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## Medicare: Selected Prescription Drug Proposals

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## Summary

The Medicare program does not offer protection against the costs of most outpatient prescription drugs. Some observers suggest that a drug benefit should be added to the federal program while others recommend alternative approaches to assuring access for the target population.

In 1999, the issue received attention as part of the overall discussion of Medicare reform. The National Bipartisan Commission on the Future of Medicare was charged with making recommendations concerning a number of program issues. The Commission failed to get the necessary votes for a reform proposal. The plan designed by Senator Breaux and Congressman Thomas (Co-Chairmen of the Commission) failed 10-7. A modified version of this reform plan was introduced by Senators Breaux and Frist as S. 1895. A significantly modified measure, S. 2807 (referred to as "Breaux-Frist 2000") was introduced June 28, 2000. S. 2807 would give beneficiaries access to outpatient drugs and, in certain cases, other supplemental benefits, through enrollment in either a Medicare Prescription Plus plan offered by a private entity or a Medicare+Choice plan.

The Administration's Medicare reform plan introduced by Senator Moynihan (S. 2342) would establish, as part of the Medicare program itself, an optional prescription drug benefit for all beneficiaries. The federal government would assume the financial risk of covering drug costs up to a specified limit. On June 24, 2000, the Administration announced a revision to its bill; under the revision the benefit would begin in 2002 rather than 2003, have a \$25 monthly premium, and include a first year limit on beneficiary out-of-pocket costs of \$4,000. The Congressional Budget Office (CBO) cost estimate of the revised proposal is \$98.4 billion over the FY2001-FY2005 period and \$337.7 billion over the FY2001-FY2010 period.

On June 28, 2000, the House passed H.R. 4680 (Thomas et al.) by a vote of 217-214. Under the bill, beneficiaries could choose from a variety of private sector plans which would be partially subsidized for assuming the risk of prescription drug costs. There would be a maximum limit on beneficiary out-of-pocket costs (\$6,000 in 2003) and assistance would be provided to low income seniors. The drug benefit and the current Medicare+Choice program would be administered by a new Medicare Benefits Administration. The estimated premium for private sector plans would be \$35 - \$40. The CBO cost estimate for the new drug program is \$35 billion over the FY2001-FY2005 period and \$142 billion over the FY2001-FY2010 period. Associated administrative costs would total an additional \$2 billion over the FY2001-FY2005 period and \$5 billion over the FY2001-FY2010 period.

Senator Roth, Chairman of the Senate Finance Committee has taken a different approach. On September 7, 2000, he introduced two bills (S. 3016 and S. 3017) which would set up a temporary program to provide assistance to states to provide coverage for the low-income and, at state option, to beneficiaries with high drug costs. The Roth bills are intended to be a stop-gap measure until Congress can agree on permanent reforms. This report provides an overview of *selected* plans currently pending before the Congress. It will be updated to reflect any legislative action.

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# Medicare: Selected Prescription Drug Proposals

## Introduction

### Background

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program does not offer protection against the costs of most outpatient prescription drugs. Many observers contend that this is a significant coverage gap. Even though 65% of beneficiaries have some private or public coverage for these costs, they state that many persons do not have adequate supplemental coverage for drug costs and note that, on average, beneficiaries themselves pay for half of their drug costs out-of-pocket.<sup>1</sup>

The absence of a significant drug benefit is not a new concern. The potential cost of adding prescription drug coverage has been the primary impediment to its implementation. Recently the issue has received renewed attention as part of the overall discussion of Medicare reform.

The Balanced Budget Act of 1997 (BBA 97) established the National Bipartisan Commission on the Future of Medicare. This Commission was charged with making recommendations concerning a number of specific program issues. The Commission was required to report its recommendations to Congress by March 1, 1999. However, by statute, any recommendations had to have the approval of 11 of the 17 Commission members.

Coverage of prescription drugs was one of the most difficult issues facing the Commission. Senator Breaux (Statutory Chairman) and Congressman Thomas (Administrative Chairman) offered a Medicare reform proposal to the Commission members. This proposal established a new drug benefit for the low income population. On March 16, 1999, the Commission voted 10-7 for the Breaux-Thomas plan. Since the proposal failed to get the necessary 11 votes, no formal report was made to the Congress or the President.

### 106th Congress Legislation

To date a number of bills have been introduced in the 106<sup>th</sup> Congress which would establish a prescription drug benefit for Medicare beneficiaries. Some measures would add a new benefit to the Medicare program itself. Other proposals

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<sup>1</sup> For background information about Medicare beneficiaries' total and out of pocket prescription drug expenditures see CRS Report RS20612, *Medicare: Prescription Drug Expenditures, 1996*, by Paulette Como.

would establish a separate drug benefit for the Medicare population. Other measures would focus on private insurance coverage. Still other bills would focus on the prices seniors pay for drugs.

The House passed the Medicare Rx 2000 Act (H.R. 4680, as amended) on June 28, 2000. This bill, originally presented as the House GOP plan, was first outlined on April 12, 2000. On June 15, 2000, the plan, now labeled the bipartisan plan, was introduced (H.R. 4680, Thomas, Bliley, Hall, Burr, and Peterson). It was reported by the House Committee on Ways and Means on June 27, 2000 (H.Rept. 106-703, Part 1). The House bill would rely on private insurance companies and other private sector entities to provide coverage. These entities would be partially subsidized for assuming the risk of prescription drug costs. At a minimum plans would have to provide "qualified coverage". "Qualified coverage" would be defined as "standard coverage" or coverage that was actuarially equivalent (i.e. had an equivalent value). "Standard coverage" would be defined as having a deductible (\$250 in 2003), 50% cost-sharing up to the initial coverage limit (the next \$2,100 in 2003, accounting for total spending of \$2,350), and full coverage after an annual limit in out-of-pocket spending (\$6,000 in 2003) had been reached. Assistance would be provided to low-income seniors. The drug benefit and the Medicare+Choice program would be administered by a new Medicare Benefits Administration.

There are several other proposals which have received considerable attention to date. These are the President's plan (S. 2342), the Daschle bill (S. 2541), "Breux-Frist 2000" (S.2807), the Medicare Outpatient Drug Act of 2000 (S.2758), and the Medicare Temporary Drug Assistance Act (S. 3016 and the similar measure S.3017).<sup>2</sup>

On June 29, 1999, President Clinton announced the Administration's Medicare reform plan. Legislative language was sent to the Congress March 20, 2000. It was introduced by Senator Moynihan (S. 2342) on April 4, 2000. A key component of the proposal is the establishment of an optional prescription drug benefit for all beneficiaries. Under this proposal, the government would bear the financial risk of coverage. Beneficiaries would pay a monthly premium estimated at \$26 a month beginning in 2003 (the program's first year) rising to \$51 a month when the program is fully phased-in in 2009. There would be no deductible, the program would pay half of drug costs beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. The federal government would pay a maximum of \$1,000 per person per year in 2003, rising to \$2,500 per person per year in 2009. On June 24, 2000, the Administration announced a revision to the bill; under the revision the benefit would begin in 2002, have a \$25 monthly premium, and include a first year limit on out-of-pocket costs of \$4,000.

On May 10, 2000, Senator Daschle introduced the Senate Democrats bill (S. 2541) which was announced at the White House. This measure is substantially the same as the prescription drug portion of the Administration bill. The phase-in begins in 2002 as does the revised Administration plan.

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<sup>2</sup> For a summary of other prescription bills introduced in the 106<sup>th</sup> Congress, see CRS Report *RL30250, Medicare Prescription Drug Proposals*, by Jennifer O'Sullivan.

On November 9, 1999, Senators Breaux and Frist introduced the Medicare Preservation and Improvement Act of 1999 (S. 1895). That measure built on, but contained a number of changes to, the measure considered by the National Commission. On June 28, 2000, the Senators introduced the Medicare Prescription Drug and Modernization Act of 2000 (S. 2807, labeled "Breaux-Frist 2000"). This plan, a significant modification of S. 1895, includes prescription drug provisions as well as provisions modifying the current Medicare+Choice program. Under the bill, the Commissioner of the newly established Competitive Medicare Agency (CMA) would be required to establish a Prescription Drug and Supplemental Benefit Program under Title XXII of the Social Security Act. Eligible beneficiaries would voluntarily enroll and receive access to covered outpatient drugs and, in certain cases, other supplemental benefits through enrollment in either a Medicare Prescription Plus plan offered by a private entity or a Medicare+Choice plan. The definition of "qualified coverage" under Breaux-Frist 2000 is similar to that under the House-passed bill. Under the Senate bill, all persons would receive a minimum of a 25% discount on that portion of their premium related to qualified prescription drug coverage. The bill would require the Commissioner to develop procedures for the provision of standard prescription drug coverage to each beneficiary residing in an area where there were no Medicare Prescription Plus plans or Medicare+Choice plans providing coverage.

Another measure which has received considerable attention is the Medicare Outpatient Drug Act of 2000 ("MOD bill," Senator Graham et al.) This bill would establish a voluntary prescription drug benefit under a new Part D, beginning in 2003. The government would bear the financial risk of coverage. The drug benefit would be subject to a \$250 deductible, 50% coinsurance until beneficiary out-of-pocket costs reached \$3,500, and then 25% coinsurance until out-of-pocket costs reached \$4,000. The annual out-of-pocket limit would be \$4,000. In general, beneficiaries would pay a monthly premium equal to 50% of program costs with the remaining 50% paid by the federal government. Higher income beneficiaries (singles with incomes over \$75,000 and couples with incomes over \$150,000) would receive a lower federal contribution. All beneficiaries would receive a minimum 25% government subsidy.

On September 7, 2000, Senator Roth, Chairman of the Senate Finance Committee, introduced S. 3016 and S. 3017. With a few exceptions, these bills are identical. They establish a new temporary Outpatient Prescription Drug Assistance Program under a new Title XXII of the Social Security Act. Funds would be provided to states (individually or as part of a group) who voluntarily set up prescription drug programs for low-income Medicare beneficiaries. States programs could also provide assistance to Medicare beneficiaries with high drug costs. A state's Title XXII program would be separate from its Medicaid program. The bills would establish a default program, administered by HCFA, for persons residing in states which did not establish a program.

