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Medicare: Prescription Drug Proposals

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ABSTRACT

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to offer protection against the costs of most outpatient prescription drugs. President Clinton has offered a Medicare reform plan (S. 2342). A key component of this proposal is the establishment of an optional prescription drug benefit for all beneficiaries. Another Medicare reform plan (S. 1895) has been introduced by Senator Breaux (formerly co-Chairman of The National Bipartisan Commission on the Future of Medicare) and Senator Frist; this measure provides access for Medicare beneficiaries to high option plans with drug coverage. The Senate Democrats have introduced a measure similar to the President's plan.

A number of other bills whose primary focus is prescription drug coverage for the Medicare population have been introduced in the 106th Congress. This report provides an overview of the President's plan and the legislation introduced to date in the 106th Congress. It will be updated as additional bills are introduced. It will also track any legislative action. This report is a supplement to CRS Report RL30147, *Medicare: Prescription Drug Coverage for Medicare Beneficiaries.*

Medicare: Prescription Drug Proposals

Summary

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to offer protection against the costs of most outpatient prescription drugs. Many observers contend that this is a significant coverage gap. 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.

Beginning in 1999, the issue received renewed 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. This measure provides access for Medicare beneficiaries to high option plans with drug coverage. A modified version of S. 1895 is currently being developed.

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. Beneficiaries would pay a monthly premium of $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 May 10, 2000, Senator Daschle introduced the Senate Democrats' plan (S. 2541) which is similar to the Administration's bill except that the program would begin in 2002.

On April 12, 2000, the House GOP announced the outlines of its drug plan. Under the proposal, beneficiaries could choose from a variety of private sector plans. There would be a maximum limit on beneficiary out-of-pocket costs ("stop-loss" coverage); and assistance would be provided to low-income seniors. The plan is currently being drafted.

A number of other bills whose primary focus is prescription drug coverage for the Medicare population have been introduced in the 106th Congress. This report provides an overview of legislation introduced to date in the 106th Congress. It will be updated as additional bills are introduced. It will also track any legislative action. **This report is a supplement to CRS Report RL30147, *Medicare: Prescription Drug Coverage for Medicare Beneficiaries.*** That report provides an overview of prescription drug coverage currently available to beneficiaries, presents information on the utilization of drugs by the target population, and outlines some of the major issues that would need to be considered in the design of a drug benefit.

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Introduction

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to 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 beneficiaries themselves pay for half of their drug costs out-of-pocket.

The absence of a significant drug benefit is not a new concern. However, 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.

On June 29, 1999, President Clinton announced the Administration's Medicare reform plan. Further details were issued by the White House on July 2, 1999. 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 President's proposal is the establishment of an optional prescription drug benefit for all beneficiaries. The benefit would be phased-in over 6 years.

On November 9, 1999, Senators Breaux, Frist, Kerry and Hagel introduced the Medicare Preservation and Improvement Act of 1999 (S. 1895). This measure builds on, but contains a number of changes to, the measure considered by the National Commission. The bill provides for comprehensive Medicare reform. It establishes, a competitive premium system under which beneficiaries could choose from competing

private health plans to obtain their health services; they could also remain in the traditional fee-for-service program. Private health plans and the government run fee-for-service program would be required to offer high option plans which included prescription drug benefits.

A number of other bills whose primary focus is prescription drug coverage for the Medicare population have been introduced in the 106th Congress. The following bills would add a new benefit to the Medicare program itself: Medicare Outpatient Prescription Drug Coverage Act of 1999 [H.R. 1109 (Engel, et al.)]; Access to Prescription Medications in Medicare Act of 1999 [H.R. 1495 (Stark, et al.) and S. 841 (Kennedy, et al.)]; Medicare Chronic Disease Prescription Drug Benefit Act of 1999 [H.R. 1796 (Cardin et al.)]; Medicare Prescription Drug Benefit Act of 1999 [H.R. 2012 (Deutsch and Wexler)]; Seniors Prescription Insurance Coverage Equity (SPICE) Act of 1999 [H.R. 2782 (Pallone and Roukema) and S. 1480 (Snowe and Wyden)], and a similar bill, New Insurance Equity (NICE) Act of 1999 [H.R. 3482 (Maloney)]; Healthy Seniors Promotion Act of 1999 [S. 1204 (Graham)], Medicare Ensuring Prescription Drugs for Seniors Act of 1999 [S. 1535 (Grams)] and Voluntary Medicare Prescription Drug Plan Act of 2000 [Smith and Allard (S. 2319)].

One measure, Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 1999 [H.R. 2925 (Bilirakis, et al.)], adds benefits for the Medicare population through the Public Health Service Act. Another measure, Healthy Seniors Act of 1999 [S. 1837 (Baucus)] adds a benefit for the low-income through Medicaid. Still another measure, Medicare Low-Income Prescription Drug Assistance Act of 2000 [Foley (H.R. 4235)] establishes a separate voluntary program.

One measure modifies Medigap policies to include drug-only policies and provides assistance to low income persons purchasing drug policies [DrugGap Insurance for Seniors Act of 1999 [S. 1725 (Jeffords)]. Another measure, Seniors Security Act of 1999 [S. 2237 (Craig)] provides for the deductibility of premiums for Medigap and Medicare+Choice plans which contain a drug benefit and modifies Medigap standardized policies. One measure does not add a benefit but establishes a financing mechanism: Medicare Prescription Drug Coverage Act of 1999 [H.R. 886 (Frank, et al.) and S. 696 (Wellstone)]. Two bills would not modify the Medicare program, but would substantially modify the prices seniors pay for drugs: Prescription Drug Fairness for Seniors Act [H.R. 664 (Allen, et al.) and S. 731 (Kennedy, et al.)] and Making Affordable Prescriptions Available for Seniors Act [H.R. 723 (Kennedy, et al.)].

