an appropriate transition to take into account previously published interim final rules. With respect to logical outgrowth, effective for final rules published on or after December 8, 2003.

Sec. 903. Compliance with Changes in Regulations and Policies

Current law:

- In general, there is a presumption against retroactive rulemaking. The Supreme Court has recognized that the Medicare Act did not authorize retroactive final rules. The Administrative Procedure Act specifies that there be a 30-day delay between publication of a final rule and the effective date of that rule. The statute permits an agency to waive this requirement in appropriate circumstances.

Provision:

- Substantive changes in policy will not be applied retroactively, unless the Secretary determines that such retroactive application would be necessary to comply with statutory requirements or that failure to apply substantive changes retroactively would be contrary to the public interest.
- A substantive change may not take effect until at least 30 days after the Secretary has issued a substantive change. If waiver of the 30-day period is necessary to comply with statutory requirements or if the application of the 30-day period is contrary to the public interest, the Secretary may alter the timeline by including an explanation of such finding in the issuance or publication of the substantive change.
- No action shall be taken against a provider for noncompliance before the effective date of a substantive change.
- Prohibits certain penalties and interest if a provider or supplier follows erroneous written guidance from the government or its agents, who are acting within the scope of the contractor's authority, in specified circumstances. The remedy is available for providers and suppliers. The erroneous guidance must relate to the furnishing of items and services and submission of a claim for benefits for such item or service with respect to such provider or supplier. Permits recoupment or repayment of overpayment in certain circumstances.

Effective Date:

- No retroactive application of substantive changes applies to changes issued on or after the date of enactment; 30 day timeline goes into effect regarding compliance actions taken on or after the date of enactment; for reliance on guidance provisions the effective date is upon enactment but only for guidance provided on or after July 24, 2003.

Sec. 904. Reports and Studies Relating to Regulatory Reform

Current law:

- None.

Provision:

- Directs the GAO to conduct a study to determine the appropriateness and feasibility of providing the Secretary with authority to issue legally binding advisory opinions on the

interpretation and application of Medicare regulations and submit a report to Congress within one year of enactment.

- In 2 years, and to continue every 3 years, the Secretary will report to Congress about areas of inconsistency and conflict among Medicare's various statutory and regulatory provisions.
- This report will also include (1) information from eligible individuals, providers, suppliers, the Medicare Beneficiary Ombudsman, and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and (3) recommendations from the Secretary for appropriate legislation or administrative actions.

Effective Date:

- Upon enactment

Subtitle B—Contracting Reform

Sec. 911. Increased Flexibility in Medicare Administration

Current law:

- Under current law, Medicare contracting is not subject to competition (contracts generally operate on an automatic renewal basis from year to year). In addition, current Medicare contracts are not framed to offer performance incentives.

Provision:

- Consolidation and flexibility in contracting - (1) Establishes Medicare Administrative Contractors (MACs) in place of fiscal intermediaries and carriers; (2) allows the Secretary to enter into contracts with "any eligible entity" for: determining and making payments, eligible individual education and assistance, provider consultation, communication, provider education, and technical assistance; (3) authorizes MACs to make local coverage determinations; (4) sets forth minimum conditions for eligibility to be a MAC: ability to perform the functions, compliance with Federal Acquisition Regulation (FAR) conflict of interest standards, sufficient financial assets to support performance of the functions; and permits the Secretary to impose other requirements; (5) requires the Secretary to assure that contracts with MACs do not duplicate activities carried out under the Medicare Integrity Program; and (6) states that the FAR applies, except when inconsistent with other requirements.
- Contracting requirements—Sets forth a number of requirements including that the Secretary use competitive procedures when entering into contracts with MACs; allowing the Secretary to renew a contract if the MAC has met or exceeded all applicable performance requirements, but contracts must be re-competed every 5 years; allowing the Secretary to transfer functions among MACs without regard to competition; requiring the Secretary the notify providers of services and suppliers when a function is transferred to another

provider Additionally, the Secretary may provide incentives for MAC's to provide higher quality and efficiency services; the Secretary is required to develop contractor performance requirements and standards for measuring whether the contractor has met such requirements. MACs must

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furnish information and reports to the Secretary on a timely basis and maintain records sufficient to assure the correctness of information and reports. Finally, surety bonds may be required of MACs and any of their officers or employees certifying payments or disbursing funds.

- Terms and Conditions—Contracts with MACs may contain such terms and conditions as the Secretary finds necessary. The Secretary may not require MACs to match data obtained from other non-Medicare activities for the purposes of MSP and other activities.
- Limitation on liability—Limits liability of certifying/ disbursing officers who did not act with reckless disregard or intent to defraud and no MAC will be liable to the United States unless it acted with reckless disregard of its obligations under its contract, or with intent to defraud. Authorizes the same indemnification to contractors as is current practice so long as the contractor's conduct giving rise to the dispute was not criminal, fraudulent or grossly negligent).
- The amendments do not apply to section 1816 and 1842 contracts in effect (or entered into) before October 1, 2005 until such contracts are let out for competitive bidding (all such contracts that begin on or after October 1, 2011 must go through a competitive bidding process.).
- Report on implementation—Requires the Secretary to submit to Congress several reports and proposals regarding the implementation and progress associated with this provision.

Effective Date:

- Requirement to submit a proposal for implementation - October 1, 2004; MAC contracts begin to be competitively bid October 1, 2005; All MAC contracts set to begin on or after October 1, 2011 must be competitively bid; All contracts must be re-competed every 5 years, first re-competition no later than October 1, 2010; Secretarial reports to Congress October 1, 2008.

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

Current law:

- There are no comparable provisions in Title XVIII however other statutory and regulatory provisions already require existing Medicare contractors to comply with extensive information security requirements, many of which parallel the requirements established here.

- Specifically, the contractors are already required to comply with the provisions of the Federal Information Security Management Act of 2002, including the eight subsections of 44 U.S.C. 3544(b). In addition, by April 20, 2005, all contractors are required to come into compliance with HIPAA Security Rule provisions. While both of these require periodic system testing and evaluation, they do not require such activities on an annual basis.

