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Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Updated December 9, 2003

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Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Summary

On December 8, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173. On November 22, the House of Representatives voted 220 to 215 to approve H.R. 1, the Medicare prescription drug and modernization conference agreement. The Senate voted 54 to 44 to approve the conference agreement on November 25.

The Act creates a prescription drug benefit for Medicare beneficiaries and establishes a new Medicare Advantage program to replace the current Medicare+Choice program. The prescription drug benefit, which begins in 2006, is voluntary and beneficiaries would pay a monthly premium after enrolling. Until that time, beneficiaries would have access to a drug discount card to obtain discounts on their drug purchases.

Medicare Advantage establishes payments based on a system of bids and benchmarks. One area of major difference during the conference was the so-called “premium support” provisions of H.R. 1 whereby the original Medicare fee-for-service program would be required to compete against the new Medicare Advantage program. The Act creates a 6-year Comparative Cost Adjustment program in which the concept of premium support would be applied in a limited number of Metropolitan Statistical areas (MSAs). The Act also provides a stabilization fund to create incentives for plans to enter into and remain in the Medicare Advantage program.

The Act includes a measure that would require congressional consideration of legislation if general revenue funding for the entire Medicare program exceeds 45%. In addition, the Medicare Part B premium would be increased for high-income beneficiaries beginning in 2007 and phased in over 5 years and the Part B deductible would increase to \$110 in 2005 and be indexed beginning in 2006. The Act contains numerous provisions that would generally increase fee-for-service Medicare payments, especially for rural health care providers, and would modify numerous regulatory and administrative practices. The Act also makes changes to the Medicaid program and authorizes new tax-advantaged accounts for medical expenses called health savings accounts.

Earlier this year, under Congress' FY2004 budget resolution, \$400 billion was reserved for Medicare modernization, creation of a prescription drug benefit, and, in the Senate, to promote geographic equity payment. The Congressional Budget Office (CBO) has estimated that the conference agreement for H.R. 1 would increase direct (or mandatory) spending by \$394.3 billion from FY2004 through FY2013. Prescription drug spending is estimated at \$409.8 billion over the 10-year period and Medicare Advantage spending at \$14.2 billion. The fee-for-service provisions are estimated to save \$21.5 billion over the 10-year period and the cost containment measures are estimated to save \$13.3 billion over the period.

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The Act adds a prescription drug benefit and replaces the existing Medicare+Choice program with a new program, called the Medicare Advantage program. The prescription drug benefit, which begins in 2006, is voluntary and beneficiaries would pay a monthly premium after enrolling. Until that time, beneficiaries would have access to a drug discount card to obtain discounts on their drug purchases.

Medicare Advantage establishes payments based on a system of bids and benchmarks. One area of major difference during the conference was the so-called “premium support” provisions of H.R. 1 whereby the original Medicare fee-for-service program would be required to compete against the new Medicare Advantage program. The Act creates a 6-year Comparative Cost Adjustment program in which the concept of premium support would be applied in a limited number of Metropolitan Statistical areas (MSAs). The Act also provides a stabilization fund to create incentive for plans to enter into and remain in the Medicare Advantage program.

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Prescription Drugs

Voluntary Prescription Drug Benefit Program

Overview.

The legislation establishes a new Voluntary Prescription Drug Benefit Program under a new Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new optional benefit will be established under a new Part D. Beneficiaries will be able to purchase either “standard coverage” or alternative coverage with actuarially equivalent benefits. In 2006, “standard coverage” will have a \$250 deductible, 25% coinsurance for costs between \$251 and \$2,250, then no coverage until the beneficiary has out-of-pocket costs of \$3,600 (\$5,100 in total spending). Once the beneficiary reaches the catastrophic limit, the program will pay all costs except for nominal cost-sharing. Low income subsidies will be provided for persons with incomes below 150% of poverty. Coverage will be provided through prescription drug plans or Medicare Advantage prescription drug (MA-PD) plans. The program will rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies covering the bulk of the risk will be provided to encourage participation. Plans will determine payments and will be expected to negotiate prices.

Program Design.

Eligibility and Enrollment. Each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage through enrollment in a prescription drug plan. A beneficiary enrolled in a Medicare Advantage (MA) plan (see below) providing qualified prescription drug coverage (MA-PD plan) will obtain coverage through that plan. In general, MA enrollees may not enroll in a prescription drug plan under Part D.

The Secretary is required to establish a process for enrollment, disenrollment, termination, and change of enrollment of eligible beneficiaries in prescription drug plans. The Secretary is required to use rules similar to, and coordinated with rules established for MA-PD plans. A 6-month initial enrollment period, beginning November 15, 2005, will be established for all persons who are eligible beneficiaries on that date; it is the same period established for enrollment for MA plans for that year. An initial enrollment period will apply for individuals becoming eligible after that date; in no case can such period be less than 6 months.

The Secretary is required to conduct activities that are designed to broadly disseminate information to eligible beneficiaries and prospective eligible beneficiaries. It must be available at least 30 days prior to the initial enrollment

¹ See [ftp://ftp.cbo.gov/48xx/doc4808/11-20-MedicareLetter.pdf] for cost estimate.

period. The information dissemination requirements are similar to and are to be coordinated with the activities the Secretary is required to perform for MA plans. Comparative information is to include information on benefits and formularies under a plan; monthly beneficiary premium; and beneficiary cost-sharing.

Prescription Drug Benefits. The legislation specifies the requirements for qualified prescription drug coverage. Qualified coverage is defined as either “standard prescription drug coverage” or “alternative prescription drug coverage” with at least actuarially equivalent benefits. In both cases, access would have to be provided to negotiated prices for covered drugs. Plans are permitted to provide supplemental prescription coverage consisting of either certain reductions in cost-sharing (i.e. reduction in deductible, reduction in coinsurance percentage, and increase in initial coverage limit) or coverage of drugs which are excluded because of application of the Medicaid definition of covered drugs. A PDP sponsor may not offer a plan that provides supplemental benefits unless it also offers a basic plan in the area.