## **FY2001 Budget Resolution**

The FY2001 Budget resolution (H.Con.Res. 290), has earmarked specific funds for a drug benefit for the Medicare population. The conference report (H.Rept. 106-577, approved by both House and Senate on April 13, 2000) contains assumptions of both the House and Senate bills. In the House, there is a \$40 billion reserve fund over

5 years (2001-2005) for legislation that provides for Medicare reform and prescription drug coverage. In the Senate, there is a two-part reserve fund. The first part is a 5-year \$20 billion fund for legislation that provides for prescription drugs. The second part is a \$40 billion reserve fund for legislation improving the solvency of Medicare and improving access to prescription drugs (or continuing access provided under the first part). Funds available under the second part would be reduced by any amounts made available under the first part. The \$40 billion figure was close to the 5-year cost estimate for the drug benefit included in the Administration's original bill. The CBO estimate for the Administration's revised proposal is higher (\$98.5 billion over the FY2001-FY2005 period.)

The CBO cost estimate for the new drug program under the House-passed bill is \$35 billion over the FY2001-FY2005 period and \$142 billion over the FY2001-FY2010 period. Associated administrative costs would total an additional \$2 billion over the FY2001-FY2005 period and \$5 billion over the FY2001-FY2010 period.

## **Overview of Major Proposals**

There are a number of common themes in the major prescription drug bills pending before the Congress. In general, they would make coverage available to all Medicare beneficiaries on a voluntary basis. They would have a limit on the amount of federal spending for the new benefit. Further, they would provide assistance for the low-income.

The bills introduced by Senator Roth take a different approach. They would set up a temporary program to provide assistance to states to provide coverage for the low-income and, at state option, to beneficiaries with high drug costs. The Roth bills are intended to be a stop-gap measure until Congress can agree on permanent reforms.

### **Private vs. Public Sector Responsibility**

All of the measures would place some measure of responsibility on the private sector for administration of a drug plan. It is the degree of reliance placed on the public versus the private sector that is one of the key areas of difference among the various proposals. The House-passed bill would provide access to a drug-only benefit through private insurance companies and other entities who wished to offer the benefit. The Breaux-Frist 2000 plan would also provide access to a drug benefit through private entities or Medicare+Choice plans. Under the House bill, the Administrator of the new Medicare Benefits Administration would administer the program in a manner such that eligible individuals would be assured access to at least two plans. If necessary to ensure access, the Administrator would be authorized to provide financial incentives. The Breaux-Frist 2000 bill specifically requires the Commissioner of the new Competitive Medicare Agency (CMA) to develop procedures for the provision of standard prescription drug coverage to each beneficiary residing in an area where there were no private entities providing coverage. Under both bills, the private plans would be a risk for any costs in excess of federal subsidy or reinsurance payments.

Under the Administration and Daschle plans, the new benefit would be administered at the federal level like other Medicare benefits and the federal government would bear the financial risk of coverage. The actual operation of the benefit would be through contracts with private entities such as pharmaceutical benefit managers (PBMs). The MOD bill also provides for federal administration; entities contracting with the government to administer the benefit could assume a limited amount of financial risk, subject to the terms of their contract with the government.

Under the Roth bills, states would be responsible for administering the temporary benefit. The federal government would set allotment amounts for states and would make matching payments to states from these allotments. Within federal guidelines, states would establish eligibility and other program criteria and could therefore limit their financial risk. The federal government would administer the benefit in any state which chose not to establish a program.

### **Scope of Benefits**

Another key difference among the plans is the scope of benefits. Under the Administration, Daschle, and MOD bills there would be *one specific benefit* available to all enrollees nationwide. Conversely, under the House-passed bill and Breaux-Frist 2000 there would be a *minimum* benefit level established. Under the House-passed bill and Breaux-Frist 2000, the minimum benefit (referred to as “qualified coverage”) would be either specified “standard coverage” or alternative coverage, provided it was actuarially equivalent to standard coverage and had the same limit on out-of-pocket spending. Under the Roth bills, the scope of benefits is left up to the states.

### **Catastrophic Costs**

The bills also differ on the treatment of catastrophic costs (also called “stoploss” coverage). Both the Administration and Daschle bills would provide funding for catastrophic costs, but the coverage levels were not specified in the bills. However, under the revision to the Administration’s bill announced June 24, 2000, there would be a first year limit on out-of-pocket costs of \$4,000. The MOD bill would also include a \$4,000 limit. The House-passed bill and Breaux-Frist 2000 would provide full funding once such costs exceeded \$6,000. Under the Roth bills, a state program could include coverage for catastrophic costs (as defined by the states); the federal default program could also include such coverage, subject to the availability of funds.

### **Administration**

Medicare is currently administered by the Health Care Financing Administration (HCFA) within the Department of Health and Human Services (HHS). Several of the bills would establish a new entity to administer the drug benefit at the federal level. Under the House-passed plan, a new Medicare Benefits Administration (MBA) would be established (outside of HCFA, but within HHS) to administer the drug benefit and Medicare+Choice. Under Breaux-Frist 2000, a new Competitive Medicare Agency (outside of HHS) would be established to administer the drug benefit and Medicare+Choice.

## Low-Income

Under current law, some low income aged and disabled Medicare beneficiaries are also eligible for drug coverage under Medicaid. Those persons *entitled to full Medicaid protection* generally have prescription drug coverage. Some groups receive more limited Medicaid benefits. Qualified Medicare Beneficiaries (QMBs) are persons with incomes below poverty and resources below \$4,000; these persons receive Medicaid assistance for Medicare cost-sharing and premium charges. Specified Low Income Beneficiaries (SLIMBs) meet the QMB definition except that their income limit is above the QMB level; the SLIMB limit is 120% of poverty. QMBs and SLIMBs only receive drug benefits if they are also entitled to full Medicaid coverage. Under a temporary program, the SLIMB level can be extended to certain persons under 135% of poverty who are not otherwise eligible for Medicaid. All of the major pending bills would provide significant assistance to persons below 135% of poverty – in terms of premiums that would have to be paid for coverage and/or cost sharing once persons used benefits. The plans provide for no, or very limited, beneficiary liability for covered services for this population group. Some of the bills would extend the low-income assistance protections to persons at slightly higher income levels.

## Summary of Proposals

The following is a summary of the key features of the major bills currently under consideration. *The House -passed bill (also referred to as the Republican plan or the Bipartisan plan) is summarized first. The Senate bills are summarized in the order they have been introduced in the Senate.*

The following major features are described for each plan: a) general approach; b) persons covered; enrollment; c) scope of benefits; beneficiary cost-sharing; d) covered drugs; e) administration of benefits; f) payments for drugs; g) beneficiary protections, h) cost control mechanisms; formularies; i) relationship to group health plans, j) relationship to Medigap; k) relationship to Medicaid; assistance for low-income; and l) financing mechanism.

### **Medicare Rx 2000 Act [H.R. 4680 (Thomas et al.), passed House June 28, 2000]**

**General Approach.** The bill would establish, effective January 1, 2003 a new voluntary prescription drug program under a new part D. Coverage would be provided either through a prescription drug plan (PDP) offered by a plan sponsor such as a private insurer or through enrollment in Medicare+Choice plan with qualified drug coverage. The measure would partially subsidize private insurance to cover pharmaceutical costs for beneficiaries. The drug benefit and the Medicare+Choice program would be administered by a new Medicare Benefits Administration (MBA).

**Persons Covered; Enrollment.** Coverage would be extended to all persons, otherwise eligible for Part B, who elect to enroll in Part D. Beneficiaries who elect to participate in Part D would select and enroll in a plan available in their area through

a process similar to that now in effect for Medicare+Choice enrollment. All beneficiaries would be able to enroll in a plan without a late enrollment penalty during a 6-month period at the beginning of the program. They could change plans during annual open enrollment periods. Special election periods would be permitted for those who involuntarily lose drug coverage. Persons who elect coverage at the first opportunity (either during the initial enrollment period for current beneficiaries or during the initial 7-month enrollment period for future beneficiaries) and who maintain continuous coverage would be guaranteed the protection of community rating. Persons who delayed enrollment (and who did not maintain alternative drug coverage through such sources as Medicaid, group health plans, or state programs) could be subject to late enrollment penalties.

**Scope of Benefits; Beneficiary Cost-Sharing.** “Qualified prescription drug coverage” would be defined as either “standard coverage” or actuarially equivalent coverage. “Standard coverage” would be defined as having a deductible (\$250 in 2003), 50% cost-sharing up to the initial coverage limit (the next \$2,100 in 2003, accounting for total spending of \$2,350), and full coverage after an annual limit in out-of-pocket spending (\$6,000 in 2003) had been reached. Thus in 2003, the beneficiary would pay the first \$250, \$1,050 of the next \$2,100 (with the plan paying the other \$1,050), and all costs for drug spending between \$2,350 and \$7,050. The plan would pay in full for all costs over \$7,050 (\$6,000 in out-of-pocket costs). Qualified alternative coverage would have to be actuarially equivalent to standard coverage; the unsubsidized value (i.e., the value less reinsurance payments) would have to be actuarially equivalent; and it would have to include the same limit on out-of-pocket spending. Both standard coverage and actuarially equivalent coverage would have to provide beneficiaries access to negotiated prices (including applicable discounts) even when no benefits may be payable because the beneficiary has reached the initial coverage limit. Plans could offer more generous coverage, if approved by the MBA Administrator.

The beneficiary premium amount would vary by plan selected. Congressman Thomas estimated that the monthly premium would approximate \$35-\$40. The premium for a prescription drug plan could not vary among individuals enrolled in the plan in the same service area, unless the individuals were subject to penalties for late enrollment.

**Covered Drugs.** In general coverage would be extended to outpatient prescription drugs, meeting FDA (Food and Drug Administration) criteria, biologicals, and insulin. Drugs excluded under Medicaid would not be covered except those for smoking cessation. Drugs currently covered under Medicare would continue to be covered under the basic program. Plans would be allowed to have formularies restricting coverage to certain drugs; enrollees would have appeal rights with respect to drugs not on the formulary (see discussion below).