Provision:

- The provision requires MACs, as well as existing FIs and carriers, to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program is required to meet certain requirements for information security programs already imposed on Federal agencies and their data contractors by the Federal Information Security Reform Act under title 44 of the United States Code. MACs are also required to undergo an annual independent testing and evaluation of their information security programs. The independent audits are to be performed by entities that meet standards for independence established by the OIG. The MACs are required to submit the results of the independent evaluations to the Secretary and the HHS OIG. The OIG of HHS is required to report to Congress annually on the results of the evaluations. The Secretary is required to address the results of the evaluations in required management reports.

Effective Date:

- Current FIs and carriers are required to undergo the first independent evaluation within one year after the date of enactment and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. Provisions affecting MACs are effective when MAC contracts begin to be effective, sometime after 10/1/2005.

Subtitle C—Education and Outreach

Sec. 921. Provider Education and Technical Assistance

Current law:

- None, but some duplicate current CMS practice.

Provision:

- Directs the Secretary to coordinate the education activities provided through Medicare contractors to maximize the effectiveness of Federal education efforts for providers; directs the Secretary to use specific claims payment error rates or similar methodology to give contractors an incentive to implement effective provider education and outreach; requires prompt responses from contractors to provider and eligible individual questions, including written responses within 45 days and responses to toll free lines;

requires monitoring of contractor responses for accuracy; provides increased funding beginning in FY 2005 for enhanced provider education and training through the MIP; and requires Medicare contractors to take into consideration the special needs of small providers when conducting education and training activities.

Effective Date:

- Use of specific claims error rates - October 1, 2005; Coordination of education activities - October 1, 2004.

Sec. 922. Small Provider Technical Assistance Demonstration Program

Current law:

- None.

Provision:

- Requires the Secretary to establish a demonstration program and contract with qualified entities to offer technical assistance, upon request, to small providers and suppliers. Providers who participate in this demonstration program must pay an amount equal to 25% of the technical assistance.

Effective Date:

- October 1, 2008

Sec. 923. Medicare Beneficiary Ombudsman

Current law:

- Under current law, the Secretary is required to prepare and distribute an annual notice explaining Medicare benefits and limitations on coverage. The Secretary is also required to provide information via a toll-free telephone number.

Provision:

- Directs the Secretary to appoint a Medicare Beneficiary Ombudsman within HHS who would receive complaints and requests for information from Medicare eligible individuals; provide assistance to those eligible individuals; and submit an annual report describing activities and recommending changes to improve program administration. Requires that HHS provide a toll-free number to allow eligible individuals to get answers to Medicare questions.

Effective Dates:

- Appointment of Medicare Beneficiary Ombudsman - 1 year after enactment.
- Provision of information through toll-free number - upon enactment.

Sec. 924. Beneficiary Outreach Demonstration Program

Current law:

- None.

Provision:

- Requires the Secretary to establish a 3-year demonstration program under which Medicare specialists will provide advice and assistance to Medicare eligible individuals in at least 6 local Social Security offices (including 2 in rural areas).

Effective Date:

- Upon enactment

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

Current law:

- None.

Provision:

- Requires the Secretary to provide information concerning the number of remaining covered days in a skilled nursing facility (SNF) stay on notices to eligible individuals.

Effective Date:

- 6 months after enactment

Sec. 926. Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans

Current law:

- None.

Provision:

- Requires the Secretary to make available information identifying Medicare-participating SNFs. Also requires such information to be provided in hospital discharge plans.

Effective Date:

- Not later than 6 months after enactment

Subtitle D—Appeals and Recovery

Sec. 931. Transfer of Responsibility for Medicare Appeals

Current law:

- Historically, Social Security Administration (SSA) administrative law judges (ALJs) have performed the Medicare hearings function, pursuant to a Memorandum of Understanding with HHS. Section 522 of the Benefits Improvement and Protection Act of 2000 (BIPA) requires ALJs of the SSA to handle appeals of Medicare local coverage decisions.

Provision:

- Requires SSA and HHS to develop and implement a plan for transferring the Medicare hearings function from SSA to HHS, while maintaining ALJ independence from CMS.
- Requires GAO to evaluate the plan within 6 months of the plan's submission to Congress. Contains a technical amendment deleting the requirement that SSA ALJs hear all appeals of local coverage determinations.

Effective Dates:

- Plan—Not later than April 1, 2004
- Transfer—Not earlier than July 1, 2005; not later than October 1, 2005

- Technical amendment regarding SSA ALJs - Upon enactment.

Sec. 932. Process for Expedited Access to Review

Current law:

- Under the current process, a single ALJ or DAB member may determine a case is appropriate for expedited access to the Federal courts. Additionally, the current process is not subject to stringent timelines for decision making. Generally, administrative appeals must be exhausted prior to judicial review.
- There is currently no expedited process for appealing provider agreement determinations.

Provision:

- Requires the Secretary to establish a process to expedite access to judicial review for legal issues that cannot be resolved administratively, and requires expedited review of certain provider agreement determinations, including determinations where termination or certain other immediate remedies are being imposed, or where a facility's nurse aide training program is disapproved based on a finding of substandard quality of care. Requires the

Secretary to establish a process for waiver of disapproval of nurse-aide training programs if an imposed CMP is not related to quality of care.

Effective Date:

- October 1, 2004

Sec. 933. Revisions to Medicare Appeals Process

Current law:

- Under current law, the third level of appeal is to an administrative law judge (ALJ). The ALJs who hear Medicare cases are employed by the Social Security.
- Also under current law, at the reconsideration, fair hearing and ALJ levels, there are no limits on the submission of evidence.
- Determinations and denials of appeals currently include the reasons for the denial and information on how to appeal the denial.
- Section 521 of the Benefits Improvement and Protection Act of 2000 (BIPA) requires the creation of a new level, the qualified independent contractor, or QIC, to review appeals from the contractor. Appeals from QIC decisions are to an ALJ. Section 521 of BIPA also required not fewer than 12 QICs.