For 2006, “standard prescription drug coverage” is defined as having a \$250 deductible; 25% coinsurance up to the initial coverage limit (\$2,250, accounting for \$750 in total out-of-pocket costs and \$2,250 in total spending); then no coverage until the beneficiary had out-of-pocket costs of \$3,600 (\$5,100 total spending). Once the beneficiary reached the catastrophic (“stop loss”) limit, the program would pay costs, except for nominal cost-sharing. The cost-sharing is equal to the greater of: 1) a copayment of \$2 for a generic drug or preferred multiple source and \$5 for any other drug; or 2) 5% coinsurance. Nothing is to be construed as preventing a PDP sponsor or MA organization from reducing the cost-sharing for preferred or generic drugs. Beginning in 2007, the annual dollar amounts would be increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12-month period ending in July of the previous year.

Plans would be permitted to substitute cost-sharing requirements, for costs up to the initial coverage limit, that were actuarially consistent with an average expected 25% coinsurance for costs up to the initial coverage limit. They could also apply tiered copayments (i.e. different levels, depending on whether a generic, preferred multiple source, or other drug is used) provided such copayments were actuarially consistent with the average 25% cost-sharing requirements.

The Act specifies incurred costs that count toward meeting the catastrophic limit. Costs are only considered incurred if they are incurred for the deductible, cost-sharing, or benefits not paid because of application of the initial coverage limit. Incurred costs do not include amounts for which no benefits are provided because of the application of a formulary. Costs would be treated as incurred costs only if they were paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, or under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs.

Coverage offered by a PDP plan sponsor or a MA-PD entity would be required to provide beneficiaries with access to negotiated prices. Access would be provided even when no benefits were payable because of the application of cost-sharing or an initial coverage limits. Negotiated prices are to take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include dispensing fees. The PDP sponsor or MA-PD entity is required to disclose to the Secretary the aggregate negotiated price concessions made available to the sponsor or organization and passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Secretary.

Beneficiary Protections for Qualified Prescription Drug Coverage.

The Act establishes beneficiary protection requirements for qualified prescription drug plans. PDP plan sponsors are required to disclose to each enrolling beneficiary information about the plan's benefit structure. Sponsors will be required to furnish to enrollees, at least monthly, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors are required to permit the participation of any pharmacy that meets the plan's terms and conditions. A PDP could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Secretary to the plan. The PDP sponsor is required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. The Secretary will establish convenient access rules that are no less favorable to enrollees than rules for convenient access established for the TRICARE Retail Pharmacy program. The rules would include adequate emergency access for enrolled beneficiaries. Sponsors will permit enrollees to receive benefits (which may include a 90-day supply) through a community pharmacy, rather than through mail-order, with any differential in charge paid by enrollees.

If a PDP sponsor uses a formulary, it would have to meet certain requirements. A pharmaceutical and therapeutic committee would develop and review the formulary. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice. The committee would also take into account whether including a particular covered drug in the formulary (or in a particular tier in a formulary) had therapeutic advantages in terms of safety and efficacy. The formulary would have to include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes.

The Secretary is required to request the United States Pharmacopeia to develop in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by plans. The Secretary's request would also include the revision of such classification from time to time to reflect changes in therapeutic uses of covered drugs and the addition of new covered drugs. The plan sponsor can not change therapeutic categories and classes in a formulary

other than at the beginning of a plan year, except as the Secretary may permit to take into account new therapeutic uses and newly approved covered drugs. Each sponsor is required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary. Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to the Secretary, beneficiaries, and physicians, pharmacies, and pharmacists. The plan must provide for periodic evaluation and analysis of treatment protocols and procedures.

The PDP sponsor would be required to have (directly, or indirectly through arrangements) a cost-effective drug utilization management program; quality assurance measures, a medication therapy management program; and a program to control fraud, waste, and abuse.

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

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

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

PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs. The Secretary will provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology.

Electronic Prescription Program. The Act requires the Secretary to develop electronic prescription standards. The standards apply to prescriptions for covered part D drugs and required information that are transmitted electronically under an electronic prescription drug program that meets the following requirements. The program must provide for the electronic transmittal of information on eligibility and benefits (including formulary drugs, any tiered formulary structure, and prior authorization requirements), information on the drug being prescribed and other drugs listed in the patient's medication history (including drug-drug interactions), and information on the availability of lower-cost, therapeutically appropriate alternative drugs. Additionally, the program must provide for the electronic transmittal of the patient's medical history. Disclosure of information must meet the requirements of the HIPAA privacy rule and, to the extent feasible, be on an interactive, real-time basis.

Access, PDP Regions; Submission of Bids; Plan Approval.

Access to a Choice of Qualified Prescription Drug Coverage. The Secretary is required to assure that each beneficiary has available a choice of enrollment in at least 2 qualifying plans in the area in which the beneficiary resides. At least one plan has to be a prescription drug plan. The requirement is not satisfied for an area if only one PDP sponsor or one MA organization offering a MA-PD plan offers all the qualifying plans for the area.

The Act permits the Secretary, in order to assure access, to approve limited risk contracts (as discussed below). Only if access is still not provided, will the Secretary provide for the offering of a fallback plan.

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

Submission of Bids. Each PDP sponsor is required to submit to the Secretary specified information at the same time and in a similar manner as such information is submitted by MA organizations. The information to be submitted is: 1) information on the prescription drug coverage to be provided; 2) the actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile; 3) information on the bid including the basis for the actuarial value, the portion of the bid attributable to basic coverage and if applicable, the portion attributable to supplemental benefits, and assumptions regarding reinsurance subsidy payments; 4) service area; 5) level of risk assumed including whether the sponsor requires a modification of risk level and if so the extent of the modification; and 6) such other information required by the Secretary..

Plan Approval. The Secretary will review the submitted information for purposes of conducting negotiations with the plan. The Secretary has the authority to negotiate the terms and conditions of the plans. The authority is similar to the

authority the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans. The Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors. Further, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.

After review and negotiation, the Secretary will approve or disapprove the plan. The Secretary may only approve a plan if certain requirements are met. The plan must comply with Part D requirements, including those relating to beneficiary protections. The Secretary must determine that the plan and the sponsor meet requirements relating to actuarial determinations. Further, the Secretary may not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to discourage enrollment by certain beneficiaries. The Secretary may not make a finding with respect to design of categories and classes within a formulary if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

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

Fallback. If required access is not provided, including through a limited risk plan, the Act establishes a fallback process. The Secretary is required to establish a separate process for the solicitation of bids from eligible fallback entities. A single fallback entity may not offer all fallback plans throughout the United States. The Secretary can only approve one fallback plan for all fallback service areas in any PDP region for a contract period. Competitive contracting provisions apply. The Secretary shall approve fallback plans so that if there are any fallback service areas in the region for the year, they are offered at the same time as prescription drug plans would otherwise be offered. Fallback prescription drug plans are permitted to offer only standard prescription drug coverage and meet such other requirements specified by the Secretary. The fallback plan would not be permitted to engage in any marketing or branding of the contract.