**Administration of Benefits.** The new MBA would be outside of HCFA, but within HHS. The MBA Administrator would be required to review and approve plans before they were made available to beneficiaries and could terminate the contract of any plan sponsor engaged in activities designed to result in favorable selection of the plan. The MBA Administrator would be required to establish processes for

determining the actuarial valuation of prescription drug coverage and for determining the annual percentage increase in the coverage limits.

A PDP plan sponsor would be required to make available to Part D enrollees information on access to covered drugs, how its formulary works, copayment and deductible requirements, and grievance and appeals procedures. Plan sponsors would also be required to furnish explanation of benefits forms to enrolled beneficiaries using services. Plan sponsors would be required to secure agreements with a sufficient number of pharmacies to make access to covered benefits convenient for enrollees and guarantee that beneficiaries would continue to have access to negotiated prices, even when the plan was not under an obligation to pay benefits. Plan sponsors would have to meet certain organizational requirements including licensure under state law as a risk bearing entity and assumption of financial risk for the provision of benefits. Alternatively they could meet standards established for entities not licensed by states.

The MBA Administrator would be required to enter an agreement with a plan sponsor which could cover one or more drug plans. The Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans.

Many of the plan requirements would be comparable to those imposed under Medicare+Choice. As is the case for Medicare+Choice, standards established for plans and plan sponsors would supersede state laws to the extent they were inconsistent. The following state standards would be preempted: benefit requirements, requirements relating to inclusion or treatment of affiliated providers, coverage determinations (including related appeals and grievance processes), and establishment and regulations of premiums.

The Administrator, acting through the new Office of Beneficiary Assistance would be required to establish and maintain plan election procedures consistent with those now provided for the election of Medicare+Choice plans. These procedures would include the conducting of open annual enrollment periods in which beneficiaries already enrolled in a plan under Part D could elect to change plans, the active dissemination of comparative plan information (including price, quality and comparative benefit information) in a manner consistent with and in coordination with the dissemination of information regarding Medicare+Choice plans, and the coordination of elections. Medicare+Choice beneficiaries in a plan offering qualified drug coverage could only get drug benefits through their Medicare+Choice plan. Medicare+Choice plans offering a drug benefit could only offer qualified coverage.

The Administrator would administer the program in a manner such that all eligible individuals would be assured of the availability of at least two qualifying plan options in their area of residence. If necessary to ensure such access, the Administrator would be authorized to provide financial incentives, including the partial underwriting of risk, for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan (including offering such plan on a regional or nationwide basis). However, the MBA Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and Medicare+Choice organizations. The

Administrator would be required to report to Congress annually on the exercise of this authority.

Each plan sponsor would be required to submit to the MBA Administrator information on the qualified drug coverage to be provided, the actuarial value of the coverage, and the monthly premium to be charged for the coverage. The PDP sponsor would have to include an actuarial certification of the actuarial basis for the premium, the portion of the premium attributable to benefits in excess of the standard coverage, and the reduction in the premium resulting from reinsurance subsidies. The Administrator would review the submitted information for purposes of conducting negotiations with the plan.

The MBA Administrator would provide for reinsurance payments to qualifying entities for excess costs incurred in providing prescription drug coverage. Reinsurance payments would be provided for individual drug costs exceeding \$1,250; the percentage of costs subject to reinsurance payments would be increased from 30% for costs over \$1,250 to 90% for costs that exceed \$1,550 but are below \$2,350. Reinsurance, not to exceed 90%, would also be provided for coverage of costs over the out-of-pocket limit. The MBA Administrator would be required to estimate the total payments that would be made during the year without regard to the reinsurance provisions, and the total payments to be made by qualifying entities for standard coverage during the year. The Administrator would proportionately adjust the payments so that total reinsurance payments made during the year equal 35% of total payments made by qualifying plans for standard coverage during the year. The payment method would be determined by the MBA Administrator and could use an interim payment system based on estimates.

A Medicare+Choice plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was qualified prescription drug coverage. Medicare+Choice organizations would be required to compute and publish: a) a premium for drug benefits that is separate from other coverage; b) the ratio of the actuarial value of standard drug coverage to the actuarial value of prescription drug coverage offered under the plan; and c) a standard premium. Medicare+Choice organizations would be permitted to reduce the amount of premiums charged. For purposes of low-income subsidy payments, the organization would be required to accept the reference premium as the full premium if there is no standard or equivalent coverage in the area.

**Payments for Drugs.** PDP sponsors would determine payments. They would be expected to negotiate discounts for beneficiaries.

**Beneficiary Protections.** Persons who elected coverage at the first opportunity and who maintained continuous coverage would be guaranteed issue of any plan offered at the community-rated premium.

PDP plan sponsors would be required to have in place: 1) an effective cost and drug utilization management program; 2) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including a medication therapy management program; and 3) a program to control waste, fraud, and abuse. Medication therapy management programs would have to be developed in

cooperation with licensed pharmacists and physicians. PDP sponsors would be required to maintain meaningful procedures for hearing and resolving grievances, protecting the confidentiality of enrollee records, and providing enrollees access to both expedited coverage determinations and a procedure for the consideration of any benefit denial.

**Cost-Control Mechanisms; Formularies.** Plans electing to use a formulary would be required to establish a pharmaceutical and therapeutic committee (that included at least one physician and one pharmacist) to develop the formulary. The formulary would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes). An enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the therapeutically similar drug that was on the formulary was not as effective for the enrollee or had significant adverse effects for the enrollee.

**Relationship to Group Health Plans.** Qualified retiree prescription drug plans would be eligible for reinsurance payments. A qualified retiree prescription drug plan would be defined as employment-based retiree health coverage meeting certain requirements for persons enrolled or eligible to enroll in the plan. The sponsor of the plan would be required to annually attest to the MBA Administrator (and to provide such assurances as required by the Administrator) that the coverage met the requirements for qualified coverage. The sponsor and the plan would have to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made.

**Relationship to Medigap.** No Medigap policy that provided coverage for prescription drugs could be sold to an individual after January 1, 2003, unless it replaced a policy for an individual that included drug coverage. Individuals enrolled in Part D who terminated enrollment in a Medigap policy with prescription drug coverage or another policy with drug coverage would be guaranteed enrollment in a Medigap non-drug policy if enrollment occurred within 63 days of the termination of prior coverage.

**Relationship to Medicaid; Assistance for Low-Income.** Subsidies would be provided for low-income individuals. Individuals under 135% of poverty would have a premium subsidy equal to 100% of the premium for standard coverage (or actuarially equivalent coverage). Beneficiary cost-sharing for such individuals would be nominal. For individuals between 135% and 150% of poverty, there would be a sliding scale premium subsidy ranging from 100% for persons at 135% of poverty to 0% for those at 150% of poverty. There is no cost-sharing subsidy for this group. The determination of whether an individual is eligible for a subsidy and the amount of the subsidy would be determined under the state's Medicaid plan.

The maximum amount of cost-sharing subsidy that could be provided for an enrollee under 135% of poverty could not exceed 95% of the maximum cost-sharing that could be incurred for standard coverage. Beneficiary cost-sharing for these persons would be nominal as determined by the MBA Administrator. A plan could waive or reduce the amount of cost-sharing otherwise applicable.

Part D coverage would be primary to any drug benefits under Medicaid. The plan would require states to make eligibility determinations for low income subsidies; there would be a phase-in of increased matching rates for these activities. The bill also would provide for a phase-in of federal assumption of Medicaid responsibility for premiums and cost-sharing for the dually eligible.

**Financing Mechanism.** A Medicare Prescription Drug Account would be created within the Part B trust fund. Funds provided under Part D to the Account would be kept separate from all other funds within Part B. The FY2001 budget resolution (see earlier discussion) earmarked up to \$40 billion over 5 years for drug benefits. Federal funds for the subsidies and reinsurance payments fall within this limit. The remaining costs would be paid by beneficiaries through premiums.

### **Medicare Modernization Act of 2000 – President’s Bill [S. 2342 (Moynihan, by request)]**

**General Approach.** S. 2342 is the President’s plan for comprehensive Medicare reform. A major component of the plan is the establishment of a new optional Medicare prescription drug benefit under a newly established Part D. The plan would pay for 50% of beneficiaries drug costs, beginning with the first prescription filled, up to a maximum program payment of \$1,000 in the first year (2003) and \$2,500 in 2009 when the program is fully phased in. (The drug portion of S. 2342 is similar to the plan outlined by the Administration on July 2, 1999. Two major changes are a 1-year delay in the implementation date and the establishment of a catastrophic prescription drug coverage reserve fund.) On June 24, 2000, the Administration announced a revision to its proposal; under the revision the benefit would begin in 2002, have a \$25 premium, and include a first year limit on out-of-pocket costs of \$4,000. Note that the following summary reflects the bill as introduced in April 2000.

**Persons Covered; Enrollment.** Coverage would be extended to all persons, otherwise eligible for Medicare, who enroll in Part D. Persons would only have one chance to enroll. For current beneficiaries, there would be an open enrollment period for the first year the program is in effect. For other persons, the enrollment opportunity would generally occur when an individual first becomes eligible for Medicare. There would be two exceptions. Beneficiaries who are covered by their employer while still working (or by an employer of a working spouse) would have a one-time enrollment opportunity after retirement (or after retirement or death of the working spouse). Beneficiaries covered under a retiree health plan would have a onetime enrollment opportunity if the former employer drops retiree drug coverage. During 2003 and 2004, the Secretary would conduct a study concerning the feasibility of establishing an annual open enrollment period.

**Scope of Benefits; Beneficiary Cost-Sharing.** There is no deductible. The program would pay half of the negotiated price beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. Benefit managers could propose a higher government percentage for generic drugs, drugs on the formulary, or mail order drugs provided that aggregate costs will not be increased.

The program would be phased-in over the 2003-2009 period. In 2003 and 2004, the federal government would pay up to a maximum of \$1,000 per person per year (out of the first \$2,000 in total spending). In 2005 and 2006, the government would pay up to \$1,500 (out of the first \$3,000 in total spending). In 2007 and 2008, it would pay up to \$2,000 (out of the first \$4,000 in total spending). In 2009, it would pay up to \$2,500 (out of the first \$5,000 in total spending). Beginning in 2010, the limit would be increased by the increase in the consumer price index. (The Administration has estimated that 90% of beneficiaries would not reach the cap when the program was fully implemented.)