Provision:

- Section 933(a) requires providers and suppliers to present all evidence for an appeal to a qualified independent contractor (QIC). Absent a showing of good cause, providers and suppliers are precluded from introducing evidence at a later stage.

- Section 933(b) provides for the use of beneficiaries' medical records in appeals reconsiderations by QICs.
- Section 933(c) amends the notice requirements for Medicare appeals by requiring that where a claim is denied, a written notice of decision is required. The notice must include the reasons for the decision and must be written in a manner calculated to be understood by the beneficiary. This notice must inform the beneficiary of the right to appeal the decision and include instructions on how to initiate such an appeal.
- Finally, section 933(d) imposes new eligibility requirements and qualifications for QICs and reduces the minimum number of QICs from 12 to 4.

Effective Dates:

- Evidence requirements - October 1, 2004
- Use of Patients' Medical Records - Upon enactment
- Notice Requirements for Medicare Appeals - Upon enactment

- Reduction in Minimum Number of QICs - Upon enactment
- Other QIC requirements - as if enacted by BIPA 2000

Sec. 934. Prepayment Review

Current law:

- Although not required by law, it is current CMS policy to use random prepayment review only to develop contractor-wide or program-wide payment error rates as required by this provision.

Provision:

- Limits random prepayment review to the development of contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations. A contractor may not initiate a non-random prepayment review of a provider based on the voluntary disclosure by the provider of an improper billing practice unless there is a likelihood of a sustained or high level of payment error. Requires the Secretary to issue regulations establishing a concrete endpoint for prepayment review.

Effective Date:

- Random prepayment review limitation goes into effect 1 year after enactment; regulations must be issued no later than 1 year after enactment.

Sec. 935. Recovery of Overpayments

Current law:

- Although not required by law, CMS currently offers a repayment plan for providers who need an extension. CMS instructs its contractors to provide individual consideration to every provider who requests a repayment plan and CMS also currently offers consent settlements in certain situations. Many of these provisions are current practice under CMS' Progressive Corrective Action policy.

Provision:

- Requires the Secretary to establish repayment plans in case of hardship. If a provider chooses to appeal, efforts to recoup an overpayment cannot be taken until a reconsideration is made by a QIC. Until the QICs are implemented, Medicare contractors cannot recoup an overpayment until their internal level of review has been exercised. A contractor may request the periodic production of supporting documentation for a limited sample of submitted claims to ensure that a previous practice is not continuing. Prohibits Medicare contractors from using extrapolation to determine

overpayment amounts to be recovered unless there is a sustained or high level of payment error or documented educational intervention has failed to correct the payment error. Describes the process surrounding consent settlements, including the information the Secretary must give the provider, the timeframe for a provider response, and the courses of action available if there is an overpayment. Requires the Secretary to establish a process to notify classes of providers when a particular code is being over-utilized. Describes the rights of a provider when under audit by a Medicare contractor, including the right to written notice, review and explanation of the audit, and appeal rights. Requires the Secretary to establish a standard methodology for Medicare contractors to use when selecting a probe sample of claims for review in the presence of an aberrant billing pattern.

Effective Dates:

- The majority of the provisions in this section are effective upon enactment.
- The limitation on extrapolation applies to statistically valid random samples initiated after one-year after enactment of the Act.
- The Secretary must establish the procedure for notification of overuse of billing codes no later than one year after enactment.
- The Secretary must first establish a standard methodology for selection of sample claims for abnormal billing patterns no later than one year after enactment.

Sec. 936. Provider Enrollment Process; Right of Appeal

Current law:

- None.

Provision:

- Requires the Secretary to establish a process by regulation under which there are deadlines for action on enrollment applications, including renewals. Providers whose applications to enroll (or renew) are denied are provided a mechanism to appeal the denial. Requires the Secretary to consult with providers, physicians, practitioners and suppliers before making changes in the provider enrollment forms.

Effective Date:

- Enrollment process must be created within 6 months of enactment, consultation process is effective January 1, 2004, and hearing rights are effective for denials occurring no later than 1 year after enactment.

Sec. 937. Process for Correction of Minor Errors and Omissions Without Pursuing Appeals Process

Current law:

- None. Under current CMS policy, CMS has a wage data correction process wherein hospitals may verify the accuracy of wage data used to calculate the wage index and request changes when their data are incorrect. This process is bounded by the CMS timeline for finalizing the wage data to be published in the hospital inpatient PPS final rule.

Provision:

- Directs the Secretary to develop a process where, in the case of minor errors or omissions that are detected in the submission of claims, a provider or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal.

Effective Date:

- No later than 1 year after enactment.

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

Current law:

- None.

Provision:

- Requires the Secretary to establish a process under which physicians and eligible individuals can receive a prior determination as to whether an item or service is eligible for coverage.
- Eligible individuals or "requesters" are narrowly defined for purposes of this subsection.
- The Secretary must establish a process for the collection of information regarding advance eligible individual notices and must also establish a program to provide outreach and education concerning the appropriate use of advance eligible individual notices.
- In general, prior determinations are not subject to further administrative appeal or judicial review and the decision not to seek prior determination or a negative determination does not impact the right to obtain services, seek reimbursement, or appeal rights.
- The provision requires a GAO report on the use of advance beneficiary notices not later than 18 months after the effective date of this provision. Additionally, not later than 36 months after the effective date of the provision the Comptroller General shall submit to Congress a report on the use of the prior determination process.
- This provision sunsets in 5 years.

Effective Date:

- Effective not later than 18 months after enactment, sunsetting 5 years after effective date.

Sec. 939. Appeals by Providers when there is no Other Party Available

Current law:

- Section 1870 of the Social Security Act provides for the recovery of overpayments and the settlement of claims for benefits on behalf of a deceased beneficiary.