On April 12, 2000, the House GOP announced the outlines of its drug plan. Under the proposal, beneficiaries could choose from a variety of private sector plans. There would be a maximum limit on beneficiary out-of-pocket costs ("stop-loss" coverage); and assistance would be provided to low-income seniors. The plan is currently being drafted.

The conference report on the FY2001 budget resolution (H.Con.Res. 290, H.Rept. 106-577, approved by both House and Senate on April 13, 2000) contains different assumptions for the House and Senate relating to drugs for the Medicare population. 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 is close to the 5-year cost estimate for the drug benefit included in the Administration's bill.

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. However, the phase-in begins in 2002 rather than 2003.

This report provides an overview of the legislation introduced to date in the 106th Congress. It will be updated as additional bills are introduced. It will also track any legislative action. **This report is a supplement to CRS Report RL30147, *Medicare: Prescription Drug Coverage for Medicare Beneficiaries.*** That report provides an overview of prescription drug coverage currently available to beneficiaries, presents information on the utilization of drugs by the target population, and outlines some of the major issues that would need to be considered in the design of a drug benefit.

Current Proposals

To date, a number of specific proposals have been offered for adding prescription drug coverage for the Medicare population.[1] Other proposals address the question of affordability of drugs for the senior population but do not add a new federal benefit.

New Benefit

Scope of Benefits. Several proposals add a new comprehensive benefit to Medicare. Under the President's plan, the Daschle bill (Senate Democrats measure), and the SPICE proposal, any beneficiary who voluntarily enrolled in a new Medicare Part D could obtain coverage. Under a number of the pending bills, protection would be available to anyone who was enrolled in the existing Part B program (which covers the costs of physicians and other medical services).

Under Breaux/Frist, access to drug coverage is an integral part of the reform plan. The bill establishes a competitive premium system under which beneficiaries could choose from competing private health plans to obtain their health services; they could also remain in the traditional fee-for-service program. At their option,

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[1] This report does not include a discussion of legislation which is limited to one particular category of drugs, for example bills which would eliminate the time limitation on the coverage of immunosuppressive drugs (one of the limited category of outpatient prescription drugs currently covered under the program).

beneficiaries could purchase a high option plan which included prescription drug benefits.

An alternative approach would add benefits for the Medicare population through the Public Health Service Act. Under this plan, catastrophic protection ("federal stop-loss protection") would be available for all Medicare beneficiaries if their expenses exceeded a specified amount. Assistance for the low income would only be available to persons in states which chose to set up state prescription drug assistance programs. [H.R. 2925, Bilirakis].

Many of the measures would add protection for all outpatient prescription drugs provided they met FDA (Food and Drug Administration) criteria and were medically necessary. One bill (H.R. 1796, Cardin) would restrict coverage to prescription drugs used to treat specified chronic conditions such as hypertension. Another measure (S. 1204, Graham) would limit coverage to preventive outpatient prescription drugs which were the direct result of a beneficiary's participation in a preventive screening program.

Several measures do not establish a definition of covered benefits in law, but rather link minimum covered *benefits* to a threshold level of benefits. Under the SPICE proposal (H.R. 2782/S. 1480), this threshold would be defined by a newly created SPICE Board and would include at least threshold benefits specified by the National Association of Insurance Commissioners (NAIC) based on levels established under other insurance plans. Under H.R. 2925, states would define the scope of coverage under their drug assistance programs for the low-income. Coverage could not be less than that offered under a benchmark program such as Medicaid, coverage available to Blue Cross/Blue Shield enrollees under the Federal Employees Health Benefits program (FEHBP), coverage available to state employees, or coverage available to enrollees in the state's largest health maintenance organization (HMO).

S. 1725 (Jeffords) would not establish a new federal benefit. Instead it would provide for changes in Medigap policies and development of new supplemental drug-only DrugGap policies meeting minimum coverage levels. S. 2237 (Craig) would also modify Medigap policies. In addition, it would permit all persons (not just those that itemize) to deduct premiums for Medigap and Medicare+Choice plans which contain a drug benefit.

Beneficiary Cost-Sharing and Premiums. A key consideration in the development of a Medicare drug bill is the amount beneficiaries will be asked to pay both in cost-sharing and premium charges. Under the President's plan and the Daschle bill there would be no deductible; the program would pay half of the drug costs beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. Most of the other proposals would not cover costs until the beneficiary had satisfied a calendar year deductible (e.g., $200). However, many of these plans would cover 80% of the costs once the deductible had been met. S. 1535 would establish a *monthly* deductible after which 75% of the recognized costs would be paid. Under S. 1895 (Breaux/Frist), individual plans would determine beneficiary cost-sharing. S. 2319 (Smith) provides that a beneficiary enrolled in the Rx Option would be subject to a combined deductible ($675 in 2001) for Medicare Part A,

Medicare Part B, and drug expenses; after the deductible is met the program would pay 50% of drug costs up to a specified annual maximum ($5,000 in 2001).

Most proposals would limit the federal exposure. Several measures would place an absolute cap on federal expenditures per person per year. For example, under the President's plan and the Daschle bill, the federal government would pay 50% of the first $2,000 in drug costs for a maximum federal payment of $1,000. When the plan is fully phased-in, the plan would pay the first 50% of the first $5,000 in expenses for a maximum contribution of $2,500. Under H.R. 2012, no coverage would be provided for costs exceeding $5,200. An alternative approach (H.R. 1495/S. 841) would cover 80% of the costs up to $1,700, provide no coverage of costs between $1,700 and $3,000, and offer full coverage for costs over $3,000. Under Breaux/Frist federal assistance is limited to a specified percentage (based on income) of the portion of the premium attributable to drug coverage; this calculation is based on the actuarial value of the minimum benefit.

The federal stop-loss program established under H.R. 2925 (Bilirakis) would not cover any costs until the beneficiary (who had qualified prescription drug coverage) had incurred out-of-pocket expenditures exceeding a specified amount ($1,500 in 2000); at that point no further beneficiary cost-sharing would be required.