Beneficiaries would pay a premium equal to 50% of program costs; the remaining 50% would be paid by the federal government. (Premiums paid by former employers would equal two-thirds of the total.) The Administration estimates that the premium for 2003 would be \$26 per month, rising to \$51 per month in 2009. (CBO estimates the 2003 premium at \$24.10, rising to \$48.20 in 2009 and \$50.90 in 2010.) Premiums would be collected in the same way as Part B premiums; for most persons this is a deduction from monthly social security checks.

The bill also establishes a catastrophic prescription drug coverage reserve fund. Specified amounts would be credited to the fund over for 2006-2010, with a total of \$35 billion credited to the fund over the period. However, there were no specifics of how this fund would be used.

Note that in the revision announced June 24, 2000, the program would begin one year earlier (2002) and would include a first-year limit on out-of-pocket costs of \$4,000.

**Covered Drugs.** In general, all therapeutic classes of drugs would be covered. In addition, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and have basic appeal rights when coverage is denied. The exceptions would be for classes of drugs currently excluded under Medicaid except that: 1) the Secretary could specifically provide for such coverage; and 2) smoking cessation drugs excluded under Medicaid would be covered under Part D. Drugs currently covered under Medicare would continue to be covered under the Part B program.

**Administration of Benefits.** The Secretary would contract with an entity which would competitively bid to serve as a benefit manager for the new drug benefit in a geographic region. At least 15 regions would be designated; only one contract would be awarded in each region. The initial contract would be awarded for 3-5 years and could be renewed noncompetitively. Any entity that is capable of administering the drug benefit could compete for the contract. (Specific types of entities are not enumerated in the bill; however they have been described as including pharmacy benefit managers (PBMs), retail drug chains, health plans or insurers, states (through mechanisms established for Medicaid) or multiple entities in collaboration (such as alliances of pharmacies) provided the collaboration is not anti-competitive.) The entity's contract proposal would include: a cost proposal setting forth proposed administrative charges; a proposal for drug prices including annual increases in prices; details of cost and utilization management; information as the Secretary may require on past performance; information on ownership and shared financial interests with

other entities involved in benefit delivery; and a proposal for deterring medical errors related to drugs. The Secretary would consider the comparative merits of the applications as determined on the basis of past performance and other factors. Contracts with benefit managers could include incentive payments for cost and utilization management and quality improvement.

The benefit manager for an area would: 1) establish, through negotiations, with manufacturers, wholesalers, and pharmacies, a schedule of prices for drugs; 2) enter into participation agreements with pharmacies; 3) track enrolled individuals; 4) process claims; 5) meet cost and utilization management and quality assurance measures; 6) have in place education and information activities; 7) have in effect beneficiary protections, and 8) maintain adequate records.

Pharmacies meeting certain requirements would be eligible to enter an agreement with a benefit manager to furnish covered prescription drugs to enrolled individuals. The requirements include: licensing; access and quality standards; adherence to established prices; having in effect management information systems (including electronic systems) and procedures for carrying out required functions; maintenance of adequate records; implementation of effective measures for quality assurance, cost management, and reduction of medical errors with respect to drugs; and adherence to confidentiality standards.

Enrollees in managed care plans would receive their benefit through the Medicare+Choice plans.

**Payments for Drugs.** Medicare would not set prices for drugs. Prices would be determined through negotiations between the benefit managers for an area and drug manufacturers, wholesalers, and pharmacies. It is expected that this process would result in discounts. The proposal would require that beneficiaries would continue to have access to negotiated prices even after they had exceeded the cap.

**Beneficiary Protections.** Benefit managers would be required to have in effect systems to safeguard the confidentiality of health information. They would also be required to have in place grievance and appeals procedures as specified by the Secretary.

**Cost Control Mechanisms; Formularies.** Benefit managers could use various cost containment tools in administering the program, subject to limitations and guidelines set in the contract. They would be permitted to use formularies. However, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and would have appeal rights when coverage was denied. The Secretary could not authorize a particular formulary or institute a price structure for benefits or otherwise interfere with the competitive nature of providing the benefit through benefit managers.

**Relationship to Group Health Plans.** Employers would receive a partial drug premium subsidy if their retiree health coverage for drugs is at least as good as the Part D benefit. The subsidy would equal two-thirds of the amount that would otherwise be provided to the benefit manager for Medicare Part D enrollees. The

Secretary would make these premium subsidy payments to the health plan sponsor used by the employer.

**Relationship to Medigap.** Medigap policies would be revised to conform to the revised program structure.

**Relationship to Medicaid; Assistance for Low-Income.** The bill would make available Part D protection for all beneficiaries, including the low-income. Medicare would therefore pick up some costs currently paid by Medicaid. States would be permitted to pay Part D premiums for individuals who are dually eligible for Medicare and Medicaid instead of providing drug benefits through Medicaid. If they elect this option, they must cover all dually eligible individuals under Part D and must purchase all prescriptions for such individuals in accordance with Part D requirements, without regard to whether or not the benefit limit for an individual has been reached.

Under the bill, Medicaid would pay the Part D drug premiums and coinsurance charges (up to the benefit limit) for Medicare beneficiaries up to 100% of poverty, using the current federal/state matching rate.

“Qualified Medicare drug beneficiaries” (defined as persons with incomes between 100% and 150% of poverty and assets below \$4,000 for an individual and \$6,000 for a couple) would receive assistance through Medicaid (except for dually eligible persons noted above). However, unlike regular Medicaid, benefits for this population would be paid 100% by the federal government. Medicaid would pay Part D drug premiums and coinsurance charges (up to the benefit limit) for beneficiaries with incomes between 100% and 135% of poverty. Medicaid would pay a portion of the beneficiary premium, determined on a linear sliding scale based on income, for persons with incomes between 135% and 150% of poverty.

Medicaid drug price rebates would not apply to prescription drugs purchased under Part D.

**Financing Mechanism.** The Administration estimated net federal costs (after deduction of beneficiary premiums) at \$38.1 billion over 5 years (2001-2005) and \$160 billion over 10 years (2001-2010). A portion of the costs would be financed by savings achieved through efficiencies and economies included under the larger reform plan; the remainder would be financed through the surplus. CBO estimated net 5-year costs at \$34.5 billion and net 10-year costs at \$149 billion.

The CBO) cost estimate of the revised proposal is \$98.4 billion over the FY2001-FY2005 period and \$337.7 billion over the FY2001-FY2010 period.

A separate account – the Prescription Drug Insurance Account – would be set up within the Federal Supplementary Insurance Trust fund. Premiums would be credited to the account and benefit payments made from the account.

## **Medicare Expansion for Needed Drugs (MEND) Act of 2000 [S. 2541 (Daschle, et al.)]**

**General Approach.** S. 2541 is the Senate Democrats bill which was announced May 10, 2000, at the White House. This measure is substantially the same as the prescription drug portion of the Administration bill (S. 2342). The following are the major changes incorporated in S. 2541: 1) the phase-in begins in 2002 rather than 2003; 2) the benefit would be administered by “private entities” rather than “benefit managers”; 3) the requirements for contract proposals from these entities are revised, and there is no provision for noncompetitive renewal of contracts; 4) the amount in the catastrophic reserve fund is increased and the Secretary is required to report recommendations on structuring a catastrophic drug benefit within 6 months of enactment; and 5) the measure includes provisions designed to provide special attention for rural and hard to serve areas. S. 2541 does not include the non-drug provisions incorporated in the President’s plan; it does require several studies relating to expanding Medicare’s preventive benefits.

S. 2541 provides for the establishment of a new optional Medicare prescription drug benefit under a newly established Part D. The plan would pay for 50% of beneficiaries drug costs, beginning with the first prescription filled, up to a maximum program payment of \$1,000 in the first year (2002) and \$2,500 in 2009 when the program is fully phased in.

**Persons Covered; Enrollment.** Coverage would be extended to all persons, otherwise eligible for Medicare, who enroll in Part D. Persons would only have one chance to enroll. For current beneficiaries, there would be an open enrollment period for the first year the program is in effect (2002). For other persons, the enrollment opportunity would generally occur when an individual first becomes eligible for Medicare. There would be two exceptions. Beneficiaries who are covered by their employer while still working (or by an employer of a working spouse) would have a one-time enrollment opportunity after retirement (or after retirement or death of the working spouse). Beneficiaries covered under a retiree health plan would have a one-time enrollment opportunity if the former employer drops retiree drug coverage. During 2002 and 2003, the Secretary would conduct a study concerning the feasibility of establishing an annual open enrollment period.

**Scope of Benefits; Beneficiary Cost-Sharing.** There is no deductible. The program would pay half of the negotiated price beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. Private entities administering the benefit could propose a higher government percentage for generic drugs, drugs on their formulary, or mail order drugs provided that aggregate costs will not be increased.

The program would be phased-in over the 2002-2009 period. In 2002-2004, the federal government would pay up to a maximum of \$1,000 per person per year (out of the first \$2,000 in total spending). In 2005-2007, the government would pay up to \$1,500 (out of the first \$3,000 in total spending). In 2008, it would pay up to \$2,000 (out of the first \$4,000 in total spending). In 2009, it would pay up to \$2,500

(out of the first \$5,000 in total spending). Beginning in 2010, the limit would be increased by the increase in the consumer price index.

Beneficiaries would pay a premium equal to 50% of program costs; the remaining 50% would be paid by the federal government. (Premiums paid by former employers would equal two-thirds of the total.) Premiums would be collected in the same way as Part B premiums; for most persons this is a deduction from monthly social security checks.

Within 6 months of enactment, the Secretary would be required to submit recommendations to the Congress on structuring a catastrophic drug benefit for Medicare beneficiaries. The recommendations must: ensure coverage of the costs of prescription drugs above a specified level; conform to the administrative structure established in the bill; have projected costs not exceeding \$50 billion over the 2003-2010 period; and take effect no later than January 1, 2003. If legislation is not enacted by June 1, 2001, the Secretary would promulgate final regulations by January 1, 2002. Such a final regulation could not take effect unless the Director of the Office of Management and Budget and the Chief Actuary of HCFA certified that aggregate federal expenses would not exceed \$50 billion between 2003 and 2010. The Secretary would be required to submit a revised recommendation if either certification were not provided. A catastrophic reserve fund would be established; amounts appropriated to the fund would equal \$50 billion over the 2003-2010 period.