Provision:

- Allows a provider or supplier to appeal a determination by the Secretary in the case where an eligible individual dies before assigning appeal rights.

Effective Date:

- Upon enactment.

Sec. 940. Revision to Appeals Timeframes and Amounts.

Current law:

- Section 521 of the Benefits Improvement and Protection Act of 2000 (BIPA) requires fiscal intermediaries (FIs) and carriers and QICs to render redeterminations and reconsiderations, respectively, in 30 days. Currently, FIs are required to complete 90% of reconsiderations in 90 days; Part B carriers are required to complete 95% of reviews in 45 days, and 90% of hearings in 120 days.

Provision:

- Increases timeframes for decision-making at the lower levels of the appeals process (contractor and QIC) to 60 days (from 30). Requires dollar amounts in controversy to be adjusted annually by the percent increase of the Medicare component of the consumer price index for urban consumers.

Effective Dates:

- Timeframes - Upon enactment
- Amounts in Controversy - January 1, 2005

Sec. 940A. Mediation Process for Local Coverage Determinations

Current law:

- None.

Provision:

- Establishes a mediation process wherein a physician trained in mediation, and employed by CMS, shall mediate in disputes between providers of services, suppliers, and the medical director for a Medicare Administrative Contractor

(MAC) whenever the regional administrator determines there was a pattern and large number of complaints regarding decisions made by the medical director or there is a complaint from the co-chair of the advisory committee for that contractor to the regional administrator regarding a dispute. Contract performance requirements for MACs used by the Secretary to measure a MAC's performance must include specific performance duties expected of a MAC's director,

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including requirements related to professional relations and the availability of the director to conduct medical determination activities within the MAC's jurisdiction.

Effective Date:

- Upon enactment

Subtitle E—Miscellaneous Provisions

Sec. 941. Policy Developments Regarding Evaluation and Management (E&M) Documentation Guidelines

Current law:

- None.

Provision:

- Requires the Secretary if he wishes to implement any new modified documentation guidelines, to (1) conduct pilot testing of new evaluation and management documentation guidelines used for physician services; (2) develop a program to educate physicians on using the evaluation and management guidelines; (3) conduct a study of simpler, alternative systems of documentation for physician claims; and (4) conduct a study of the appropriate coding for certain extended office visits.

Effective Date:

- Upon Enactment

Sec. 942. Improvement in Oversight of Technology and Coverage

Current law:

- CMS addresses issues related to coverage of new technology through the Medicare Technology Council, which was established by CMS in early 2003. The Council meets on a regular basis to review medical technologies and to facilitate coordination between CMS components.
- The Benefits Improvement and Protection Act of 2000 (BIPA) required CMS to establish coding and payment procedures for new clinical laboratory tests,

including opportunities for public consultation. Those procedures have been in place for over two years, including an annual public meeting to receive public testimony and evidence.

Provision:

- This provision establishes a Council for Technology and Innovation charged with coordinating coverage, coding and payment processes with respect to new technologies and procedures (including new drug therapies), as well as the exchange of information between CMS and other entities making similar decisions. The Council is comprised of CMS staff and chaired by an official designated by the Secretary.

- The provision requires the Secretary to establish procedures for determining the basis for, and amount of, payment for new clinical diagnostic laboratory tests, including procedures for public input into such determinations. The required procedures include notice and an opportunity for public comment. The provision applies to tests for which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.
- The provision directs GAO to study external data collection for use in the inpatient payment system. Such study may include an evaluation of the feasibility and appropriateness of using quarterly samples, special surveys, or other methods, and shall consider whether other executive agencies are best suited to collect such information.

Effective Date:

- Council for Technology: no date specified.
- Lab payment processes: applicable to tests assigned new or substantially revised HCPCS codes on or after January 1, 2005.
- GAO report due October 1, 2004.

Sec. 943. Treatment of Hospitals for Certain Services Under Medicare Secondary Payor (MSP) Provisions

Current law:

- In certain instances when an eligible individual has other insurance coverage, Medicare becomes the secondary payor. Currently, the law requires an entity furnishing a Part B service to obtain information from the eligible individual on whether other insurance coverage is available.

Provision:

- Prohibits the Secretary from requiring a hospital which furnishes reference laboratory services to obtain information relating to the MSP provisions in

connection with those services if the same requirements are not imposed upon those provided by an independent laboratory.

Effective Date:

- Upon enactment.

Sec. 944. EMTALA Improvements

Current law:

- Medicare covers items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury, including medically necessary emergency services. There is no current law provision specifically addressing coverage obligations under the Medicare fee-for-service program for EMTALA-related services.
- Current law requires review by a peer review organization (now called quality improvement organizations) prior to the imposition of civil monetary penalties for certain EMTALA violations.

Provision:

- This provision requires that Medicare medical necessity determinations for EMTALA-mandated services shall be based on information (including the patient's presenting symptoms or complaint) available at the time the item or service was ordered or furnished (not on the patient's principal diagnosis). Such determinations shall not consider the frequency with which the item or service was provided before or after the time of the emergency admission or visit.
- The provision also requires the Secretary to establish a procedure for notifying hospitals and physicians when an EMTALA investigation is closed, and to request review by a peer review organization before making a compliance determination that could lead to termination of a hospital's Medicare participation for EMTALA violations related to the appropriateness of a screening exam, stabilizing treatment, or an appropriate transfer.

Effective Dates:

- Medicare coverage: January 1, 2004.
- Notification process: no date specified.
- Peer review: upon enactment.

Sec. 945. Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group

Current law:

- None.

Provision:

- This provision establishes a 19-member technical advisory group to review EMTALA regulations, provide advice and recommendations to the Secretary regarding those regulations, solicit comments and recommendations regarding the implementation of regulations, and disseminate information regarding the application of such regulations.

Effective Date:

- No date specified.