Under a fallback contract, the Secretary would pay actual costs of Part D covered drugs taking into account negotiated price concessions. Payment would also be made for prescription management fees tied to performance management requirements established by the Secretary. Beneficiary premiums under fallback plans would be uniform and equal to 26% of the Secretary's estimate of the average monthly per capita actuarial cost (including administrative costs) to the entity offering the fallback plan. The federal government would pay the remainder.

In general, contract requirements for fallback plans would be the same as those established for prescription drug plans. A contract for a fallback plan would be for

3 years (and be renewable after a subsequent bidding process. However, a contract could not apply in an area in any year unless the area was a fallback service area.

Contract Requirements. The Act establishes organizational requirements for PDP sponsors. In general, a PDP sponsor must be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the Secretary for entities not licensed by the state. To the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that are not covered by direct subsidy payments. PDP plan sponsors would be required to enter into a contract with the Secretary under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment.

Premiums.

The conferees have stated that the average monthly beneficiary premium in 2006 will be \$35 and represent, on average, 26% of the cost of the benefit provided. The Act specifies the calculation as follows. The monthly beneficiary premium for a prescription drug plan is defined as the base beneficiary premium, as adjusted. The base beneficiary premium equals the product of the beneficiary premium percentage and the national average monthly bid amount. The beneficiary premium percentage is equal to: 1) 26%, divided by 2) 100% minus a percentage equal to total reinsurance payments divided by the sum of such reinsurance payments and total payments the Secretary estimates will be paid to prescription drug plans in a year that are attributable to the standardized bid amount (taking into account amounts paid by the Secretary and enrollees and the application of risk adjustment). The national average monthly bid amount is a weighted average of standardized bid amounts for each prescription drug plan and each MA-PD plan. Once the base beneficiary premium is calculated, it is adjusted up or down, as appropriate, to reflect differences between it and the geographically-adjusted national average monthly bid amount. It is further increased for any supplemental benefits and decreased if the individual is entitled to a low-income subsidy. The premium is uniform for all persons enrolled in the plan, except for those receiving low-income subsidies or those subject to a late enrollment penalty.

Late enrollment penalties would be applied to beneficiaries who failed to maintain creditable coverage for a period of 63 days (within a continuous period of eligibility), beginning on the day after the individual's initial enrollment period and ending on the date of enrollment in a prescription drug plan or MA-PD plan.

Beneficiary premium payments may be paid directly to the PDP sponsor or MA organization. Alternatively the beneficiary has the option of having the amount withheld from his or her social security payment or having payment made through an electronic funds transfer mechanism. Payments withheld are to be paid to the PDP sponsor.

Premium and Cost-Sharing Subsidies for Low-Income Individuals.

The Act provides premium and cost-sharing subsidies for low-income subsidy-eligible individuals. There are two groups of subsidy eligible individuals. The first group is composed of persons who: 1) are enrolled in a prescription drug plan or MA-PD plan; 2) have incomes below 135% of poverty; and 3) have resources in 2006 below \$6,000 for an individual and \$9,000 for a couple (increased in future years by the percentage increase in the CPI). Also included in this group are persons who are dually eligible for Medicare and Medicaid, regardless of whether or not they meet the other eligibility requirements. The second group of subsidy eligible individuals are persons meeting the same requirements, except that the income level is 150% of poverty and an alternative resources standard may be used; this alternative standard in 2006 is \$10,000 for an individual and \$20,000 for a couple (increased in future years by the percentage increase in the CPI).

Individuals with incomes below 135% of poverty, and resources meeting the requirement for the first group, would have a premium subsidy equal to 100% of the low-income benchmark premium amount (essentially a weighted average for the region), but in no case higher than the actual premium amount for basic coverage under the plan. Other low-income subsidy eligible persons will have a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. Persons below 135% of poverty would have a premium subsidy for any late enrollment penalty equal to 80% for the first 60 months of delayed enrollment and 100% thereafter.

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

Eligibility determinations are to be made under the state Medicaid plan for the state or by the Commissioner of Social Security. The determinations shall remain effective for a period determined by the Secretary, not to exceed one year. Full dual eligible persons are to be treated as subsidy eligible persons; the Secretary may provide that other Medicaid beneficiaries be treated as subsidy eligible. The Secretary will provide a process whereby the Secretary will notify the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy.

The Act specifies that Medicare is the primary payer for covered drugs for dual eligibles. Medicaid coverage is not available for such drugs or any cost-sharing for such drugs. In 2006, states are liable for approximately 90% of the costs they would otherwise incur if drug coverage for dual eligibles continued to be offered under Medicaid; by 2015, this percentage drops to 75%.

Subsidies.

Direct subsidies. Federal subsidy payments will be made to qualifying entities. The stated purpose of such payments is to reduce premiums for all beneficiaries consistent with an overall subsidy level of 74% for basic coverage, reduce adverse selection among plans, and promote the participation of PDP sponsors and MA organizations. Such payments would be made as direct subsidies and through reinsurance.

The Act specifies a formula for the calculation of the direct monthly per capita subsidy amount. It is equal to the plans standardized bid amount adjusted for health status and risk and reduced by the base beneficiary premium as adjusted to reflect the difference between the bid and the national average bid. Reinsurance payments, equal to 80% of allowable costs, would also be provided for an enrollee whose costs exceeded the annual out-of-pocket threshold (\$3,600 in 2006).

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

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

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

For 2008-2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5.0% above or below the target level. Plans would be at risk for 50% of spending exceeding 5.0% and below 10.0% of the target level. Additionally, they would be at risk for 20% of any spending exceeding 10% of the target level.

Subsidies for Retiree Plans. Under certain conditions, the Secretary is required to make special subsidy payments to sponsors of qualified retiree prescription drug plans. These payments are to be made on behalf of an individual covered under the retiree plan, who is entitled to enroll under a PDP or MA-PD plan but elected not to. Subsidy payments will equal 28% of a retiree's gross covered retiree plan-related prescription drug costs over the \$250 deductible but not over \$5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.)

Relationship to Other Programs.