**Covered Drugs.** In general, all therapeutic classes of drugs would be covered. In addition, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and have basic appeal rights when coverage is denied. The exceptions would be for classes of drugs currently excluded under Medicaid except that; 1) the Secretary may specifically provide for such coverage; 2) such drug is certified as medically necessary by a health care professional; and 3) smoking cessation drugs excluded under Medicaid would be covered under Part D. Drugs currently covered under Medicare (including self-administered drugs) would continue to be covered under the Part B program. The current durational limits on coverage of immunosuppressive drugs following an organ transplant would be eliminated; these drugs would be covered under Part B.

**Administration of Benefits.** The Secretary would contract with a private entity which would competitively bid to administer the new drug benefit in a geographic region. At least 15 regions would be designated; only one contract would be awarded in each region. The initial contract would be awarded for 2-5 years and would be subject to review after 2 years. A private entity that is capable of administering the drug benefit could compete for the contract. An eligible entity is a prescription drug vendor, wholesale and retail pharmacist delivery system, health care provider or insurer, any other type of entity the Secretary may specify, or a consortium of such entities. The entity's contract proposal would include material and information required by the Secretary including a detailed description of: 1) the schedule of negotiated prices that will be charged to enrollees; 2) how the entity will deter medical errors related to prescription drugs; and 3) proposed contracts with local pharmacy providers designed to ensure access, including compensation for local pharmacists' services. Contracts with private entities could include incentive payments for cost and utilization management and quality improvement.

The private entity for an area would: 1) establish, through negotiations with manufacturers, wholesalers, and pharmacies, a schedule of prices for drugs; 2) enter into participation agreements with pharmacies; 3) process claims; 4) meet cost and utilization management and quality assurance measures; 5) have in place education and information activities; 6) have in effect beneficiary protections; and 7) maintain adequate records.

Pharmacies meeting certain requirements would be eligible to enter an agreement with a private entity to furnish covered prescription drugs and pharmacists' services to enrolled individuals. The requirements include: 1) licensing; 2) limiting total charges to negotiated prices and charges to beneficiaries to the individual's share; and 3) compliance with performance standards relating to measures for quality assurance, reduction of medical errors, participation in a drug utilization review program, and ensuring compliance with confidentiality standards.

The Secretary would be required to ensure that all beneficiaries have access to the full range of pharmaceuticals under Part D. The Secretary would be required to give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas. This could include bonus payments to retail pharmacists in rural areas and extra payments to the private entity for the cost of rapid delivery of pharmaceuticals. A General Accounting Office (GAO) report on the issue would be required within 2 years of enactment.

Enrollees in managed care plans would receive their benefit through the Medicare+Choice plans.

**Payments for Drugs.** Medicare would not set prices for drugs. Prices would be determined through negotiations between the private entities for an area and drug manufacturers, wholesalers, and pharmacies. It is expected that this process would result in discounts. The bill would require that beneficiaries continue to have access to negotiated prices even after they had exceeded the cap.

**Beneficiary Protections.** Private entities administering the benefit would be required to have in effect systems to safeguard the confidentiality of health information. They would also be required to have in place grievance and appeals procedures as specified by the Secretary.

**Cost Control Mechanisms; Formularies.** Private entities could use various cost containment tools in administering the program, subject to limitations and guidelines set in the contract. They would be permitted to use formularies. However, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and would have appeal rights when coverage was denied. The Secretary could not require a particular formulary or institute a price structure for benefits, interfere in any way with negotiations between private entities and drug manufacturers or wholesalers, or otherwise interfere with the competitive nature of providing the benefit through private entities.

**Relationship to Group Health Plans.** Employers would receive a partial drug premium subsidy if their retiree health coverage for drugs is at least as good as the Part D benefit. The subsidy would equal two-thirds of the amount that would

otherwise be provided to the benefit manager for Medicare Part D enrollees. The Secretary would make these premium subsidy payments to the health plan sponsor used by the employer.

**Relationship to Medigap.** No provision.

**Relationship to Medicaid; Assistance for Low-Income.** The bill would make available Part D protection for all beneficiaries, including the low-income. Medicare would therefore pick up some costs currently paid by Medicaid. States would be permitted to pay Part D premiums for individuals who are dually eligible for Medicare and Medicaid instead of providing drug benefits through Medicaid. If they elect this option, they must cover all dually eligible individuals under Part D and must purchase all prescriptions for such individuals in accordance with Part D requirements, without regard to whether or not the benefit limit for an individual has been reached.

Under the bill, Medicaid would pay the Part D drug premiums and coinsurance charges (up to the benefit limit) for Medicare beneficiaries up to 100% of poverty, using the current federal/state matching rate.

“Qualified Medicare drug beneficiaries” (defined as persons with incomes between 100% and 150% of poverty and assets below \$4,000 for an individual and \$6,000 for a couple) would receive assistance through Medicaid. However, unlike regular Medicaid, benefits for this population would be paid 100% by the federal government (except for any dually eligible persons noted above). Medicaid would pay Part D drug premiums and coinsurance charges (up to the benefit limit) for beneficiaries with incomes between 100% and 135% of poverty. Medicaid would pay a portion of the beneficiary premium, determined on a linear sliding scale based on income, for persons with incomes between 135% and 150% of poverty.

Medicaid drug price rebates would not apply to prescription drugs purchased under Part D.

**Financing Mechanism.** A separate account – the Prescription Drug Insurance Account – would be set up within the Federal Supplementary Insurance Trust fund. Premiums would be credited to the account and benefit payments made from the account. The financing source is not specified.

## **Medicare Prescription Drug and Modernization Act of 2000 [S. 2807 (Breux and Frist et al.) labeled “Breux-Frist 2000”]**

**General Approach.** The Commissioner of the newly established Competitive Medicare Agency (CMA) would be required to establish a Prescription Drug and Supplemental Benefit Program under title XXII of the Social Security Act. Eligible beneficiaries would voluntarily enroll and receive access to covered outpatient drugs and, in certain cases, other supplemental benefits through enrollment in either a Medicare Prescription Plus plan offered by a private entity or a Medicare+Choice plan. All persons would receive a minimum of a 25% discount on that portion of their premium related to qualified prescription drug coverage. The program would begin

January 2003. All current Medicare benefits would be guaranteed and be unaffected by the new program.

**Persons Covered; Enrollment.** Coverage would be extended to all persons, enrolled in both Parts A and B, who voluntarily enrolled in the new Title XXII program. The enrollment process would be similar to that established for Medicare Part B. Beneficiaries would have a one-time enrollment opportunity. For current beneficiaries this would be the 6-month period beginning November 2002; for future beneficiaries it would be the same 7-month period applicable for initial Part B enrollment. A special enrollment period would be established for persons involuntarily losing other drug coverage such as that under Medicaid, a group health plan, Medigap, or a state pharmaceutical assistance program; persons would be required to enroll within 63 days of losing other coverage.

The Commissioner would establish a process, consistent with that established for Medicare+Choice for individuals to make an annual election to enroll in a Medicare Prescription Plus Plan.

**Scope of Benefits; Beneficiary Cost-Sharing.** “Qualified prescription drug coverage” would be defined as “standard coverage” or “actuarially equivalent coverage.” “Standard coverage” would be defined as having a deductible (\$250 in 2003), 50% cost-sharing up to the initial coverage limit (the next \$2,100 in 2003, accounting for total spending of \$2,350), and full coverage after an annual limit in out-of-pocket spending (\$6,000 in 2003). Thus in 2003, the beneficiary would pay the first \$250, \$1,050 of the next \$2,100 (with the plan paying the other \$1,050), and all costs for drug spending between \$2,350 and \$7,050. The plan would pay in full for all costs over \$7,050 (\$6,000 on out-of-pocket costs). The annual dollar amounts would be increased by the increase in average per capita aggregate expenditures for drugs. Plans could offer a package that was actuarially equivalent (i.e., had an equivalent value) to the standard package, provided the limit on out-of-pocket costs was the same as that under standard coverage. Both standard and actuarially equivalent coverage would have to provide beneficiaries access to negotiated prices through a drug discount card.

A Medicare Prescription Plus plan could provide more generous drug benefits. It could also offer coverage of non-drug benefits subject to certain conditions. If these non-drug benefits included coverage of any Medicare cost-sharing charges, the plan would have to cover at least what would be covered under a basic Medigap plan (labeled Plan A). If an entity offered more generous coverage, it would also be required to offer a Medicare Prescription Plus plan in the area meeting qualified coverage criteria only. Further, the Commissioner would have to find that the benefits were not designed to result in favorable selection of beneficiaries.

A plan would be required to charge a uniform premium for individuals enrolled in the plan in the same service area. The Commissioner would pay to each eligible entity the full amount of the premium for each beneficiary minus administrative costs levied on the plan.

Beneficiaries would pay the premium amount (less any discount) in the same manner as Part B premiums are paid (generally as a deduction from an individual's

social security check). All beneficiaries would receive a discount of at least 25% (see **Relationship to Medicaid; Assistance to Low-Income**, below). This discount would be included as taxable income to the beneficiary.

**Covered Drugs.** In general coverage would be extended to outpatient prescription drugs meeting FDA criteria, biologicals, and insulin. Drugs excluded under Medicaid would not be covered, except those for smoking cessation. Drugs currently covered under Medicare would continue to be covered under the basic program. Plans would be allowed to have formularies restricting coverage to certain drugs; enrollees would have appeal rights with respect to drugs not on the formulary (see below).