Cost sharing charges are in addition to any premiums that may be required. Under the President's plan and the Daschle bill, a separate premium, equal to 50% of program costs, would be established for coverage under the new optional Part D. The Administration estimates that the premium under its bill would initially be $26 per month, rising to an estimated $51 when the plan is fully phased-in.

Many of the other bills include prescription drugs as a new Part B benefit. They are by definition providing for an increase in the Part B premium (currently $45.50 per month). By law, beneficiary premiums currently cover 25% of program costs (with federal general revenues covering the remaining 75%). Certain low income beneficiaries can have these Part B premium costs paid for by the federal/state Medicaid program. These persons are known as either: (1) Qualified Medicare Beneficiaries (QMBs) — persons with incomes below 100% of poverty; or (2) Specified Low Income Medicare Beneficiaries (SLIMBs) — persons with incomes below 120% of poverty. In certain cases, persons below 135% of poverty can qualify for payment of their Part B premiums.

The SPICE proposal (H.R. 2782/S. 1480) would provide financial assistance, for persons obtaining drug coverage through a Medicare+Choice plan, a Medicare supplemental policy, or a group health plan. Federal assistance would equal at least 25% of the drug portion of the premium cost; any remaining premium, if any, would be paid by the beneficiary. The specified levels of assistance would be reduced if there were insufficient funds available in the newly established trust fund.

Under S. 1895 (Breaux/Frist), beneficiaries would not pay any Part B premiums but would instead be liable for a portion of the premium for the standard or high option plan selected by the beneficiary. (If beneficiaries selected a low cost plan, the liability for core benefits could be zero). All persons enrolled in a high option plan

would receive some assistance on that portion of their premium attributable to drug coverage.

Administration. A major issue in the design of a prescription drug benefit is how the program would be administered. Some would propose using the existing Medicare structure with some changes to permit more private sector involvement in the processing of claims (H.R. 1109, S. 1535). Most proposals recommend the use of private entities, selected on a competitive basis, to administer the program. For example, Stark/Kennedy, Cardin, Deutsch, and Graham would award competitively-bid contracts to provide benefits in a geographic area; eligible entities would include pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. The President's plan also proposes using similar entities to administer the plan though the types of entities are not specified in the bill. The Daschle bill specifies that the benefit would be administered by private entities. Breaux/Frist would use similar entities to administer high option HCFA-sponsored plans (i.e. those plans for persons remaining in the fee-for-service program); however, it does not specify the types of entities that could administer the new private plans.

Payments for Drugs/Cost Controls. An issue closely linked to program administration is how payments for drugs would be determined. The industry has registered its strong opposition to federal determination of prices — what they label as federal price controls.

Many of the proposals would let the administering entities set up the payment rules that would apply in a geographic area. They would also specifically permit the use of cost control mechanisms, including formularies (which are lists of drugs which are preferred for use by the health plan). Alternatively, two bills (Engel and Grams) would set up specific federal payment rules; they would also prohibit the use of formularies.

Protection for Low-Income. Many of the proposals would provide special protections for the low income. The President's plan and the Daschle bill would ensure that beneficiaries with incomes below 135% of poverty would not pay for premiums or cost-sharing charges. Persons with incomes between 135% and 150% of poverty would receive some assistance for premium costs. Stark/Kennedy and Cardin would provide that persons meeting the SLIMB criteria (and not otherwise eligible for Medicaid) would receive comprehensive wrap-around coverage through Medicaid. Under the Baucus bill, persons with incomes below 175% of poverty would receive some assistance for out-of-pocket costs through Medicaid with persons below poverty receiving full assistance for such costs.

The SPICE proposal would provide enhanced financial assistance in meeting drug coverage premium costs for persons below 175% of poverty; persons below 150% of poverty would receive 100% of such costs. The Jeffords bill would provide financial assistance to low income persons to assist them in purchasing new supplemental DrugGAP insurance.

Under the Bilirakis bill , the state drug assistance programs would be limited to persons whose income fell below a level set by the state between 120% and 200% of

poverty. No cost-sharing could be imposed on persons whose income was below 120% of poverty.

Under Breaux/Frist, beneficiaries at or below 135% of poverty would pay zero premium for enrollment in the lowest cost high option plan in their area. All other beneficiaries enrolled in a high option plan would receive a discount on that portion of their premium attributable to the minimum drug benefit The discount for persons with incomes between 135% and 150% of poverty would range from 50% phasing-down to 25%.

Financing Mechanism. Many of the bills do not specify a new funding source for the drug benefit.

The President's plan specifies that beneficiaries would pay monthly premiums equal to 50% of the program's cost for the new optional benefit. The President's plan includes a number of modernization proposals for the Medicare program as a whole; the savings from these changes would finance a significant portion of the benefit. Breaux/Frist uses current funding sources though the amount of an individual's premium obligation could be greater or less than the current Part B premium depending on the plan selected; the bill would limit general revenue financing.

The SPICE proposal would be financed through a combination of increases in tobacco taxes and amounts from the federal budget surplus. The bill specifically provides that financial assistance under SPICE could not exceed the amount of money available.

Many of the other proposals would add a new Part B benefit. By definition a portion of the costs would be financed through an increase in the Part B premium (currently $45.50 per month); the remaining costs would be financed from general revenues. Most of the pending bills do not contain specific financing proposals for the remainder of the costs. One measure (Frank/Wellstone) calls for the use of federal estate tax revenues to finance a new benefit.

The sponsors of one measure, Smith/Allard, claim that implementation of the new Rx Option would require no new federal costs and no beneficiary premiums.

Bills Directed Toward Amounts Seniors Pay for Drugs

Several measures would not add a new Medicare benefit but would limit the prices seniors pay for prescription drugs. One measure (Allen bill) would provide for substantial reductions in these prices. Another measure (Kennedy, H.R. 723) would establish a pharmacy assistance program to help elderly low income persons, with no other insurance coverage, to pay for drugs.