The Act requires the Secretary, by July 1, 2005, to establish requirements to ensure effective coordination between a Part D plan (both a prescription drug plan and MA-PD plan) and a state pharmaceutical assistance program. The coordination requirements are to relate to payment of premiums and coverage and payment for supplemental drug benefits. Requirements must be included for enrollment file-sharing, claims processing, claims reconciliation reports, application of the catastrophic out-of-pocket protection, and other administrative procedures specified by the Secretary. Similar coordination provisions are to be applied to other prescription plans including Medicaid (including a plan operating under an 1115 waiver), group health plans, federal employees health benefits plan, military coverage (including TRICARE), and other coverage specified by the Secretary.

Medigap.

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

Medicare Prescription Drug Discount Card

For the period prior to implementation of the new drug program, the Secretary is required to establish a temporary program to endorse prescription drug discount card programs meeting certain requirements. The purpose is to provide access to prescription drug discounts through card sponsors to persons who voluntarily enroll in the program. Each card sponsor is to provide each enrollee with access to negotiated prices. The program will also provide transitional assistance for low-income persons enrolled in endorsed programs.

The Act requires the Secretary to implement the program so that discount cards and transitional assistance are available no later than 6 months after enactment. It would not apply to covered discount card drugs dispensed after December 31, 2005. The Act specifies that persons eligible for the discount card are those entitled to or enrolled under Part A or enrolled under Part B. However, individuals enrolled in Medicaid (or under any Section 1115 Medicaid waiver) who are entitled to any medical assistance for outpatient prescribed drugs would not be a discount card eligible individual.

An individual not enrolled in a card program may enroll in any card program serving residents of the state at any time beginning on the initial enrollment date and before January 1, 2006. A discount eligible individual may only be enrolled in one endorsed card program at a time. An individual enrolled in one program in 2004 could change the election for 2005. A card sponsor may charge an annual enrollment fee, not to exceed \$30.

The Act provides special provisions for low-income persons (defined as those with incomes below 135% of poverty). A transitional assistance eligible individual will be entitled to have his or her discount card enrollment fee paid. Those individuals with incomes below 100% of poverty (special transitional assistance eligible individuals) would be liable for coinsurance charges of 5% of incurred costs up to \$600 in both 2004 and 2005. Other transitional assistance eligible individuals (those with incomes between 100% and 135% of poverty) would be liable for coinsurance charges of 10% of incurred costs up to \$600 in both 2004 and 2005. Thus, the program will pay 95% of a special transitional eligible individual's incurred drug costs up to \$600 in 2004 and 90% of other transitional eligible individual's incurred drug costs up to \$600 in 2004. Similarly, payment would be made for 95% or 90%, whichever is appropriate, of the individual's incurred drug costs up to \$600 in 2005. In addition, any balance left over from 2004 may be added to the amount available in 2005, except no rollover would be permitted if the individual voluntarily disenrolled from an endorsed program. Certain persons would not be eligible for transitional assistance. These are persons who had coverage for drugs under a group health plan, federal employees health benefits plan, or through coverage made available to members of the uniformed services.

Medicare Advantage

The Act establishes the Medicare Advantage (MA) program under Part C of Medicare, to replace the Medicare+Choice program. As under current law, MA local plans will continue to be offered as coordinated care and other plans on a county-wide basis. Beginning in 2006, in addition to the MA *local* plans, the MA program will begin to offer MA *regional* coordinated care plans that cover both in- and out-of-network required services. Beginning in 2010, the Comparative Cost Adjustment (CCA) program will be established for a 6-year period, to: (1) examine a new MA payment system under which payments to MA plans would be based on a weighted average of plans bids; and (2) introduce possible adjustments (either increases or decreases) to fee-for-service Part B premiums, based on a comparison of the costs of providing required fee-for-service benefits to the costs of providing the same benefits in the MA program.

Beneficiaries in MA plans will not be required to enroll in the new prescription drug program, Part D. However, at least one plan offered by an MA organization in an area is required to offer Part D prescription drug coverage. Therefore, if the beneficiary has only one available MA plan from which to choose, then in effect, the beneficiary must enroll in Part D in order to enroll in a plan.

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

For 2004, payments to MA plans will be modified. First, a 4th payment mechanism will be added so that plans will be paid the highest of the floor, minimum percent increase, the blend, or a new amount. The new payment amount is 100% of fee-for-service (FFS) payments made for persons enrolled in traditional Medicare. The FFS payment is calculated based on the adjusted average per capita cost for the year for an MA payment area (a county), for services covered under Medicare Parts A and B for beneficiaries entitled to benefits under Part A, enrolled in Part B and not enrolled in an MA plan. Second, there will be a change made to the blend payment, so that there is no adjustment for budget neutrality in 2004.² Third, the calculation of the minimum percentage increase will also be revised. For 2004 and beyond the minimum percentage increase will be the greater of a 2% increase over the previous year's payment rate (as under current law), or the previous year's payment increased by the national per capita MA growth percentage.

² Under current law, a budget neutrality adjustment is made so that estimated total M+C payments in a given year will be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates, because rates cannot be reduced below the floor or moneyman increase amounts.

Additional changes to the MA program will be made, beginning in 2006. The Secretary will determine MA payment rates by comparing plan bids to a benchmark. Plans will submit bids for providing required Parts A and B benefits. The benchmark will be calculated by updating the previous year's capitation rate by the annual increase in the minimum percentage increase. For plans with bids below the benchmark, the payment will equal the unadjusted MA statutory non-drug monthly bid amount, as adjusted, and the rebate. The rebate will equal 75% of any average per capita savings (the amount by which the risk-adjusted benchmark exceeds the risk adjusted bid). The rebate may be used to provide additional benefits, reduce cost sharing, or may be applied towards the monthly Part B premium, prescription drug premium, or supplemental premium. The remaining 25% of the average per capita savings will be retained by the federal government. For plans with bids at or above the benchmark (for which there are no average per capita monthly savings), the payment amount will equal the FFS area-specific non-drug monthly benchmark amount, as adjusted. For the plans with bids above the benchmark, the enrollee's premium will equal the full amount by which the bid exceeds the benchmark.