Sec. 946. Authorizing Use of Arrangements to Provide Core Hospice Services in Certain Circumstances

Current law:

- Hospices are required by law and regulation to provide "substantially all" core services using their own employees. A hospice that cannot provide substantially all core services with its own employees may not be able to accept some patients. Currently, if a patient travels outside of the hospice's service area, the patient must transfer to another hospice.

Provision:

- Authorizes use of arrangements with other hospice programs to provide core hospice services in certain exigent or extraordinary circumstances. Also allows contracting for highly specialized services.

Effective Date:

- Upon enactment.

Sec. 947. Application of OSHA Blood Borne Pathogens Standard to Certain Hospitals

Current law:

- None.

Provision:

- Requires participating hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 to comply with the Bloodborne Pathogens standard. A hospital that fails to comply with this requirement is subject to a civil money penalty in an amount similar to the amount of civil money penalties that may be imposed under section 17 of the Occupational

Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard.

Effective Date:

- July 1, 2004

Sec. 948. BIPA-Related Technical Amendments and Corrections

Current law:

- Provides for advisory committees and panels of experts organized by those committees to provide advice and recommendations concerning national or local coverage determinations at section 1114.

Provision:

- Transfers national or local coverage determination advisory panel provisions from section 1114 to section 1862, changes certain statutory references from "policies" to "coverage determinations," and makes other technical corrections.

Effective Date:

- Effective as if included in BIPA.

Sec. 949. Conforming Authority to Waive a Program Exclusion

Current law:

- The Secretary is required to exclude individuals and entities from participation in federal health programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under state health programs; (2) convicted of a criminal offense related to patient abuse or neglect under federal or state law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program finance or operated by the federal, state or local government; or (4) convicted of a felony related to a controlled substance.

Provision:

- Expands the waiver authority applicable to mandatory program exclusions, permitting the granting of exclusion waivers in cases where an administrator of a Federal health care program determines that the subject is a sole community physician or sole source of essential specialized items or services in a community, and that the exclusion would impose a hardship on the Medicare program's eligible individuals. The Secretary may waive the exclusion after consulting with the HHS Office of Inspector General.

Effective Date:

- Upon enactment.

Sec. 950. Treatment of Certain Dental Claims

Current law:

- Under current law, providers of services submitting claims to Medicare must be enrolled in the Medicare program. Certain services, including dental services are excluded from coverage under Medicare except in rare instances.

Provision:

- Prohibits group health plans providing supplemental or secondary coverage from requiring dental providers to file claims for services excluded from coverage under §1862(a)(12) of the Social Security Act.
- Enables a group health plan to obtain a Medicare claim decision in cases involving (or appearing to involve) inpatient dental hospital services or dental services expressly covered by Medicare based upon actions of the Secretary.

Effective Date:

- 60 days after the date of enactment.

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

Current law:

- None. Hospitals currently may obtain Medicaid information only through the state eligibility verification system or by filing a Medicaid claim.

Provision:

- Beginning not later than 1 year after enactment, the Secretary shall arrange to furnish hospitals the data necessary to compute the number of patient days used in computing the Medicare DSH formula for the hospital for the current cost year.

Effective Date:

- Effective immediately, with a delay of required implementation.

Sec. 952. Revisions to Reassignment Provisions

Current law:

- Section 1842(b)(6) of the Social Security Act establishes the Medicare reassignment prohibitions. In order for an independent contractor to reassign Medicare benefits, the services must be performed on the premises of the entity to which the benefits will be reassigned.

Provision:

- Allows physicians to reassign payment for Medicare covered services to entities with which they have an independent contractor arrangement, such as a medical group, a physician management organization or staffing company.

Effective Date:

- Upon enactment.

Sec. 953. Other Provisions

Current law:

- None.

Provision:

- Requires the Comptroller General to submit a report on the appropriateness, stability, and predictability of the updates in the conversion factor for the physician fee schedule, including the appropriateness of the sustainable growth rate formula for 2002 and succeeding years and possible alternatives to the formula, within 6 months of enactment.
- Requires the Secretary to make available to the public a list of the national coverage determinations issued the previous year along with information on how to get more information with respect to such determinations.
- Requires the Comptroller General to submit within 6 months of enactment a report on the implications of allowing flexibility in the application of the Medicare conditions of participation for home health agencies with respect to those patients who are not Medicare eligible individuals.
- Requires the Inspector General to submit a report within a year of enactment on the extent to which hospitals provide notice to Medicare eligible individuals before they use the 60 lifetime reserve days and the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they completely exhaust the lifetime reserve days.
- Requires the Comptroller General to submit to Congress a report within 12 months of the date of enactment on all aspects of physician compensation for services furnished under Medicare, including how the aspects interact, the effect on appropriate compensation for physician services, and a review of alternatives to the current physician fee schedule.

Effective Dates:

- Within 6 months of enactment.
- Upon enactment.

- Within 6 months of enactment.
- Within a year of enactment.
- Within 12 months of enactment.

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

Sec. 1001. Medicaid Disproportionate Share Hospitals (DSH) Payments

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 each fiscal year 1998 through 2002. 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. Such increases are not available, however, to the extent that a state's DSH payment would exceed 12% of spending for medical assistance under the state plan 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 FY 2001 and for FY 2002. The provision also clarified that the FY 2003 allotments were to be calculated in the same manner as regular states, using the lower, pre-BIPA levels for FY 2002 in those calculations.
- 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 are equal to 1% of the state's total amount of expenditures under its plan for such assistance during that fiscal year. For subsequent fiscal years, the allotment for an extremely low DSH state is equal to its allotment for the previous year, increased by the percentage change in the CPI-U for the previous year; except that such increases are only available if the total DSH payment would be below 12% of that state's total medical assistance payments in that year.
- 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.