Summary of Proposals to Establish a New Benefit

The following is a summary of the key features of bills introduced in the 106th Congress which would add a new prescription drug benefit. *The bills are summarized in the order they have been introduced in the House. Senate bills with no companion House measure are at the end.*

The following major features are described for each plan: general approach, persons covered, scope of drug benefits, administration of benefits, reimbursement, beneficiary cost-sharing and premium charges, beneficiary protections, cost control mechanisms/formularies, relationship to group health plans, relationship to Medigap, relationship to Medicaid/assistance for low-income, and financing.

Medicare Outpatient Prescription Drug Coverage Act of 1999 [H.R. 1109 (Engel et al.)]

General Approach. The bill creates, beginning in 2001, a new drug benefit under Part B. Program payments would equal 80% of program costs after the beneficiary met a deductible ($200 in 2001). The benefit would be administered in a manner similar, but not identical, to that used for other Part B services.

Persons Covered. Coverage is extended to all persons enrolled in Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Part B would be part of the new benefit and subject to the new payment and cost-sharing rules.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish a point-of-sale electronic claims system for use by Part B carriers and participating pharmacies. (A point-of-sale electronic system would allow for the immediate processing of claims, including a determination of whether the deductible has been met.) The Secretary could contract with entities other than Part B carriers for implementation and operation of the system; such entities could include a voluntary association, corporation, partnership, or other non-governmental organization which the Secretary determines to be qualified to conduct such activities. The Secretary could require carriers to subcontract with such entities to implement and operate the electronic claims system. The Secretary would develop a standard claims form (and standard electronic claims format) for drug claims.

The law would establish a participating pharmacy program under which pharmacies authorized under state law to dispense drugs would enter into agreements with the Secretary to: (1) accept "assignment" (i.e., agree not to charge patients more than the coinsurance) once the entity is notified the individual has met the deductible; (2) agree not to refuse to dispense covered drugs and not to charge beneficiaries more than charged to the general public; (3) keep patient records, (4) submit information necessary to administer the benefit; and (5) consistent with state law, offer to counsel or to provide information to beneficiaries on the appropriate use of a drug, whether

there are potential interactions with other drugs dispensed to the beneficiary, and advise the beneficiary on the availability of therapeutically equivalent drugs.

A new 11-member Prescription Drug Payment Review Commission would be established; it would consist of experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescription drug reimbursement as well as at least one beneficiary. The Commission would submit an annual report to Congress concerning methods of determining payments for covered outpatient drugs. Beginning in 2002, the report would include information on changes in prices and utilization. The Secretary would also be required to submit an annual report on these issues.

Reimbursement. Payments would equal 80% of the lesser of the actual charge or the payment limit. There would be two payment limits. One category is for multiple source drugs without restrictive prescriptions. Multiple source drugs are those for which there are two or more products rated therapeutically equivalent by the FDA; they must also be pharmaceutically equivalent and bioequivalent. The second category is for non-multiple source drugs and multiple source drugs with a restrictive prescription. A drug has a restrictive prescription if the physician indicates in handwriting (with an appropriate phrase such as "brand medically necessary") that the particular drug must be dispensed.

Beneficiary Cost Sharing and Premiums. The deductible would be $200 in 2001 increased in future years by the percentage increase in the Part B premium. Coinsurance would equal 20% of the payment limit. (The deductible would not apply to immunosuppressive drugs used during the first year following a covered organ transplant.)

Civil monetary penalties would apply if charges by participating or nonparticipating pharmacies to beneficiaries exceed charges to the general public.

Beneficiary Protections. The Secretary would be required to establish a program to identify (and educate physicians and pharmacists concerning): (1) instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered drugs; (2) instances or patterns of substandard care for such drugs; and (3) potential adverse reactions. The Secretary would be required to establish prescribing standards for each covered drug based on acceptable medical practice.

Cost Control Mechanisms/Formularies. The Secretary would be prohibited from establishing a formulary to exclude from coverage: (1) any specific drug or class of drug; or (2) any specific use of a drug unless the exclusion is based on a finding that the use is not safe and effective.

The Secretary would be required to develop, update annually, and distribute an information guide for physicians concerning comparative AWPS of at least 500 of the most commonly prescribed covered outpatient drugs.

Payments would generally be limited to a 30-day supply, although the Secretary could authorize up to 90 days (or beyond in unusual cases.)

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. No provision.

Financing Mechanism. No provision.

Access to Prescription Medications in Medicare Act of 1999 [H.R. 1495 (Stark et al.) and S. 841 (Kennedy et al.)]

General Approach. The bill creates a new outpatient prescription drug benefit under Part B beginning July 1, 2000. The benefit has two parts — a basic benefit which covers costs up to $1,700 annually (subject to a deductible and coinsurance) and a "stop loss" benefit under which the program would pay 100% of costs over $3,000 annually. There would be no out-of-pocket costs once the beneficiary reached $3,000 in total drug spending in a year. The benefit would be administered by private entities under contract with Health and Human Services (HHS).

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Medicare Part B would continue to be covered under the basic Part B program.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. Bids would include the amount of proposed copayment. Contracts could be awarded on a capitation or other basis. At least two contracts would be awarded per area unless only one entity met requirements. Contracts would be for 2-5 years.

The Secretary would assure that the entity: (1) complies with access requirements, (2) complies with formulary requirements (if it employs one); and (3) makes available the full scope of benefits. The Secretary could not enter a contract unless the Secretary determines that the average cost (excluding cost-sharing) for all drugs provided under the contract is comparable to the average cost charged (exclusive of cost-sharing) by large private sector purchasers.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts, and (3) to

ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

Beneficiary Cost Sharing and Premiums. The deductible would be $200. Coinsurance could not exceed 20% of cost (as stated in contract). No coverage would be provided for costs between $1,700 and $3,000; however, the beneficiary could continue to purchase drugs at contract price. Full coverage would be provided for costs over $3,000. Basic and stop loss benefit amounts would be annually adjusted based on changes in per capita prescription costs for beneficiaries.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) establishment of educational program, meeting criteria established by the Secretary, to assure appropriate prescribing, dispensing, and use of covered therapies; (4) procedures to assure proper utilization and to avoid adverse drug reactions; (5) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); (6) compensation of pharmacists for providing counseling to beneficiaries regarding use of drugs; and (7) procedures to review and resolve complaints and denials (that are comparable to those under Medicare+Choice). The entity is required to safeguard the privacy of any individually identifiable information.