Beginning in 2006, the MA program will also begin to offer MA regional coordinated care plans that cover both in- and out-of-network required services. There will be at least 10 regions established and no more than 50 regions. Each MA regional plan must offer a maximum limit on out-of-pocket expenses and a unified deductible. Each year an organization will submit a separate monthly bid amount for *each* plan it intends to offer in a region. Payments will be based on a competitive bidding system, so that the benchmark for MA regions will be calculated using a statutory formula that includes a weighted average of plan bids for the region. For plans with bids below the benchmark (for which there are average per capita monthly savings), the payment will equal the unadjusted MA regional statutory non-drug monthly bid amount, as adjusted, and the rebate. The plan will provide the enrollee a monthly rebate equal to 75% of the average per capita savings. For plans with bids at or above the benchmark (for which there are no average per capita monthly savings), the payment amount will equal the region-specific non-drug monthly benchmark amount, as adjusted. For the plans with bids above the benchmark, the enrollee's premium will be increased by the full amount by which the bid exceeds the benchmark.

The Act also establishes a stabilization fund to provide incentives for plans to enter into and to remain in the MA program. There will be \$10 billion initially provided to the stabilization fund and additional amounts will be added to the fund from a portion of any average per capita monthly savings amounts.³ The Secretary will be responsible for determining the amounts that may be given to MA plans from this fund, based on statutory requirements. For example, the national bonus payment will be available to an MA organization that offers an MA regional plan in every MA region in the year, but only if there was no national plan in the previous year.

³ Beneficiaries receive 75% of average per capita savings in the form of a rebate. The federal government retains the remaining 25% of the average per capita savings and one-half of the amount retained by the federal government is available to the stabilization fund.

During 2006 and 2007, Medicare will share risk with MA regional plans if plan costs fall above or below a statutorily-specified risk corridor. If the Secretary determines that a plan's allowable costs are over 103% of a specified target amount, the plan will receive an additional payment. Conversely, if a regional plan's allowable costs are under 92% of the specified target amount, the plan will receive a decrease in its payment.

The Act requires the Secretary to establish a program for the application of comparative cost adjustment (CCA) in CCA areas. The 6-year CCA program begins January 1, 2010 and ends December 31, 2015. The CCA program is designed to examine the efficiency of private plans in the Medicare program versus traditional Medicare. For that purpose: (1) payments to local MA plans would be based on competitive bids (similar to payments for the regional MA plans), and (2) premiums for individuals enrolled in traditional Medicare could be adjusted, either up or down. Upon completion of the CCA program, the Secretary will submit a report to Congress that evaluates the cost of the program, provider access, beneficiary satisfaction and recommendations for any extension or expansions.

The Secretary will select CCA areas from among those Metropolitan Statistical Areas (MSA), or such similar area as the Secretary recognizes, that meet certain requirements. The requirements for an MSA to qualify as a CCA include: (1) for the reference month in 2010 (defined as the most recent month during the previous year for which the Secretary determines that data are available to compute the relevant calculation) at least 25% of MA eligible individuals who reside in the MSA are enrolled in an MA local plan; and (2) before the beginning of 2010, at least 2 MA local plans will be offered by different organizations in the MSA during the annual coordinated election period, each meeting the current law minimum enrollment requirements for a plan, as of the reference month. The number of MSAs selected may not exceed the lesser of 6 sites or 25% of the number of MSAs meeting the requirements. Additionally, an MA local area (a county) in an MSA will be excluded from the CCA area, if, in 2010, it does not offer at least 2 MA local plans, each offered by a different MA organization.

Payments will be based on a competitive bidding system, so that the benchmark for CCA areas will be calculated using a statutory formula that includes a weighted average of plan bids for the area. Similar to the rebates under the MA program, beneficiaries in CCA areas will receive a rebate, equal to 75% of the average per capita monthly savings, for plans with bids below the CCA benchmark. For plans with bids above the benchmark, the enrollee's premium will be equal to the full amount by which the bid exceeds the benchmark. The CCA program is phased in through 2013. During the first year of the phase-in, 2010, the benchmark is one-fourth CCA benchmark and three-fourths non-CCA benchmark, increasing the CCA share by another one-fourth each year until the benchmark is 100% CCA.

The CCA program will introduce competition between traditional FFS Medicare and local private plans. As a result, an individual residing in a CCA area who is enrolled in Part B of Medicare, but not enrolled in an MA plan, can have an adjustment to his or her Part B premium, either as an increase or a decrease. No premium adjustment will be made for individuals, for a month that they are a subsidy eligible individual (those individuals qualifying for a subsidy under the Part D

prescription drug program). The Part B premium adjustment for FFS beneficiaries in CCA areas will be made as follows: (1) if the FFS area-specific non-drug amount for the month *does not exceed* the CCA non-drug benchmark, the Part B premium is reduced by 75% of the difference; and (2) if the FFS area-specific non-drug amount for the month *exceeds* the CCA non-drug benchmark, the Part B premium is increased by the full amount of the difference. This adjustment will be phased-in over 4 years. There is also a 5% annual limit on the adjustment, so that the amount of the adjustment for a year, can not exceed 5% of the amount of the monthly Part B premium, as otherwise determined.

CBO estimates that over the 10-year period FY2004 - FY2013, direct spending will be increased by \$14.2 billion for the provisions of Title II. Of that total, \$14.1 billion will be for payments to MA plans and \$0.4 for other provisions. Offsetting those costs, CBO estimates savings from the CCA program's payments to plans of \$0.3 billion.

Cost Containment

The Act requires the President to propose and Congress to consider legislation to address Medicare spending any time general revenue funding⁴ of Medicare is projected to exceed 45% in 2 consecutive years. Specifically, the Medicare Board of Trustees of the Hospital Insurance Trust Fund (Part A) and the Supplementary Medical Insurance Trust Fund (Part B) are required to include in their annual reports a determination as to whether "excess general revenue Medicare funding" exceeds 45%. Excess general revenue Medicare funding is general revenue Medicare funding (defined as total Medicare outlays minus dedicated Medicare financing) expressed as a percentage of total Medicare outlays. For the purposes of this provision, total Medicare outlays are defined as total outlays from the Medicare trust funds and includes Medicare administrative expenditures. Dedicated Medicare financing includes Medicare payroll taxes, premiums for Part A⁵, Part B, and Part D, transfers from the Railroad Retirement accounts, taxation of certain OASDI benefits, state transfers for Medicare coverage of beneficiaries who receive public assistance, and gifts⁶.

⁴ Currently, 75% of the Part B trust fund financing comes from general revenues; the remaining 25% comes from beneficiary premiums that beneficiaries voluntarily pay to enroll in Medicare Part B. The 2003 monthly premium is \$58.70. The Part A trust fund revenues come primarily from payroll taxes. Employers and employees each pay 1.45% of the employees earnings, while self-employed workers pay 2.9% of their net income. Other HI revenue sources include interest on the investments of the trust fund, federal income taxes on Social Security benefits, premiums from voluntary enrollees into Part A, railroad retirement account transfers and reimbursement for certain uninsured persons.