Provision:

- Provides a temporary one-year 16% increase in DSH allotments for FY 2004 without regard to the 12% limit described above. Thereafter, allotments stay at the FY 2004 level until the year in which the allotments as calculated under "Benefits Improvement and Protection Act" (BIPA) "catch-up" with the new provision's allotments, at which point allotment levels are those of the previous year increased by CPI-U.
- Allotments for certain extremely low DSH states would be increased by 16% for each of five fiscal years 2004 through 2008. For FY 2009 and each succeeding fiscal year, the allotment levels would be those for the previous year increased by the CPI-U. Qualifying states include

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those which had DSH expenditures for FY 2000 that were greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year.

- Establishes a contingent DSH allotment, subject to the 12% cap, for FY 2004 or FY 2005 for Tennessee and Hawaii should these states lose their state-wide Section 1115 waivers which do not provide for a state-specific DSH allotment.
- With respect to fiscal year 2004 and each fiscal year thereafter, the Secretary shall require a state, as a condition of receiving Medicaid matching payments, to submit an annual report that:
    - Identifies each DSH hospital that received a payment adjustment for the preceding fiscal year and the amount of the payment adjustment made to such hospital for the preceding year; and,
    - Other information as the Secretary determines necessary to ensure the appropriateness of the payment adjustments for the preceding fiscal year.
- States must also submit to the Secretary an independent certified audit that verifies:
    - How much hospitals in the state have reduced their uncompensated care costs to reflect the total amount of claimed DSH expenditures;
    - That payment to hospitals complies with the requirements of section 1923(g) establishing hospital-specific payment ceilings;
    - That only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to eligible individuals (described in 1923(g)(1)(A)) are included in the calculation of these hospital-specific limits;
    - That the state included all payments including supplemental payments, in the calculation of such hospital-specific limits; and,

- That the state has separately documented and retained a record of all its costs, claimed expenditures, uninsured costs in determining payment adjustments, and any payments made on behalf of the uninsured from payment adjustments.
- Permits states to use, as the non-Federal share of Medicaid, funds that are transferred from, or expenditures that are certified by, a defined, publicly-owned regional medical center in another state so long as the Secretary determines that the use of these funds is proper and in the interest of the Medicaid program. The statute defines a qualifying center as one that: provides level 1 trauma and burn care services; provides level 3 neonatal care services; is obligated to serve patients, regardless of state of origin; is located within a Standard Metropolitan Statistical Area (SMSA) that includes at least 3 States; serves as a tertiary care provider for patients residing within a 125 mile radius; and, meets the criteria for a DSH hospital defined in section 1923 of the Social Security Act in at least one state other than the one in which the center is located. This provision is effective through December 31, 2005.

Effective Date:

- Upon enactment

Sec. 1002. Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemption for the Medicaid Drug Rebate Program

Current law:

- Medicaid drug rebates for single source and innovator multiple source drugs are calculated based on the greater of 15.1 percent of the Average Manufacturer Price (AMP) or the difference between AMP and 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 HHS Office of Pharmacy Affairs 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. This allows 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.

Provision:

- Exempts purchases of inpatient drugs from Medicaid best price calculations by public hospitals that qualify under section 340B of the Public Health Service Act. Also includes an anti-diversion provision that subjects any drug for inpatient use covered under section 340B to the auditing and record keeping requirements of the 340B program.

Effective Date:

- Upon enactment.

Sec. 1003. Extension of Moratorium

Current law:

- A moratorium for classifying Saginaw Community Hospital as an institution for mental disease (IMD) expired on December 31, 2002. Under current law, this facility could be audited with the possibility of receiving an IMD classification.

Provision:

- Permanently extends the moratorium that expired for HealthSource Saginaw (formerly known as Saginaw Community Hospital) in Michigan.

Effective Date:

- One section effective upon enactment. One provision effective as if made by the Balanced Budget Act of 1997.

Subtitle B—Miscellaneous Provisions

Sec. 1011. Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens

Current law:

- Sec. 4723 of the Balanced Budget Act of 1997 provided $25 million per year for FY 1998-

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2001, divided among the 12 States with the highest number of undocumented aliens, to pay for costs by the state and local governments for emergency health services to such undocumented aliens. That provision has expired.

Provision:

- This section appropriates $250 million per year for FY 2005-2008. Two-thirds of that amount will be allotted for use in all 50 states and the District of Columbia, based on their relative percentages of the total number of undocumented aliens. The remaining one-third will provide additional

allotments for the six states with the largest number of undocumented alien apprehensions.

- The Secretary must directly pay hospitals, physicians, and ambulance providers (including IHS and Tribal) for their otherwise un-reimbursed costs of providing services required by Sec. 1867 of the Social Security Act (EMTALA) and related hospital inpatient, outpatient and ambulance services, as defined by the Secretary, furnished to undocumented aliens, aliens paroled into the U.S. at a U.S. port of entry for the purpose of receiving such services, and Mexican citizens permitted temporary entry to the U.S. with a laser visa.
- Payment will be made from the allotment amounts for the state where the providers are located. The payments will be made quarterly and may be made on the basis of advance estimates with retrospective adjustments.

Effective Date:

- The provision became effective on December 8, 2003. Not later than September 1, 2004, the Secretary must establish a process for eligible providers to request payments.

Sec. 1012. Commission on Systemic Interoperability

Current law:

- No provision.

Provision:

- The Secretary will establish a commission on systemic interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology (IT) standards, including a time line and approaches for prioritizing the standards. The commission will be composed of 11 members appointed by the President and Members of Congress, and will hold hearings and develop a report on its findings.

Effective Dates:

- Report to be submitted no later than October 31, 2005.
- The commission will terminate 30 days after it submits its report.

Sec. 1013. Research on Outcomes of Health Care Items and Services

Current law:

- The Agency for Healthcare Research and Quality (AHRQ) is an agency within the Department of Health and Human Services and exists to support, conduct, and disseminate

research that improves access to care and the outcomes and quality of health care services.

Provision:

- The legislation authorizes and appropriates $50 million for FY 2004 for the Secretary through AHRQ to conduct research to address the scientific information needs and priorities related to improving outcomes, clinical effectiveness and appropriateness of specified health services and treatments including prescription drugs identified by the Medicare, Medicaid, and State Children Health Insurance Programs and to improving the efficiency and effectiveness of these Programs. The Secretary is required to establish a process for developing research priorities.