**Administration of Benefits.** An independent agency, the Medicare Competition Agency (MCA) would be set up in the executive branch outside of HHS. The MCA would administer the Medicare prescription drug and supplemental benefit program under the new title XXII and the Medicare+Choice program. (HHS would retain responsibility for the traditional fee-for-service program.) The head of the agency would be a Commissioner appointed by the President, with the advice and consent of the Senate, for a 6-year term. The Commissioner would have responsibility for: 1) coordinating determinations of beneficiary eligibility and enrollment with the Commissioner of Social Security; 2) entering into and enforcing contracts with entities for the offering of Medicare Prescription Plus plans; 3) disseminating comparative information regarding benefits and quality; 4) dissemination of appeals rights information; and 5) establishing a Medicare beneficiary education program. The Commissioner and the Secretary of HHS would consult on an ongoing basis and would exchange data as appropriate.

An independent 7-member Medicare Competition and Prescription Drug Advisory Board would be set up to advise the Commissioner on policies related to the Medicare Prescription Plus and the Medicare+Choice program. The Board would submit reports to the Commissioner and the Congress as determined appropriate. It would be required to submit reports directly to Congress; no officer or agency could require that they be submitted to any officer or agency for prior review or approval.

The Commissioner would establish a process through which beneficiaries would enroll, on an annual basis, in a Medicare Prescription Plus plan. A Medicare+Choice enrollee would obtain benefits through the Medicare+Choice plan if the plan provided qualified drug coverage.

The Commissioner would develop procedures for the provision of standard prescription drug coverage to each beneficiary residing in an area where there were no Medicare Prescription Plus plans or Medicare+Choice plans providing coverage.

The Commissioner would enter into contracts with entities which could cover more than one Medicare Prescription Plus plan. An eligible entity could be any entity the Commissioner determines to be appropriate to provide coverage including a pharmaceutical benefit management company, wholesale or retail pharmacist delivery system, an insurer (including a Medigap insurer), another entity, or any combination of these.

An entity would have to be licensed as a risk-bearing agency in each state in which it offered a Medicare Prescription Plus plan. Alternatively they could meet standards established for entities not licensed by the state. The entity would be required to assume full financial risk except for the portion covered by federal reinsurance payments.

As is the case for Medicare+Choice, the standards established for plans would supersede state laws to the extent they were inconsistent. The following state standards would be specifically preempted: benefit requirements, requirements relating to inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

Each entity offering a plan would be required to submit to the Commissioner information on coverage provided, actuarial value of the coverage, monthly premium to be charged for the coverage, and the service area for the plan. The Commissioner would review the information and approve or disapprove the proposal based on the information submitted. The Commissioner would have the same authority to negotiate terms and conditions of premiums and other terms of the plans as the Director of the Office of Personnel Management has with respect Federal Employee Health Benefits (FEHB) plans.

The Commissioner could approve a service area only if the Commissioner found that it was not designed so as to discriminate based on health status, economic status, or prior receipt of health care of eligible beneficiaries. Further, the benefit package could not be designed so as to lead to favorable selection of beneficiaries.

The Commissioner would provide for reinsurance payments to Medicare Prescription Plus plans, Medicare+Choice plans providing qualified prescription drug coverage, and qualified retiree drug plans. In 2003, the reinsurance payment would cover 80% of costs exceeding \$7,050 (the point at which beneficiary out-of-pocket payments cease). This amount would be increased in future years by the percentage increase in average per capita aggregate expenditures. The payment method would be determined by the Commissioner and could use an interim payment system based on estimates.

A Medicare+Choice plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. Medicare+Choice plans would be required to compute and publish: a) a premium for drug benefits that is separate from other coverage; b) the ratio of the actuarial value of standard coverage to the actuarial value of drug coverage offered under the plan; and c) the portion of the premium attributable to standard benefits. Medicare+Choice organizations would be permitted to reduce the amount of premiums charged.

**Payment for Drugs.** The plan would determine payments and would be expected to negotiate discounts.

**Beneficiary Protections.** Medicare Prescription Plus plans would be required to disclose in a clear accurate and standardized form to each enrollee information on access to covered outpatient drugs, formulary provisions, cost-sharing requirements

and grievance and appeals procedures. Beneficiaries would have the right to obtain more detailed information on request. Plans would also be required to furnish beneficiaries information on benefits provided. Further, plans would be required to provide access to negotiated prices, even when the plan is under no obligation to pay for the benefits.

Plans would be required to establish quality assurance, utilization management, and fraud and abuse control programs. Entities would be required to have meaningful procedures for resolving grievances and protecting confidentiality and accuracy of enrollee records. Further they would be required to provide enrollees access to expedited coverage determinations and a procedure for reconsideration of benefit denials.

**Cost-Control Mechanisms; Formularies.** An entity offering a Medicare Prescription Plus plan or Medicare+Choice plan could use cost control mechanisms customarily used in employer-sponsored health care plans that offer coverage of outpatient prescription drugs. These include formularies, tiered copayments, selective contracting with providers of outpatient prescription drugs, and mail order pharmacies.

Plans using formularies would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily all drugs within such categories and classes). Entities would have a process for beneficiaries to appeal denials of coverage based on application of the formulary.

**Relationship to Group Health Plans.** Qualified retiree prescription drug plans would be eligible for reinsurance payments. Qualified coverage would be defined as employment-based retiree health coverage meeting certain requirements. The sponsor of the plan would be required to annually attest to the Commissioner (and to provide such other assurances as required by the Commissioner) that coverage met the requirements for qualified prescription drug coverage. The sponsor and the plan would have to maintain and provide access to records needed to ensure the adequacy of coverage and accuracy of payments made.

**Relationship to Medigap.** No Medigap policy that provided coverage for prescription drugs could be sold to an individual after January 1, 2003, unless it replaced a policy for an individual that included drug coverage. Individuals enrolled in the new Title XXII program who terminated enrollment in a Medigap policy with prescription drug coverage or another policy with drug coverage would be guaranteed enrollment in a Medigap non-drug policy if enrollment occurred within 63 days of the termination of prior coverage.

**Relationship to Medicaid; Assistance for Low-Income.** Low-income persons would receive a discount on their premiums. Individuals with incomes below 135% of poverty (and assets below \$4,000) would have a discount equal to 100% of the value of standard drug coverage provided under the plan. Beneficiary cost-sharing for such individuals would be nominal. For individuals between 135% and 150% of poverty, there would be a sliding scale discount on their premiums ranging from 100% of such value at 135% of poverty to 25% of such value at 150% of poverty. There would be no cost-sharing subsidy for this group. The determination of whether

an individual was eligible for a subsidy would be made under the state's Medicaid program.

The maximum amount of cost-sharing subsidy that could be provided for an enrollee under 135% of poverty could not exceed 95% of the maximum amount of cost-sharing that could be incurred for standard coverage. Beneficiary cost-sharing for these persons would be nominal as determined by the Commissioner. A plan could waive or reduce the amount of cost-sharing otherwise applicable.

The new Title XXII coverage would be primary to any drug benefits under Medicaid. The plan would require states to make eligibility determinations for low income subsidies; there would be a phase-in of increased matching rates for these activities. The bill would also provide for a phase-in of federal assumption of Medicaid responsibility for premiums and cost-sharing for the dually eligible.

**Financing Mechanism.** A Medicare Prescription Drug Account would be created within the Part B trust fund. Funds provided under the new Title XXII to the Account would be kept separate from all other funds within Part B. The benefit would be funded through a combination of beneficiary premiums and federal dollars. A CBO cost estimate is not yet available.

The Commissioner could levy on Medicare Prescription plans and Medicare+Choice plans providing qualified drug coverage an assessment to pay the estimated expenses of the Commissioner for administering the new Title XXII. The assessments would be deposited in the Medicare Prescription Drug Account.

The annual reporting requirements for the Board of Trustees of the Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B) trust funds would be expanded. The Board would be required to submit a report on the two trust funds as well as the Medicare Prescription Drug Account. The report would include information on total amounts obligated from the general revenues of the Treasury for benefits; a historical overview of spending; 10-year and 50-year projections; and overall spending from general revenues in relation to GDP growth.

## **Medicare Outpatient Drug Act of 2000 [“MOD Act” S. 2758 (Graham et. al.)]**

**General Approach.** The “MOD Act” would establish a voluntary prescription drug benefit under a new Part D, effective January 1, 2003. The benefit would be subject to a \$250 deductible, 50% coinsurance until beneficiary out-of-pocket costs reached \$3,500, and then 25% coinsurance until out-of-pocket costs reached \$4,000. The annual out-of-pocket limit would be \$4,000. In general, beneficiaries would pay a monthly premium equal to 50% of program costs; the remaining 50% would be paid by the federal government. Higher income beneficiaries would receive a lower premium contribution from the federal government.

**Persons Covered; Enrollment.** Coverage would be extended to all persons otherwise eligible for Medicare who elect to enroll in Part D. The enrollment process would be similar to that for Part B. Individuals initial enrollment opportunity would

generally occur when an individual first became eligible for Medicare. The Secretary would establish an initial open enrollment period for current enrollees. Late enrollment penalties, similar to those applicable under Part B, would apply for persons who did not enroll during their initial enrollment period. Late enrollment penalties would not apply in cases where an individual was covered under a group health plan (including a qualified retiree prescription drug plan) which provides coverage at least equal to the value of Part D coverage.

The Secretary would establish a process through which beneficiaries enrolled in Part D, but not in a Medicare+Choice plan, would make an annual election to enroll with an eligible entity. The rules would be similar to those for Medicare+Choice enrollment.

**Scope of Benefits; Beneficiary Cost-Sharing.** The benefit would be subject to a \$250 deductible. An entity administering the benefit could waive the deductible for generic drugs if the Secretary determined that the waiver was tied to performance measures and other incentives applicable under its contract. (In this case any coinsurance paid with respect to the generic drug would be credited toward the deductible.)

Beneficiary cost-sharing would equal 50% of costs until out-of-pocket costs totaled \$3,500. At this point, beneficiary cost-sharing would be reduced to 25%. There would be no cost sharing once out-of-pocket costs reached \$4,000. Thus, assuming no waiver of the deductible, the beneficiary would pay 100% of the first \$250, 50% of the next \$6,500 (\$6,750 total, \$3,500 total out-of-pocket), and 25% of the next \$2,000 (\$8,750 total, \$4,000 total out-of-pocket). Any remaining costs would be paid by the program. The dollar amounts would be increased in future years (beginning in 2005) by the percentage increase in program spending. An entity administering the benefit could reduce the cost-sharing if the Secretary determined that the reduction was tied to performance measures and other incentives applicable under its contract and such reduction would not increase federal costs. Entities could also require higher cost-sharing for nonformulary drugs, except that higher cost-sharing would not be permitted if the drug was determined to be medically necessary.