Cost Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select cost effective drugs or less costly means of receiving drugs. If a formulary is used, the entity is to (1) ensure participation of physicians and pharmacists in development; (2) include at least one drug from each therapeutic class; (3) provide for coverage of other non-formulary drugs when recommended by participating providers; and (4) disclose the nature of formulary restrictions. Nothing precludes an entity from requiring higher cost-sharing for non-formulary drugs (except when medically indicated).

Relationship to Group Health Plans. If retirees receive at least equivalent benefits under a group health plan, they may continue to receive services through that plan. HHS would provide payment to the plan equal to the payment that would otherwise have been paid on behalf of the beneficiary.

Relationship to Medigap. The Secretary and NAIC would be required to revise the standard Medigap packages to reflect new coverage; an appropriate number of policies would be required to offer complimentary (not duplicative) coverage.

Relationship to Medicaid/Assistance for Low-Income. The income limit for the SLIMB program would be increased to from 120% 135% of poverty thereby extending Part B premium assistance to this group. Beneficiaries with incomes

between the level for Medicaid eligibility and 135% of poverty would receive comprehensive wrap around drug coverage through Medicaid.

Financing Mechanism. No provision. However, Senator Kennedy in his introductory remarks suggested looking at a number of options including using a portion of the federal budget surplus, recovering Medicare costs of treating tobacco related illnesses, increasing the tobacco tax, and using savings achieved from Medicare reform legislation.

Medicare Chronic Disease Prescription Drug Benefit Act of 1999 [H.R. 1796 (Cardin, et al.)]

General Approach. The bill creates, beginning in 2001, a new outpatient chronic disease prescription drug benefit under Part B. The benefit would be administered by private entities under contract with HHS.

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs, meeting FDA criteria, which are used to treat the following chronic conditions: hypertension, diabetes, congestive or ischemic heart disease, major depression, and rheumatoid arthritis. Coverage would be limited to drugs which have been shown to have a demonstrable effect in treating these conditions. The Secretary would implement a process for the timely identification of such drugs; the Secretary would utilize recommendations made by the Agency for Health Care Policy and Research.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. Bids would include the amount of proposed copayment. Contracts could be awarded on shared risk, capitation, or performance basis. Contracts would be for 2-5 years.

The Secretary would assure that the entity: (1) complies with access requirements; and (2) complies with formulary requirements (if it employs one). The entity would have to make available to each beneficiary at least one drug in each therapeutic class from those approved by the Secretary; it would also have to make available at least one generic equivalent for each drug if available. Further, the entity would also have to make available alternative drugs if a physician certifies that such alternatives are medically necessary.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts; and (3) to

ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

Beneficiary Cost-Sharing and Premiums. The deductible would be $250. Coinsurance could not exceed 20% of cost (as stated in contract). No copayments would be permitted for generic drugs.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) establishment of educational program, meeting criteria established by the Secretary, to assure appropriate prescribing, dispensing, and use of covered therapies; (4) procedures to assure proper utilization and to avoid adverse drug reactions; (5) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); (6) compensation of pharmacists for providing counseling to beneficiaries regarding use of drugs; and (7) procedures to review and resolve complaints and denials (that are comparable to those under Medicare+Choice. The entity is required to safeguard the privacy of any individually identifiable information.

Cost Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select less costly means of receiving drugs. If a formulary is used, the entity is to (1) ensure participation of physicians and pharmacists in development; (2) include at least one drug from each therapeutic class and provide at least one generic equivalent where available; (3) provide for coverage of other non-formulary drugs when recommended by participating providers; and (4) disclose the nature of formulary restrictions. Nothing precludes an entity from requiring higher cost-sharing for non-formulary drugs (except when medically indicated).

Relationship to Group Health Plans. No provision

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. Persons meeting SLIMB criteria would have their cost sharing charges paid by Medicaid.

Persons could receive benefits through an existing state non-Medicaid prescription drug program. The state program could not impose cost-sharing in excess of that specified under this bill. HHS would make payments to the state program; these could not exceed what would be paid in the absence of the state program.

Financing Mechanism. No provision.

Medicare Prescription Drug Benefit Act of 1999 [H.R. 2012 (Deutsch and Wexler)]

This bill is virtually identical to H.R. 1495/S. 841 except for the cost sharing provisions. H.R. 2012 specifies that the deductible would be $200 in 2000 increased in future years by the percentage increase in the per capita cost of drugs under the program. Coinsurance could not exceed 20% of the cost (as stated in the contract). Coverage would be provided for costs up to $5,200 (adjusted in future years by changes in per capita costs). No coverage would be provided for costs over that amount; however, the beneficiary could continue to purchase drugs at the contract price.

The other main difference from H.R. 1495/S. 841 is that H.R. 2012 does not include a requirement that an eligible entity administering the benefit be required to compensate pharmacists for providing counseling to beneficiaries on the use of drugs.

Seniors Prescription Insurance Coverage Equity (SPICE) Act of 1999 [H.R. 2782 (Pallone and Roukema) and S. 1480 (Snowe and Wyden)]

General Approach. The SPICE bill creates a new voluntary prescription drug benefit under a new Part D. Beneficiaries would be able to obtain SPICE coverage through enrollment in a Medicare+Choice plan, enrollment in a SPICE Medicare supplemental policy, or coverage under a group health plan. The policies would be required to meet a minimum threshold level of benefits. All persons who enroll in SPICE would receive financial assistance. At a minimum enrollees would receive assistance equal to 25% of the premium cost. Low-income persons below 175% of poverty would receive enhanced premium support, with those under 150% of poverty receiving 100% premium support. However, the specified levels of financial assistance would be reduced if there were insufficient funds available in the SPICE trust fund.