⁵ A small number of Medicare beneficiaries are not entitled to Part A but are eligible to purchase the Part A benefit by paying monthly premiums, currently \$316 per month.

⁶ Excluded from the list is interest on the Part A trust fund. According to the Medicare Trustees 2002 report, this amounted to approximately 7.7% of the revenue to the trust fund in 2002.

Beginning with their report in 2005, the Trustees' annual report is required to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for each year within a 7-fiscal-year timeframe, and 10, 50, and 75 years after the fiscal; (2) comparisons with the growth trends for the gross domestic product, private health costs, national health expenditures, and other appropriate measures; (3) expenditures and trends in expenditures under Part D; and (4) a financial analysis of the combined Medicare Part A and Part B trust funds if general revenue funding for Medicare were limited to 45% of total Medicare outlays. The Trustees reports are also required to include a determination as to whether there is projected to be "excess general revenue Medicare funding" for any of the succeeding 6 fiscal years in their annual reports of Medicare's trust funds.

An affirmative determination of excess general revenue funding of Medicare for two consecutive annual reports will be treated as funding warning for Medicare in the second year for the purposes of the President's budget content and submission to Congress. Whenever any Trustees report includes a determination that within the 7-fiscal-year timeframe that there is excess general revenue Medicare funding, the President is required to submit to Congress proposed legislation to respond to the warning. Procedures and timeframes for House and Senate consideration of the legislation are prescribed.

Administration of Medicare Part C and Part D

The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS). Both the House and Senate bills would have established a new agency to administer Medicare Advantage, and Part D, prescription drugs within HHS but separate from CMS. In the Act, a new Center for Beneficiary Services within CMS is established to administer Medicare Advantage, the prescription drug benefit, and beneficiary information activities.

Appeals, Regulatory, and Contracting Provisions

The Act contains numerous provisions addressing Medicare appeals, regulatory relief, and contracting reform. Specifically, the Act modifies the way Medicare regulations and guidance are communicated; modifies the procedures used to resolve payment disputes; and establishes various provider appeal processes, particularly for those who face termination of Medicare participation or denial of their application to participate in the program. The Act refines the information required to be provided in the appeals process and makes other modifications. The administrative law judge (ALJ) function for Medicare hearings is required to be transferred from the Social Security Administration (SSA) to HHS, no later than October 1, 2005. The Act gives the Secretary the authority to competitively contract for claims processing services with any qualified entities; requires these contracts to be competitively bid at least every 5 years; and places new requirements on the Medicare claims processing contractors, including an increased emphasis on provider education.

Other program changes, demonstration projects, and mandated studies are also included in the Act. The Act authorizes increased funding but action by the appropriations committees is required for CMS to receive additional money.

Provisions Affecting Medicare's Fee-for-Service Program Payments, Demonstration Projects, Expansion of Covered Benefits and Beneficiary Cost Sharing

Changes to Medicare's Fee for Service Program

The Act contains extensive changes to Medicare's fee-for-service (FFS) program, including payment increases and, in certain instances, decreases; development of competitive acquisition programs; implementation or refinement of other prospective payment systems (notably, the development of an end-stage renal disease (ESRD) basic payment system); expansion of covered preventive benefits; establishment of demonstration programs; and required studies. The anticipated financial impact of these changes on any individual provider, physician, or supplier will vary depending on many factors, such as the unique characteristics of the individual or entity participating in Medicare as well as the number and type of services provided to the Medicare beneficiaries they serve. Selected highlights of the FFS payment provisions and those establishing preventive care benefits and demonstration programs will be briefly described.

Selected Rural Provider Provisions.

Generally, Medicare payments to certain rural providers are expected to increase; many of the rural provisions will benefit urban providers as well. CBO estimates that the rural provisions in Title IV of the Act will increase Medicare's direct spending by \$9.3 billion from 2004 through 2008 and by \$19.9 billion from 2004 through 2013. It should be noted that other provider payment provisions in H.R. 1 can impact rural providers, but their cost implications for rural providers is unclear.

Rural Hospitals. Rural hospitals (and hospitals in small urban areas) will receive a permanent 1.6% increase to Medicare's base rate or per discharge payment; the limit on rural and small urban hospitals that qualify for disproportionate share hospital (DSH) payments will increase from 5.25% to 12%; hospitals in low wage areas (those with wage index values below 1) will receive additional payments through a decrease from 71% to 62% in the labor-related portion of the base payment rate; certain small rural hospitals with less than 50 beds (those in newly established scarcity areas) will receive cost reimbursement for outpatient clinical laboratory tests; rural hospitals with less than 100 beds will be protected from payment declines associated with the hospital outpatient prospective payment system (OPPS) for an additional 2 years; these OPPS hold harmless provisions will be extended to sole community hospitals for services from 2004 through 2006. CBO estimates that these provisions will increase direct Medicare spending by \$15.6 billion over the 10-year period.

Critical Access Hospitals. Critical access hospitals (CAHs) will have their bed limit increased from 15 to 25; there will be no restriction on the number of these beds that can be used for acute care services at any one time; CAHs will be able to establish distinct part rehabilitation and psychiatric units of up to 10 beds that will not be included in the CAH bed count; cost reimbursement of CAH services will increase to 101% of reasonable costs, starting January 1, 2004; periodic interim payments for CAHs will be authorized; state authority to waive the 35-mile requirement for new entities to qualify as a CAH will be eliminated as of January 1, 2006. CBO estimates that these provisions will increase direct Medicare spending by \$900 million over the 10-year period.

Rural Physicians. Rural physicians in newly established scarcity areas will receive a 5% increase in Medicare payments; physicians in certain low-cost areas with geographic adjustment factors below 1 will receive payment increases so as to increase this factor to 1, starting in 2004 through 2006. CBO estimates that these provisions will increase direct Medicare spending by \$1.7 billion over the 10-year period.

Rural Practitioners. Rural practitioners in rural health clinics and federally qualified health centers will be able to bill separately for services provided to beneficiaries in skilled nursing facilities. CBO estimates that these provisions will increase direct Medicare spending by \$100 million over the 10-year period.