In general, beneficiaries would pay a monthly premium equal to 50% of program costs; the remaining 50% would be paid by the federal government. (Premiums paid by former employers would equal two-thirds of the total). Premiums would be collected in the same way as Part B premiums, for most persons this is a deduction from social security checks.

Higher income beneficiaries would receive a lower premium contribution from the federal government. Individuals with adjusted gross incomes between \$75,000 and \$100,000 and couples with adjusted gross incomes between \$150,000 and \$200,000 would have the government premium contribution reduced from 50% to 25%, calculated on a sliding scale basis. (These income amounts would be adjusted for inflation as measured by the consumer price index for years after 2003). All beneficiaries would receive a minimum 25% government subsidy.

**Covered Drugs.** In general, coverage would be extended to outpatient prescription drugs meeting FDA criteria, biologicals, and insulin. In addition,

coverage would be extended to over-the-counter products meeting the coverage criteria for outpatient prescription drugs and biologicals. Drugs excluded under Medicaid (except for smoking cessation products) would not be covered. Drugs currently covered under Medicare would continue to be covered under the basic program. The program would provide coverage of all therapeutic classes of covered drugs. Entities would be required to cover nonformulary drugs when determined to be medically necessary.

**Administration.** The Secretary would establish a competitive bidding process for the award of contracts to eligible entities to administer the drug benefit. At least 10 different coverage areas would be established. At least 2 contracts would be awarded in each area unless only one entity met the bidding requirements. Each contract would be awarded for 2-5 years. An eligible entity is defined as a pharmacy benefit management company, retail pharmacy delivery system, health plan or insurer, a state (through mechanisms established under Medicaid), any other entity approved by the Secretary, or any combination of these if the Secretary determined the combination increased the scope or efficiency of benefits and was not anti-competitive. Eligible entities would be required to offer contracts on a regional basis, except that the Secretary could permit coverage on a partial regional basis if the region was at least the size of the commercial service area of the entity and the area was not smaller than a state.

The entity's bid would include: 1) a proposal for the estimated prices for covered drugs, projected annual increase in prices, including differentials between formulary and nonformulary prices, if applicable; 2) the amount the entity would charge the government for administering the benefit; 3) a statement regarding whether the entity would waive the deductible for generic drugs; 4) a statement of whether there would be any coinsurance reduction; 5) a detailed discussion of risk corridors tied to performance measures and other incentives the entity would accept under the contract and how the entity would meet these; 6) a detailed description of any ownership or shared financial interests with other entities involved in delivering the drug benefit; 7) description of the entity's estimated marketing and advertising expenditures; and 8) other information deemed necessary by the Secretary. The Secretary would consider the comparative merits of each bid based on past performance and other factors. A contracting entity would be required to provide detailed reports to the Secretary on its operations.

The Secretary would be required to ensure that an eligible entity complies with access requirements, including contracting with a sufficient number of retail pharmacies, and makes available to each beneficiary the full scope of benefits under the contract. The Secretary would develop procedures for the provision of covered drugs to beneficiaries in an area not covered by a contract.

The Secretary would conduct activities to broadly disseminate information regarding drug coverage. To the extent practicable, this information would be made available prior to a beneficiary's first enrollment period. Information would include comparative information for each eligible entity on: 1) benefits provided including a comparison of the pharmacy networks used, formularies, and appeals processes; 2) quality and performance; 3) beneficiary cost-sharing; 4) results of consumer satisfaction surveys; and 5) additional information as determined by the Secretary.

The information activities would be coordinated with other required information activities including those for Medicare+Choice. The Secretary could contract with Medicare Consumer Coalitions (nonprofit entities made up primarily of beneficiaries) to conduct information activities; such sums as may be necessary would be authorized for this purpose. The Secretary would also approve marketing materials distributed by contracting entities.

The Secretary, on the basis on tax return information from the Secretary of the Treasury and any information supplied by the beneficiary, would make determinations of anticipated modified adjusted gross income (AGI) for purposes of determining those high-income persons subject to higher premiums. (The definition of modified AGI would include nontaxable interest income). Adjustments would be made in the next year to account for any underpayment or overpayment of premiums due to a difference between anticipated and actual AGI.

The Secretary would establish procedures for making payments to eligible entities under which entities would only be subject to limited risk. The procedures could include the use of risk corridors tied to performance measures that were agreed to under the contract as well as any other incentives the Secretary determined appropriate.

Medicare+Choice plans would be required to offer, at a minimum, drug benefits. Enrollees electing the drug benefit would receive these benefits through the plan. Capitation payments to the plans would be adjusted accordingly.

A 19-member Medicare Pharmacy and Therapeutics (P&T) Advisory Committee would be established to advise the Secretary on policies related to: 1) development of guidelines for administration of the benefit; 2) development of standards for contracting entities for their P&T committees; 3) establishment of procedures for making medical necessity determinations for drug coverage, 4) entities' standards for establishing and modifying the formulary; 5) procedures to evaluate bids from eligible entities; and 6) procedures to ensure that contracting entities were in compliance with Part D requirements. The Committee membership would be representative of physicians (11 members), pharmacists (4 members), HCFA (1 member), actuaries and pharmacoeconomists (2 members), and emerging drug technologies (1 member).

**Beneficiary Protections.** Contracting entities would be required to comply with requirements relating to: 1) quality and financial standards; 2) procedures to ensure proper utilization and compliance, and avoidance of adverse drug reactions; 3) patient protections including ensuring access (including contracting with a sufficient number of retail pharmacies); and 4) procedures to guarantee patient confidentiality and timely transfer of records. Further, entities would have to have procedures (comparable to those applicable for Medicare+Choice) to ensure timely review and resolution of coverage denials.

**Cost Control Mechanisms; Formularies.** Contracting entities could employ mechanisms to provide benefits economically including formularies, alternative distribution methods, and generic drug substitution. They could use mechanisms to encourage beneficiaries to select cost-effective drugs or less costly means of receiving drugs including use of pharmacy incentive programs, therapeutic interchange

programs, and disease management programs. They could also encourage pharmacy providers to inform beneficiaries of price differences between generic and nongeneric drugs and to provide beneficiaries with medication therapy management programs. Any formulary would have to comply with standards established by the Secretary in consultation with the Medicare Pharmacy and Therapeutics Advisory Committee. The formulary would be required to include at least two drugs from each therapeutic class (unless only 1 drug was available in the class), and a generic substitute (if available) if more than 2 drugs were available in a class. Further, the contracting entity would be required to develop procedures for modification of the formulary and to disclose to current and prospective beneficiaries related information. Entities would be required to cover nonformulary drugs when determined to be medically necessary. Entities would be required to establish procedures that provide for such determinations to be based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence.

**Relationship to Group Health Plans.** The Secretary would be authorized to develop an Employer Incentive Program under which employers and other sponsors of employment-based retiree coverage that is at least equivalent to that under the new Part D would receive incentive payments. Such payments would be made in behalf of beneficiaries who obtained drug coverage under the sponsors plan rather than Medicare. The incentive payment would equal 2/3 of the amount the government would otherwise pay if the individual were enrolled in Part D.

**Relationship to Medigap.** Medigap plans that offer drug coverage would have to be revised to complement, not duplicate Part D. The revised drug packages could not offer coverage for the Part D deductible or for more than 90% of the Part D coinsurance.

**Relationship to Medicaid; Assistance for Low-Income.** Medicaid would cover Part D premiums, coinsurance, and deductible for persons below 135% of poverty. (Coinsurance and deductible amounts would be based on drug payment amounts determined under Part D not Medicaid). The current federal-state matching rate would apply for those below 120% of poverty. The federal matching rate would be 100% for those between 120% and 135% of poverty.

Beneficiaries between 135% and 150% of poverty would pay a reduced Part D premium, calculated on a sliding scale basis. The federal matching rate for the remaining premium costs would be 100%.

**Financing Mechanism.** Part D premiums would be credited to the Part B trust fund, and Part D costs would be paid from the Part B trust fund. Part D costs would be excluded from the determination of the Part B premium. The bill would authorize the appropriation of such sums as are necessary, beginning in FY2001, for the administration of the Part D program.

## **Medicare Temporary Drug Assistance Act [S. 3016 and S. 3017 (Roth et al)]**

**General Approach.** With a few exceptions, these bills are identical. They establish a new temporary Outpatient Prescription Drug Assistance Program under a new Title XXII of the Social Security Act. Funds would be provided to states (individually or as part of a group) who voluntarily set up prescription drug programs for low-income Medicare beneficiaries. States programs could also provide assistance to Medicare beneficiaries with high drug costs. A state's Title XXII program would be separate from its Medicaid program. The bills would establish a default program, administered by HCFA, for persons residing in states which did not establish a program.

The bills are identical except: 1) the level at which states could set the definition of low-income is higher under S. 3017; 2) the amount allocated is \$17.4 billion over the FY 2001-2004 period under S. 3016 and \$28.6 billion under S. 3017; and 3) the sunset date is December 31, 2003 under S. 3016 and September 30, 2004 under S. 3017. Both bills specify that the program would be repealed if a comprehensive Medicare reform plan that included coverage for outpatient prescription drugs was enacted prior to the sunset date.

**Persons Covered; Enrollment.** Persons eligible for coverage under a state program would be low-income Medicare beneficiaries, and, at state option, Medicare beneficiaries with high drug costs. Beneficiaries eligible for assistance under either program would be persons entitled to Medicare Part A or enrolled in Part B, including Medicare+Choice enrollees. Persons entitled to drug coverage under Medicaid would not be eligible.

Persons eligible for assistance as low-income Medicare beneficiaries would have to have a family income below a state-established level expressed as a percentage of the poverty line. In general, this level could not exceed 150% of poverty under S. 3016 (175% under S. 3017). However, a higher level could be established if a state, prior to enactment, had a state-based drug assistance program providing coverage for persons with incomes up to or exceeding 150% of the poverty line under S. 3016 (175% under S. 3017). In this case, the state established level under the new program could not exceed 50 percentage points above the income level established for the state-based drug program. States would also be permitted, but not required, to establish a resources limit for the new program.