Persons Covered. Coverage would be extended to all persons, entitled to both Parts A and B, who voluntarily enroll in the program. Penalties would be established for delayed enrollment.

Scope of Benefits. "SPICE prescription drug coverage" would be coverage the SPICE Board determined met certain conditions. The benefits would be: (1) limited to outpatient prescription drugs, (2) include at least specified threshold benefits as developed by NAIC; and (3) exclude coverage for drugs already covered by Medicare. Further, the benefits must be accessible and convenient, and access must be provided on a timely basis to new outpatient prescription drugs as they become available. Plans could not contain language excluding coverage relating to a pre-existing condition.

The SPICE Board would request NAIC to revise model standards for Medigap policies for the purpose of defining "outpatient prescription drugs" and specifying a threshold level of SPICE drug coverage. The definition of outpatient drugs would take into account the definition of covered drugs under Medicaid. The threshold level

would take into account the level of such coverage (including deductibles and cost-sharing requirements) offered under the FEHBP and under other large group health plans. The threshold level could permit (if determined appropriate) coverage of drugs (except those used for promotion of smoking cessation) that are restricted or excluded under Medicaid.

All "SPICE prescription drug coverage" must include at least the specified threshold level of benefits and may include coverage above the threshold level.

Administration of Benefits. The program would be administered by a seven member SPICE Board which would be broadly representative of consumers, private plan insurers (including those that offer fee-for-service and managed care plans), HCFA, and state insurance commissioners. The Board, which would run a SPICE Office within HHS, would be separate from HCFA. The SPICE Board would administer the SPICE benefit. It would be required to conduct a series of ongoing studies relating to the benefit.

The SPICE Board would broadly disseminate information to beneficiaries on the SPICE benefit program, including information on penalties for delayed enrollment. The SPICE Board would establish the procedures through which a beneficiary could elect to enroll, disenroll, and change enrollment in a SPICE Medicare supplement policy or a Medicare+Choice plan that includes SPICE drug coverage. The Board would: (1) use rules similar to those established for Medicare+Choice enrollment (including annual open enrollment periods and guaranteed issue during any enrollment period); (2) permit special enrollment periods for persons enrolled in a Medicare+Choice plan or group health plan with SPICE coverage who lose such coverage or experience a significant adverse income level change (as defined by the Board) which changes the level of financial assistance available; and (3) provide for coordination with HHS.

The SPICE Board would establish procedures for reducing the amount of financial assistance provided if an eligible individual fails to obtain or maintain SPICE coverage. The procedures could be similar to the Part B delayed enrollment penalty provisions that apply under current law. Late enrollment penalties would not apply to a Medicare+Choice or group health plan enrollee who lost SPICE coverage because the plan dropped such coverage or terminated; this exception would be contingent upon the beneficiary seeking to obtain SPICE coverage at the next available opportunity.

The SPICE Board would also establish procedures for persons desiring enhanced financial assistance to apply voluntarily for an income determination by the Board.

Financial assistance would be paid by the SPICE Board to the appropriate SPICE supplement policy, Medicare+Choice plan, or group health plan. The payment would not be made unless an application had been submitted to the Board (in accordance with procedures established by it) and approved by the Board. Further, a SPICE supplement policy or Medicare+Choice plan would have to meet enrollment requirements established by the Board. The Board could disapprove or revoke the approval of an application of such supplement policy or Medicare+Choice plan if the Board finds that the entity offering the coverage is purposefully engaged in activities

designed to result in favorable selection of beneficiaries obtaining coverage through the plan.

Financial assistance under SPICE could not exceed the amount of money available in the SPICE trust fund. The Board's annual report would include a report on the financial status of the SPICE trust fund. If necessary (based on such status) it would also include a statement on how any required reduction in financial assistance in the subsequent year would be made. (See **Cost-Sharing** below.) The report could also include recommendations concerning expanding the amount of financial assistance, to the extent funds were available.

Reimbursement. The SPICE Board would provide the financial assistance for a beneficiary directly to the issuer of the SPICE supplement policy, the Medicare+Choice organization, or the sponsor of the group health plan. Entities receiving assistance would have to provide assurances that they reduced the amount charged the beneficiary by an equivalent amount.

Beneficiary Cost-Sharing and Premiums. All persons with SPICE coverage would receive financial assistance equal to at least 25% of the "applicable cost" of coverage. Persons below 150% of poverty would receive 100% of such cost. The support would be scaled-down from 100% to 25% for those with incomes between 150% and 175% of the poverty line. "Applicable cost" is defined as: (1) the premium for a SPICE supplemental policy; (2) the actuarial value of the portion of the adjusted community rate for the Medicare+Choice plan that is related to providing SPICE coverage; or (3) the actuarial portion of a group health plan premium related to providing SPICE coverage. The financial assistance for persons enrolled in a Medicare+Choice plan cannot exceed that portion of the enrollment premium that is related to drug coverage.

Financial assistance under SPICE could not exceed the amount of money available in the SPICE trust fund. If the SPICE Board determined that the amounts in the trust fund were insufficient for the following year, it would be required to take the following steps. First, it would reduce the minimum financial assistance percentage from 25% to not less than 10%. If this reduction was insufficient, the Board would next reduce the income thresholds specified for the low-income. If these reductions was still not sufficient, the Board would immediately report to Congress and suspend the provision of financial assistance.

The SPICE bill does not specify any cost-sharing that may be required by the plans.

Beneficiary Protections. The SPICE Board would be required to study ways in which drug utilization could be used to provide better overall care for beneficiaries.

Cost-Control Mechanisms/Formularies. An entity offering SPICE coverage would be permitted to use reasonable cost containment methods such as formularies, mail order services, and generic drug substitution, consistent with the requirements of SPICE and applicable law. If a formulary is used: (1) it must be based on the medical needs of beneficiaries; (2) the entity offering coverage must have an appeals process in place that is similar to or better than that available under Medicare+Choice;

(3) the procedures do not impose a significant financial burden on beneficiaries or delay the provision of medically necessary drugs; and (4) the entity offering coverage provides at least a 60 day notice of any change in the formulary.