Rural Home Health Providers. Rural home health providers will receive a 5% increase in Medicare payments for one year beginning April 1, 2004. CBO estimates that this one-year increase will increase direct Medicare spending by \$100 million over the 10-year period.

Selected Acute Hospital Provisions.

Generally, Medicare payments to hospitals will increase under the conference report. Acute hospitals paid under the inpatient prospective payment system (IPPS) that submit data on specified quality indicators will receive a full update from 2005 through 2007; those hospitals that do not submit such data will receive an update minus 0.4 percentage points for the year in question. CBO expects that this latter provision will reduce direct spending 0.2 billion from 2004 through 2008. Teaching hospitals will receive an increase of an expected \$400 million in their indirect medical education payments from 2004 through 2006. A one-time, geographic reclassification process to increase hospitals' wage index values for 3 years that is expected to increase payments by \$900 million from 2004 through 2008 will be established. Low volume hospitals with fewer than 800 discharges that are 25 road miles away from a similar hospital may qualify for up to a 25% increase in its Medicare payments. Changes to outpatient hospital payments for covered drugs are expected to increase payments by \$700 million from FY2004 through FY2008. A redistribution of unused resident positions will increase both direct and indirect graduate medical education spending by an anticipated \$200 million from FY2004 through FY2008 and by \$600 million from FY2004 through FY2013. Certain teaching hospitals with high per resident payments will not receive a payment increase from FY2004 through FY2013; this provision was scored by CBO as a reduction in Medicare spending of \$500 million from FY2004 through FY2008 and

\$1.3 billion from FY2004 through FY2013. For 18 months from the date of enactment, physicians will not be able to refer Medicare patients to specialty hospitals in which they have an investment interest. This provision will not apply to hospitals that are in operation or under development before November 18, 2003. Both MedPAC and HHS are to complete required studies on specialty hospitals within 15 months of enactment.

Selected Physician Provisions.

The impact of the Act on Medicare's spending for physician spending is difficult to determine. Although physicians will receive a 1.5% update in 2004 and 2005 which is expected to increase spending by \$2.8 billion from FY2004 through FY2007; subsequently, from FY2008 through FY2012, the provision is expected to result in a decline of \$2.8 billion in Medicare spending. Medicare's payments for practice expenses, particularly the administration of covered drugs, will increase starting in 2004. A transitional adjustment to the drug administration payments of 32% in 2004 and 3% in 2005 is also established. These payment increases are expected to be counterbalanced by a decrease in Medicare's payments for covered outpatient drugs provided in a doctor's office. Many covered outpatient drugs furnished in 2004 will be reimbursed at 85% of the average wholesale price (AWP). Certain of these drugs may be paid as low as 80% of the AWP (as of April 1, 2003). Blood clotting factors and other blood products, drugs or biologicals (drug products) that were not available for payment by April 1, 2003, covered vaccinations, drug products furnished in during 2004 in connection with renal dialysis services, drugs provided through covered durable medical equipment will be paid at a higher rate during 2004. The decline in payments for covered outpatient drugs in 2004 can only be implemented concurrently with the increased payments for the administration of the drugs. Starting in 2005, Medicare's payment for many covered outpatient drugs will be based on average sales price methodology, that uses different pricing and cost data, depending on the prescription drug. Generally, multiple source drugs will be paid 106% of the average sales price; single source drugs will be paid 106% of the lower of the average sales price or the wholesale acquisition costs, unless the widely available market price or the average manufacturer price for those drugs exceeds a certain threshold. Starting in 2006, physicians will have the option of obtaining covered Part B drugs from selected entities awarded contracts for competitively biddable drug products under the newly established competitive acquisition program.

Selected Provisions Affecting Other Providers and Practitioners.

The follow provisions affecting other providers and practitioners are included in the legislation:

Ambulatory Surgical Centers. Payments to ambulatory surgical centers (ASCs) are expected to be lower by \$800 million from FY2004 through FY2008 and by \$3.1 billion from FY2004 through FY2013 as a result of the legislation. ASCs will receive an update of the consumer price index for all urban consumers (CPI-U) minus 3.0 percentage points starting April 1, 2004 and will receive a 0% update for services provided starting October 1, 2004 through December 31, 2009.

Therapy Caps. Application of the caps on outpatient therapy services provided by non-hospital providers is suspended for the remainder of 2003, in 2004 and 2005. CBO estimates that the therapy cap moratorium will increase direct Medicare spending by \$700 million over the 10-year period.

Durable Medical Equipment (DME). Competitive bidding for DME will be phased in beginning in 2007 with 10 of the largest metropolitan statistical areas and may be phased in first among the highest cost and highest volume items and services. The update for most DME items and services and for prosthetics and orthotics is 0 in 2004, 2005, 2006, 2007, and 2008. For 2005, payment for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses will be reduced by an amount calculated using 2002 payment amounts and specified payment amounts by FEHP. Beginning January 1, 2009, items and services included in the competitive acquisition program will be paid as determined under that program and the Secretary can use this information to adjust the payment amounts for DME, off-the-shelf orthotics, and other items and services that are supplied in an area that is not a competitive acquisition area. Class III items (devices that sustain or support life, are implanted, or present potential unreasonable risk, e.g., implantable infusion pumps and heart valve replacements, and are subject to premarket approval, the most stringent regulatory control) receive the full increase in the consumer price index for all urban consumers (CPI-U) in 2004, 2005, 2006, 2008 and subsequent year. The Secretary will determine the update in 2007. CBO scored the DME provisions of the bill as reducing spending by \$6.8 billion over the 10-year period.

Home Health. Home health agency payments are increased by the full market basket percentage for the last quarter of 2003 (October, November, and December) and for the first quarter of 2004 (January, February, and March). The update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points. CBO estimates that this provision will reduce direct Medicare spending by \$6.5 billion over the 10-year period. The Act suspends the requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) until the Secretary reports to Congress and publishes final regulations regarding the collection and use of OASIS.

Selected Fee-for Service Demonstration Projects.

The Act establishes numerous demonstration projects for the Medicare program. Several demonstrations address aspects of disease management for beneficiaries with chronic conditions.

Chronic Care Improvement under Fee-For-Service. The Act requires the Secretary to establish and implement chronic care improvement programs under fee-for-service Medicare to improve clinical quality and beneficiary satisfaction and achieve spending targets for Medicare for beneficiaries with certain chronic health conditions. Participation by beneficiaries is voluntary. The contractors are required to assume financial risk for performance under the contract. CBO has estimated that this demonstration will increase direct Medicare spending by \$500 million over the 10-year period.