States could also elect to provide assistance to Medicare beneficiaries (not covered under the low-income program) with high drug costs. Persons eligible for this assistance would be those whose family income exceeded the state-established level that would qualify them for assistance as a low-income Medicare beneficiary. A state could choose to limit the eligible population to persons meeting specified resource requirements. Individuals meeting the income (and resource requirements if applicable) would be eligible for assistance when their out-of-pocket expenditures for outpatient prescription drugs exceeded the state-established level.

For purposes of the default program, individuals eligible as low-income Medicare beneficiaries would be those with family incomes below a percentage of the poverty line, not exceeding 135%, as specified by the HCFA. HCFA would also be permitted, but not required, to establish a resources limit. Subject to the availability of funds, the default program would also include Medicare beneficiaries with high drug costs. Persons eligible for this assistance would be those whose family incomes exceeded the level that would qualify them for assistance as low-income Medicare beneficiaries. HCFA would also be permitted, but not required, to establish a resources limit for these individuals. Individuals meeting the income (and resource requirements if applicable) would be eligible for assistance when their out-of-pocket expenditures for outpatient prescription drugs exceeded a specified level in any 3-month period. The level would be established by HCFA, consistent with the availability of funds in the state where the beneficiary resides.

**Scope of Benefits; Beneficiary Cost-Sharing.** The outpatient prescription drug assistance provided under an approved state plan would be: 1) coverage that was equivalent to that provided in a benchmark benefit package; 2) coverage that had an aggregate actuarial value equivalent to that of a benchmark package, 3) coverage that was provided under an existing state-based program, or 4) another coverage package approved by the Secretary as providing appropriate outpatient prescription drug coverage for the eligible population. A state could only choose one of these options. Further, if a state chose to provide coverage equivalent to coverage in a benchmark package, only one benchmark package could be selected.

The benchmark packages from which a state (or groups of states) could select would be Medicaid coverage, coverage offered to state employees, coverage offered through the largest health maintenance organization (HMO), or Federal Employees Health Benefit Plan (FEHBP) coverage. Benchmark Medicaid coverage would be defined as that offered under the state's Medicaid program. Benchmark state employee coverage would be defined as the outpatient prescription drug coverage offered and generally available to state employees in the state. Benchmark prescription drug coverage offered through the largest HMO would be defined as the outpatient prescription drug coverage provided through a health insurance coverage plan that was offered by an HMO and that had the largest insured commercial non-Medicaid enrollment of covered lives offered by a HMO in the state. In the case of a plan offered by a group of states, the benchmark coverage selected would be the Medicaid plan, state employee plan, or largest HMO plan (whichever is appropriate) which exists in one of the states in the group. In all cases, benchmark FEHBP coverage would be defined as the coverage provided under the standard Blue Cross and Blue Shield service benefit plan.

A plan could not impose any premium or cost-sharing on a beneficiary whose family income was below 100% of the poverty line. Any such charge imposed on other low-income beneficiaries or on Medicare beneficiaries with high drug costs could be imposed on a sliding scale based on income. In no case could the annual aggregate of such premiums or cost-sharing imposed on all Medicare beneficiaries in a family exceed 5% of the family's annual income.

If an individual was covered under the default program, the benefit would be equivalent to the FEHBP-equivalent benchmark package.

**Covered Drugs.** Coverage would be provided for self-administered outpatient prescription drugs and biologicals (including insulin and insulin supplies). Coverage would not include items covered under Medicare or items for which coverage was not available under a state Medicaid plan; states would not be required to cover these drugs even if they were included in a benchmark package.

**Administration of Benefits.** State programs would be administered by the states. A state or group of states could not receive program payments unless they submitted a written plan to the Secretary of HHS. The plan would have to meet certain requirements. It would have to describe how the state, or group of states, intended to use the funds. It would have to include a description of the budget for the plan (updated periodically as necessary) and details on the planned use of funds, sources of the non-federal share of plan expenditures, and any cost-sharing requirements. The plan would be approved by the Secretary of HHS prior to receipt of program funds.

A state would be required to submit a plan, which the Secretary finds meets the applicable requirements, by September 1 prior to the start of the fiscal year, except that the submission for FY2001 would have to occur by December 30, 2000. The plan would be approved by the Secretary and become effective beginning with a calendar quarter specified in the plan, but in no case earlier than October 1, 2000. The Secretary would have to be notified within 30 days of any plan amendment.

The Secretary would be required to review promptly the plan and plan amendments to determine if they substantially complied with the requirements of Title XXII. A plan or plan amendment would be considered approved unless the Secretary notified the state or group of states within 45 days of receipt of either disapproval (and the reasons for disapproval) or the need for specified additional information. An approved state program would continue in effect, until the program's sunset date, unless and until the state or group of states amended the plan or the Secretary found substantial noncompliance with program requirements.

State plans would have to include an assurance that the state or group of states administering the plan would collect data, maintain records, and give the Secretary access to records or information needed for review or audit. The state or group of states would also be required to furnish the Secretary with periodic reports so that the Secretary could monitor program administration and compliance and evaluate and compare the effectiveness of plans.

Each state or group of states administering a plan would be required to assess annually the operation of the plan and report the result of such assessment to the Secretary. The Secretary would be required to submit an annual report to the Congress based on the state reports and the report prepared by HCFA on the default program. The report would contain any conclusions and recommendations the Secretary considered appropriate.

The bill would require the establishment of a default program in a fiscal year for beneficiaries residing in a state which failed to submit a plan to the Secretary by the required date. The default program would provide outpatient prescription drug assistance to low-income Medicare beneficiaries and, subject to the availability of

funds, Medicare beneficiaries with high drug costs. Such assistance would be provided through HCFA. HCFA would enter into contracts for the provision of outpatient prescription drug assistance. Contractors could be PBMs or other entities meeting standards established by HCFA.

For purposes of the default program, HCFA would: 1) establish procedures for making eligibility determinations; 2) establish a process for accepting bids, awarding contracts, and making payments to PBMs or other entities under such contracts; and 3) establish policies and procedures for overseeing the provision of assistance under the contracts.

For FY2001 only, HCFA would be permitted to contract with PBMs or other entities without using competitive bidding. Each contract would be for a uniform term of at least 1 year. It could be made automatically renewable from term to term in the absence of termination notification by either party. The contract would specify the amount and manner in which payments (including any administrative fees) would be made to the PBM or other entity for the provision of outpatient prescription drug assistance.

**Payment for Drugs.** States would determine payments under state programs. The entities contracting with HCFA would determine payments under the default program.

**Beneficiary Protections.** An outpatient prescription drug assistance plan could not impose any preexisting condition exclusion for covered benefits. Further, it could not discriminate in the pricing of premiums because of health status, claims experience, receipt of health care, or medical condition.

HCFA would develop and implement quality and service assessment measures for the default program. These measures would include beneficiary quality surveys and annual quality and service rankings for PBMs and other entities awarded contracts.

**Cost Control Mechanisms; Formularies.** Not specified.

**Relationship to Group Health Plans.** No federal matching funds would be available to the extent a private insurer would have been obligated to provide assistance but for an exclusion provision in its insurance contract; private insurers covered under this provision would include group health plans, service benefit plans, and health maintenance organizations.

**Relationship to Medicaid.** The new program would be separate from Medicaid. Persons eligible for drug benefits under Medicaid would not be eligible for benefits under Title XXII. The one exception is the case of a state which has established a drug program for Medicare beneficiaries under a Medicaid waiver.

**Relationship to Medigap.** Benefits and premiums payable under a Medigap policy would be suspended, at the request of a policyholder, during the period the policyholder was covered under a state program or was provided coverage under the default program. The policyholder would automatically be reinstated in the Medigap

plan if the policyholder notified the plan within 90 days of the loss of coverage under the state program or the default program.

**Financing Mechanism.** S. 3016 would appropriate the following amounts for purposes of making allotments to the states or groups of states: \$1.2 billion in FY2001, \$4.2 billion in FY2002, \$9.0 billion in FY2003, and \$3.0 billion in FY2004. The amounts under S. 3017 would be: \$1.3 billion in FY 2001; \$4.6 billion in FY 2002; \$9.7 billion in FY 2003; and \$13.0 billion in FY 2004. The Secretary would allocate the amount appropriated in a fiscal year to the states with approved outpatient prescription drug assistance plans. The amount available for allocation would be reduced by any amounts made available to the territories (0.25% from the total amount available). The amount allocated to each state would bear the same ratio to the total allotment amount as the ratio of the number of the state Medicare beneficiaries below 150% of poverty (175% under s. 3017) bore to the number of such beneficiaries in all states with plans. A minimum allotment available to any state would be 0.5% of total allotments (after subtracting amounts for territories); if needed to meet this requirement, allotments otherwise determined would be proportionately adjusted.

If a state did not submit a plan to the Secretary by the required date (see above), 90% of the allotment for the state would be made available to the Secretary for purposes of administering the default program; the other 10% would be redistributed among states with plans.

The Secretary would make quarterly payments to each state with an approved plan from the state's allotment. The amount of the federal payment would be 100% of the costs incurred in providing drug coverage for persons with family incomes that did not exceed 135% of poverty. For all other low-income Medicare beneficiaries and, if applicable for Medicare beneficiaries with high drug costs, the federal matching rate for drug costs would equal an enhanced federal matching rate. The enhanced matching rate would be defined as the federal matching rate for the state's Medicaid program plus 30% of the percentage point difference between this rate and 100%. [For example, a state with a 60% federal Medicaid match rate would have an enhanced rate of 72% ( $60\% + 0.3 \times 40\%$ ).] In no case could the federal rate exceed 85%. This is the same enhanced matching rate used for the State Children's Health Insurance Program (SCHIP). The amount of expenditures eligible for federal matching payments would be reduced by any beneficiary premiums or cost-sharing. Amounts provided by the federal government or services assisted or subsidized to any significant extent by the federal government could not be used to meet the requirement for state matching funds.