Effective Dates:

- The Secretary must establish an initial list of priorities no later than 6 months after enactment.
- The Secretary must complete the evaluation of the initial priorities and disseminate the research findings within 18 months after the development of that list.
- No later than 18 months after enactment, the Secretary is required to identify voluntary options that could be undertaken by public and private entities to improve information sharing regarding outcomes and quality of care.

Sec. 1014. Health Care that Works for All Americans: Citizens Health Care Working Group

Current law:

- No provision.

Provision:

- The Secretary, acting through AHRQ, must establish this working group to provide a nationwide public debate on improving the health care system to provide every American with the ability to obtain quality and affordable health care coverage. The Secretary will be a member, together with 14 members appointed by the Comptroller General with specified backgrounds. The Comptroller General designates the Chairperson from among the members.
- The Working Group must: hold hearings on specified health care coverage issues; issue a health report to the general public including summaries of specified health care coverage, access, cost, and payment information; hold community meetings throughout the U.S. addressing health care benefits, delivery, and financing; prepare interim recommendations for public comment; and submit final recommendations to the President and Congress, all within specified time frames.
- The President must submit a report to Congress with his views and comments on the final recommendations and his own recommendations for legislation and administrative actions he considers appropriate.

- Up to 10 employees each from HHS and the Labor Department may be detailed to the Working Group without further reimbursement. The Working Group may obtain information it considers necessary to carry out its duties directly from Federal agencies and the agency heads must furnish the information.
- Funding of $3 million per year for FY 2005 and 2006 is authorized to carry out these provisions, plus such sums as are necessary to disseminate the report to the public.

Effective Date:

- Appropriation authorized for FY 2005 and FY 2006.

Sec. 1015. Funding Start-up Administrative Costs for Medicare Reform

Current law:

- No provision.

Provision:

- The bill authorizes appropriations to fund the administrative functions necessary to carry out its provisions by transferring funds from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, not more than $1,000,000,000 for CMS and not more than $500,000,000 for the Social Security Administration (SSA). These amounts are available only until September 30, 2005. SSA may use its portion of these funds to reimburse the Internal Revenue Service for expenses incurred in carrying out provisions of this bill, and the President may authorize further transfers between CMS and SSA.

Effective Date:

- There is no separate effective date for this provision.

Sec. 1016. Health Care Infrastructure Improvement Program

Current law:

- No provision.

Provision:

- A loan program would be established to improve hospital infrastructure, including capital improvement of any hospital, that meets the following criteria. In order to receive assistance, the applicant would be required to 1) engage in cancer research; and 2) be designated by the National Cancer Institute (NCI) as a cancer center or by the state as the official cancer institute. From July 1, 2004 until September 30, 2008, $200 million would be authorized to carry out the loan program, $2 million of which may be used each year by the Secretary for the administration of the program. The Secretary is authorized to forgive such loans if the hospital establishes an

outreach program for cancer prevention, early diagnosis and treatment for a substantial majority of the residents of the state, a similar outreach program for multiple Indian tribes, and either unique research resources or an affiliation with an entity that has unique research resources. No later than 4 years after enactment, the Secretary must submit a report to Congress summarizing the financial performance of the projects that have received assistance under the loan program.

Effective Date:

- Upon enactment.

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

Current law:

- Provision modifies Federal Food, Drug, and Cosmetic Act, Sec. 505 Subchapter A-Drugs and Devices

Provision:

- Sec. 1101 30-month stay of effectiveness. Makes changes in the application process for FDA approval of a generic version of a new drug.
- Sec. 1102 Forfeiture of 180-day exclusivity period. Defines the conditions under which a first applicant for FDA approval of a generic version of a new drug would lose the 180-day exclusivity period that prevents a subsequent applicant from receiving approval for the same drug.
- Sec. 1103 Bioavailability and bioequivalence. Defines 'bioavilability' as the rate and extent to which the active ingredient is absorbed from a drug and becomes available at the site of drug action and gives the Secretary the authority to assess bioavailability and bioequivalence using scientifically valid measures for drugs not intended to be absorbed into the bloodstream.
- Sec. 1104 Conforming amendments. Replaces certain subsections of Section 505A of the Federal Food, Drug, and Cosmetic Act with different subsections.

Effective Date:

- Upon enactment, generally to abbreviated new drug applications submitted after the date of enactment, with numerous exceptions.

Subtitle B—Federal Trade Commission Review

Current law:

- None.

Provision:

- Sec. 1111 Definitions. Defines eight terms used in this subtitle.
- Sec. 1112 Notification of agreements. Outlines requirements for filing agreements between a brand name drug company and a generic drug applicant, or between two generic drug applicants, with the Department of Justice and the Federal Trade Commission
- Sec. 1113 Filing deadlines. States that any filing required under section 1112 must be filed no later than 10 business days after the date the agreement is executed.

- Sec. 1114 Disclosure exemption. Makes any information or material filed pursuant to the subtitle exempt from public disclosure, but does not prevent disclosure to Congress or where relevant to administrative or judicial action or proceeding.
- Sec. 1115 Enforcement. Sets the penalty for failure to comply with the aforementioned requirements at a civil penalty of not more than $11,000 per day for each day that a brand name drug company or generic drug applicant are out of compliance and authorizes the U.S. district court to grant equitable relief.
- Sec. 1116 Rulemaking. Allows the Federal Trade Commission with the concurrence of the Assistant Attorney General to define terms used in the subtitle and to exempt certain applicants or agreements from the aforementioned requirements, and to prescribe additional rules to carry out the purposes of the subtitle.
- Sec. 1117 Savings clause. Provides that any action or failure to take action by the Assistant Attorney General or the Commission under this subtitle shall not prevent any proceedings with respect to the aforementioned agreements under any other provision of law. Provides that any filing under this subtitle shall not create a presumption of any violation of any competition laws.
- Sec. 1118 Effective date. States the effective date of this subtitle.