Chronically Ill Beneficiary Research, Demonstration. The Act requires the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries within 6 months after enactment. The plan is required to use existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. The Secretary is required to implement the plan no later than 2 years after enactment.

Coverage of Certain Drugs and Biologicals Demonstration. The Secretary is required by the Act to conduct a 2-year demonstration where payment is made for certain drugs and biologicals that are currently provided as “incident to” a physician’s services under Part B. The demonstration is required to provide for cost-sharing in the same manner as applies under Part D of Medicare. The demonstration is required to begin within 90 days of enactment and is limited to 50,000 Medicare beneficiaries in sites selected by the Secretary.

Homebound Demonstration. The Secretary is required to conduct a 2-year demonstration project where beneficiaries with chronic conditions would be deemed to be homebound in order to receive home health services under Medicare.

Adult Day Care. The Secretary is required to establish a demonstration where beneficiaries could receive adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary’s home.

Expansion of Covered Benefits.

The Act contains a number of provisions that expand coverage beginning January 1, 2005, including the following:

Initial Physical Examination. Medicare coverage of an initial preventive physical examination is authorized for those individuals whose Medicare coverage begins on or after January 1, 2005. CBO estimates that this provision will increase direct Medicare spending by \$1.7 billion over the 10-year period.

Cardiovascular Screening Blood Tests. Medicare coverage of cardiovascular screening blood tests is authorized. CBO estimates that this provision will increase direct Medicare spending by \$300 million over the 10-year period.

Diabetes Screening Tests. Diabetes screening tests furnished to an individual at risk for diabetes for the purpose of early detection of diabetes are included as a covered medical service. In this instance, diabetes screening tests include fasting plasma glucose tests as well as other tests and modifications to those tests deemed appropriate by the Secretary. CBO estimates that this provision will increase direct Medicare spending less than \$50 million over the 10-year period.

Screening and Diagnostic Mammography. Screening mammography and diagnostic mammography will be excluded from OPPS and paid separately. CBO estimates that this provision will increase direct Medicare spending by \$200 million over the 10-year period.

Intravenous Immune Globulin. The Act includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare. CBO estimates that this provision will increase direct Medicare spending by \$100 million over the 10-year period.

Beneficiary Cost Sharing in Fee-For-Service

The Act contains two provisions changing beneficiary cost sharing responsibilities under fee-for-service Medicare.

Income Relating the Part B Premium.

The Act increases the monthly Part B premiums for higher income enrollees beginning in 2007. Beneficiaries whose modified adjusted gross income exceed \$80,000 and couples filing joint returns whose modified adjusted gross income exceeds \$160,000 will be subject to higher premium amounts. The increase will be calculated on a sliding scale basis and will be phased-in over a five-year period. The highest category on the sliding scale is for beneficiaries whose modified adjusted gross income is more than \$200,000 (\$400,000 for a couple filing jointly). CBO estimates that direct Medicare spending will be reduced by \$13.3 billion over the 10-year period 2004 through 2013.

Indexing the Part B Deductible.

The Medicare Part B deductible will remain \$100 through 2004, increase to \$110 for 2005, and in subsequent years the deductible will be increased by the same percentage as the Part B premium increase. Specifically, the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance Trust Fund will be used as the index.

Medicaid and Miscellaneous Provisions

Title X of the Act makes some changes to Medicaid and other programs. Omitted from the Act were two provisions contained in S. 1, including a provision to amend the Age Discrimination in Employment Act of 1967 to allow an employee benefit plan to offer different benefits to their Medicare eligible employees than to their non-Medicare eligible employees, and a provision to allow states to cover certain lawfully residing aliens under the Medicaid program.

CBO estimates the Medicaid and other provisions included in the conference agreement will increase direct spending by \$5.7 billion between FY2004 and FY2013. The following general points can be made about the Medicaid and Miscellaneous provisions included in Title X of the Act:

- The Act temporarily increases states' disproportionate share hospital (DSH) allotments to erase the decline in these Medicaid amounts that occurred after a special rule for their calculation expired.

- The Act includes several other Medicaid provisions, including raising the floor on DSH allotments for “extremely low DSH states,” providing DSH allotment adjustments impacting Hawaii and/or Tennessee, increasing reporting requirements for DSH hospitals, and exempting prices of drugs provided to certain safety net hospitals from Medicaid’s best price drug program.
- Miscellaneous provisions in Title X of the Act include funding federal reimbursement of emergency health services furnished to undocumented aliens, and funding administrative start-up costs for Medicare reform, various research projects, work groups and infrastructure improvement programs for the health care system.

Tax Incentives for Health and Retirement Security

Title XII of the Act authorizes new tax-advantaged accounts for medical expenses called health savings accounts (HSAs). These accounts are similar to the medical savings accounts (MSAs) that were authorized by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191), but they will be more widely available and have more generous contribution limits. As is the case with MSAs, unused balances can be carried over from year to year. Contributions to HSAs may be made when individuals have qualifying high deductible medical insurance and no other health insurance, with some exceptions; in 2004, the insurance deductible for self-only coverage must be at least \$1,000 (rather than \$1,700 for MSAs) while for family coverage it must be at least \$2,000 (rather than \$3,450 for MSAs). In 2004, contributions are limited to the lesser of the insurance deductible or \$2,600 for self-only coverage and \$5,150 for family coverage; individuals who are at least 55 years of age but not yet 65 can contribute more. Unlike MSAs, HSAs may be offered through an employer’s cafeteria plan. For more details, see CRS Report RS21573, *Tax-Advantaged Accounts for Health Care Expenses: Side-by-Side Comparison*. The Joint Committee on Taxation estimates that the revenue loss attributable to HSAs for FY2004 through FY2013 will be \$6.4 billion.

Title XII of the Act also includes a provision allowing employers to exclude from gross income the Medicare subsidy payments they receive to maintain prescription drug coverage for their retirees. The Joint Committee on Taxation estimates that the revenue loss attributable to this exclusion for FY2004 through FY2013 will be \$17.8 billion.

The Act does not include two tax provisions that had been in the House bill, one authorizing health savings security accounts (HSSAs) and another allowing up to \$500 in unused benefits in health care flexible spending arrangements to be rolled over to the following year or to an HSA, HSSA, or certain qualified retirement plans.