Relationship to Group Health Plans. Group health plans providing SPICE prescription drug coverage would receive financial assistance on behalf of enrolled beneficiaries.

Relationship to Medigap. The definition of standardized Medigap benefit packages would be changed. One package would cover only outpatient prescription drugs. This drug-only package would be consistent with SPICE prescription drug coverage and be offered only through the SPICE Board. The package would permit coverage that exceeded the threshold levels.

No other Medigap policies could include drug coverage except that persons who currently have such policies would be permitted to retain and renew them provided that: (1) they are informed that so long as they keep such a policy they cannot purchase a SPICE medicare supplemental policy; and (2) they are offered a Medigap policy which is comparable to the policy which they currently have (except for prescription drug coverage).

The SPICE Board, in conjunction with the NAIC, would be required to study permitting a Medicare supplement benefit package which included drugs but was not a drugs-only policy. The Board would submit its recommendations to Congress.

Relationship to Medicaid/Assistance for Low-Income. Low-income beneficiaries would receive enhanced financial assistance. (See **Beneficiary Cost-Sharing and Premiums,** above.)

Financing Mechanism. A separate SPICE trust fund would be created. Income to the trust fund would consist of: (1) the amount of the increase in the tobacco taxes (as provided for under the bill), and (2) amounts from the on-budget surplus.

New Insurance Coverage Equity (NICE) Act of 1999 [H.R. 3482 (Maloney)]

This bill is identical to H.R. 2782 (the SPICE bill) except: (1) all references to SPICE are changed to NICE; and (2) there is no funding from tobacco taxes.

Healthy Seniors Promotion Act of 1999 [S. 1204 (Graham)]

General Approach. The bill contains a number of provisions focusing on health promotion and disease prevention among the elderly. It authorizes coverage for several additional preventive benefits under Medicare and adds coverage for preventive outpatient drugs beginning in 2002. The drug benefit would be subject to an annual limit ($750 in 2002). The following discussion summarizes the drug provision of the bill.

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Covered drugs would be limited to preventive outpatient prescription drugs (not otherwise covered by Medicare) which are the direct result of an individual's participation in: 1) a screening mammography; 2) screening pap smear or screening pelvic exam; 3) prostate cancer screening test; 4) colorectal cancer screening test; 5) diabetes outpatient self-management training service; 6) bone mass measurement; 7) cessation of tobacco use training program; 8) screening for hypertension; 9) counseling for hormone replacement therapy; 10) screening for glaucoma; and 11) any other preventive service added by the Secretary. Screening services in items 1-6 are covered under current law while those in items 7-10 are new preventive benefits added by the bill. The Secretary is required to ensure that all preventive outpatient prescription drugs that are reasonable and necessary to prevent or slow the deterioration of, and improve or maintain the health of eligible beneficiaries are offered under a contract with an eligible entity.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, or any combination of these. Bids would include the amount of proposed coinsurance. Contracts could be awarded on shared risk, capitation, or performance basis. At least two contracts would be awarded per area unless only one bidding entity meets the criteria. Contracts would be for 2-5 years.

The Secretary would ensure that the entity complies with access requirements and makes available the full scope of benefits.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts; and (3) to ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

Beneficiary Cost-Sharing and Premiums. The deductible would be $50. Coinsurance could not exceed 20% of the cost (as stated in the contract). Each time a prescription was filled, a beneficiary would be liable for a copayment equal to the lesser of the cost of the drug (minus the deductible and coinsurance) or $5.

Program payments would cease after the aggregate amount of preventive outpatient prescription drugs exceeded $750 in a year (based on the cost as stated in the contract); however, beneficiaries could continue to purchase drugs at the contract price. The $750 limit would be increased each year by changes in the per capita cost of prescription drugs for beneficiaries.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) procedures to assure proper utilization and to avoid adverse drug reactions; (4) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); and (5) procedures to review and resolve complaints and denials (that are comparable to those under Medicare+Choice. The entity is required to safeguard the privacy of any individually identifiable information.

Cost-Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select less costly means of receiving drugs.

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision.

Relationship to Medicaid/Assistance for Low-Income. Medicaid coverage for preventive outpatient prescription drugs would be provided under Medicaid for persons with incomes below 135% of poverty. Full federal funding would be provided for any additional costs. States would be required to maintain their expenditures for any state-funded prescription drug program at least at the FY1999 level.

Financing Mechanism. Fifty percent of any amount received by the federal government from any legislation providing for a global tobacco settlement would be transferred to Part B. This money would be used to enhance the drug benefit consistent with recommendations made in an Institute of Medicine study (which is required under the under the bill).

Medicare Outpatient Prescription Drug Coverage Act of 1999 [S. 1535 (Grams)]

General Approach. The bill creates, beginning in 2001, a new drug benefit under Part B. Program payments would equal 75% of the recognized payment amount after the beneficiary met a *monthly* deductible ($150 in 2001). The deductible would be waived for persons with incomes below 135% of poverty. The benefit would be administered in a manner similar, but not identical, to that used for other Part B services.

Persons Covered. Coverage is extended to all persons enrolled in Part B.

Scope of Benefits. Coverage is extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Part B would be part of the new benefit and subject to the new payment and cost-sharing rules.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish a point-of-sale electronic claims system for use by Part B carriers and participating pharmacies. (A point-of-sale electronic system would allow for the immediate processing of claims, including a determination of whether the deductible has been met.) The Secretary could contract with entities other than Part B carriers for implementation and operation of the system; such entities could include a voluntary association, corporation, partnership, or other non-governmental organization which the Secretary determines to be qualified to conduct such activities. The Secretary could require carriers to subcontract with such entities to implement and operate the electronic claims system. The Secretary would develop a standard claims form (and standard claims format) for drug claims.