Effective Date:

- The subtitle shall take effect 30 days after enactment; and shall apply to agreements (described in Sec. 1112) that are entered into 30 days after the enactment date.

Subtitle C—Importation of Prescription Drugs

Current law:

- Provision modifies Section 804 of the Federal Food, Drug, and Cosmetic Act, which is codified but not yet effective per Section 804(1).

Provision:

- Sec. 1121 Importation of Prescription Drugs. Defines the terms and the requirements for the importation by pharmacists and wholesalers of prescription drugs from Canada, including the safeguards that must be in place such that each imported prescription complies with sections 505, 501, and 502 of the Federal Food, Drug, and Cosmetic Act. Also details the Secretary's responsibilities and discretion regarding the maintenance of information and documentation of imported drugs.
- Sec. 1122 Study and report on importation of drugs. Instructs the Secretary in consultation with other appropriate government agencies to conduct a study on the importation of drugs.
- Sec. 1123 Study and report on trade in pharmaceuticals. The President's designees shall conduct a study and report on issues related to trade and pharmaceuticals.

Effective Dates:

- The report called for by section 1122 is due no later than 12 months after enactment.
- Section 1121 is not effective until or unless the Secretary of Health and Human Services certifies to Congress under new section 804(l).

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

Sec. 1201. Health Security Accounts

Current law:

- Health Security Accounts do not exist under current law. However, there are other ways in which current law provides favorable tax status to payments for medical expenses.
- Employer contributions to employee health plans are excludable from employees' gross income (and wages for employment tax purposes). The exclusion applies to coverage for employees, former employees, and dependents.
- Current law provides for two employer-provided arrangements that can be used to pay for or reimburse medical expenses of employees on a tax-favored status; Flexible Spending Accounts (FSAs) and Health Reimbursement Arrangements (HRAs).
    - FSAs - for cafeteria plans, amounts paid for medical care expenses are excludable from gross income and wages for employment tax purposes, as long as the contributions are made on a salary reduction basis. Contributions into these accounts must be used by the end of each year, or they will be forfeited.
    - HRAs - for non-cafeteria plans, amounts paid for medical care expenses are excludable from gross income and wages for employment tax purposes, but contributions cannot be made on a salary reduction basis. Unused fund balances may be rolled over from year to year.
- Archer Medical Savings Accounts (MSAs) permit contributions up to certain limits on a tax-deductible basis when determining adjusted gross income and wages for employment tax purposes when made by an individual or an employer of an eligible individual. Distributions for qualified medical expenses are not includible in gross income. Archer MSAs are only available to the self-employed and to employees of small employers (50 or fewer employees) who are covered under an employer-sponsored high deductible health plan. The tax-deductibility of contributions is limited to 65% of the annual deductible for self-only coverage, and 75% for family coverage.

Provision:

- The provision establishes Health Savings Accounts or HSAs. HSAs are tax-advantaged savings accounts that can be used to pay for medical expenses incurred by individuals, their spouse or their dependents. HSAs may be offered under a cafeteria plan.
- HSAs are similar to MSAs. However, MSA eligibility has been restricted to employees of small businesses and the self-employed. HSAs are open to everyone with a high deductible health insurance plan. The only limitation on the health plan is that the annual deductible must be at least $1,000 for individual coverage and at least $2,000 for family coverage. Rollover contributions from Archer MSAs into HSAs are permitted.

- Contributions to the HSA by an employer are not included in the individual's taxable income. Contributions by an eligible individual are tax deductible. Contributions made by family members of an eligible individual are deductible by the eligible individual. Eligible individuals in 2004 may take above-the-line tax deductions of up to the total yearly contributions, not to exceed $2,600 for individual coverage and $5,150 for family coverage. These amounts will be indexed annually for inflation.
- The interest and investment earnings generated by the account are also not taxable while in the HSA. Amounts distributed are not taxable as long as they are used to pay for qualified medical expenses, such as prescription and over-the-counter drugs and long-term care services as well as the purchase of continued health care coverage for the unemployed individual (via COBRA). Amounts distributed which are not used to pay for qualified medical expenses will be taxable, plus an additional 10% tax will be applied in order to prevent the use of the HSA for non-medical purposes, except if the beneficiary becomes disabled, dies, or attains the age of Medicare eligibility.
- HSAs are portable, so an individual is not dependent on a particular employer to have an HSA. If the individual changes jobs, the HSA goes with the individual. Unused funds in an HSA may be carried over from one year to the next.
- In addition, individuals over age 55 can make extra contributions to their accounts and still enjoy the same tax advantages. In 2004, an additional $500 can be added to the HSA. By 2009, an additional $1,000 can be added to the HSA.

Effective Date:

- For payments made after December 31, 2003.

Sec. 1202. Exclusion from Gross Income of Certain Federal Subsidies for Prescription Drug Plans

Current law:

- Treasury provision.

Provision:

- Special subsidy payments under 1860D-22 made to employment-based retiree health plans for part D eligible participants that attest to being actuarially equivalent to the value of standard prescription drug coverage shall not be counted as gross income.

Effective Date:

- For taxable years ending on or after the date of enactment.

Sec. 1203. Exception to Information Reporting Requirements Related to Certain Health Arrangements

Current law:

- Treasury provision.

Provision:

- FSAs and HRAs are exempted from certain reporting requirements to Treasury.

Effective Date:

- For payments made after December 31, 2003.

The summary nature of this document does not lend itself to a full explanation of all of these changes. There may be nuances and exceptions contained in the statutes that are not discussed in this summary. Moreover, this general summary is not a legal document and is not intended to grant rights, impose obligations, create interpretive rules, or establish general statements of policy. While we have made significant efforts to verify the accuracy of this publication, we refer readers to the United States Public Law for a full and accurate statement of its contents.