The law would establish a participating pharmacy program under which pharmacies authorized under state law to dispense drugs would enter into agreements with the Secretary to: (1) accept "assignment" (i.e., agree not to charge patients more than the coinsurance) once the entity is notified the individual has met the deductible; (2) agree not to refuse to dispense covered drugs and not to charge beneficiaries more than charged to the general public; (3) keep patient records, (4) submit information necessary to administer the benefit; and (5) consistent with state law, offer to counsel or to provide information to beneficiaries on the appropriate use of a drug, whether there are potential interactions with other drugs dispensed to the beneficiary, and advise the beneficiary on the availability of therapeutically equivalent drugs.

A new 11-member Prescription Drug Payment Review Commission would be established; it would consist of experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescription drug reimbursement as well as representatives of the prescription drug manufacturing industry and at least one beneficiary. The Commission would submit an annual report to Congress concerning methods of determining payments for covered outpatient drugs. Beginning in 2002, the report would include information on changes in prices and utilization. The Secretary would also be required to submit an annual report on these issues.

Reimbursement. Payments would equal 75% of the *lesser of* the actual charge or the average wholesale price.

Beneficiary Cost Sharing and Premiums. The deductible would be $150 *a month* ($300 for a couple) in 2001 increased in future years by the percentage increase in the Part B premium. Coinsurance would equal 25% of the recognized payment amount.

Civil monetary penalties would apply if charges by participating or nonparticipating pharmacies to beneficiaries exceed charges to the general public.

Beneficiary Protections. Participating pharmacies would be required, consistent with state law, to offer to counsel or provide information to beneficiaries on the appropriate use of a drug and whether there are potential interactions with other drugs dispensed to the beneficiary.

Cost Control Mechanisms/Formularies. The Secretary would be prohibited from establishing a formulary to exclude from coverage: (1) any specific drug or class

of drug; or (2) any specific use of a drug unless the exclusion is based on a finding that the use is not safe and effective.

Payments would generally be limited to a 30-day supply, although the Secretary could authorize up to 90 days (or beyond in unusual cases.)

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. The deductible would not apply to persons below 135% of poverty.

Financing. No provision.

Medicare Preservation and Improvement Act of 1999 [S. 1895 (Breaux and Frist, et al.)]

General Approach. The bill provides for comprehensive Medicare reform. It establishes, effective January 1, 2003, a competitive premium system under which beneficiaries could choose from competing private health plans to obtain their health services; they could also remain in the traditional fee-for-service program. Private health plans and the government run fee-for-service program would be required to offer high option plans which included prescription drug benefits.

Persons Covered. All Medicare beneficiaries would have to be enrolled in both Parts A and B. Beneficiaries, at their option, could choose to enroll in a high option plan.

Scope of Benefits. All plans would be required to offer the core benefits (essentially current Medicare benefits). High option plans would have to offer: (1) at least the core benefits; (2) stop loss coverage for out-of-pocket costs for core benefits exceeding a specified threshold ($2,000 in 2003); and (3) prescription drug coverage. The minimum drug benefit for high option plans would be actuarially equivalent to $800 on Jan. 1, 2003; this amount would be adjusted in future years for any increase in the reasonable costs of drugs in the preceding year. The government-run fee-for-service plan would be required to offer high option plans that covered prescription drugs.

Administration of Benefit. An independent seven member Medicare Board would be established to administer the competitive premium system. The Board would enter into and enforce contracts with entities offering plans, including contracting with HCFA for the offering of the HCFA-sponsored plans. It would coordinate the determination of eligibility and enrollment with the Commissioner of Social Security. The Board would disseminate information on available plans to beneficiaries, and establish a beneficiary education program. The Board would not be responsible for the establishment and operation of HCFA-sponsored plans but would have oversight authority (including overseeing the financial solvency of HCFA-

sponsored plans). HCFA would be reorganized with a new Division of HCFA-Sponsored Plans which would have oversight of the fee-for-service program and the HCFA-sponsored high option plans; it would not have oversight over other plans.

Each entity intending to offer a Medicare plan in a year would submit to the Board information on the plan's benefits, proposed premium bid, and service area. The Board could approve the offering of a standard plan only if the entity offered a high option plan. The Board would approve a plan provided it met certain requirements. The benefits must include at least the core benefits and must not be designed in such a manner as to result in favorable selection of beneficiaries. Premium rates must be adequate in terms of actuarial soundness to assure financial solvency of the entity offering the plan. The service area must be adequate and cannot be designed so as to discriminate based on health status, economic status, or prior receipt of health care of beneficiaries. The Board could negotiate with any entity regarding the terms and conditions of the plan. (The bill does not specify which kinds of entities may apply). It can approve a plan only if it finds that the terms and conditions are consistent with Medicare requirements.

HCFA would be reorganized with a Division of HCFA-Sponsored Plans. It would offer one standard Medicare plan throughout the U.S. which would include only the core benefits. It would also offer at least one high option plan in each area. HCFA-sponsored plans would be required to meet the same requirements as private plans including those pertaining to submission of plan information to the Board and approval of plans by the Board. Premiums for the standard plan and each HCFA-sponsored high option plan would be computed separately to ensure that each is self-sustaining. The Division of HCFA-sponsored plans would bear full financial risk for the provision of services under HCFA sponsored plans (except for drug benefits under high option plans).

The Division of HCFA-Sponsored plans would contract with private entities for the provision of outpatient prescription drug benefits under a high option plan. These entities could include insurers, pharmaceutical benefit managers, chain pharmacies, groups of independent pharmacies, and other private entities determined appropriate by the Board. Contracts could be awarded on a local, regional, or national basis. Drug benefits could only be offered through private entities who would bear full financial risk for the drug benefits. However, the Board would establish an arrangement through which the Board would guarantee benefits in areas where contracts with private entities were not in effect; the guarantee would be for the actuarial equivalence of the minimum drug benefit required under high option plans.

The Board would establish Medicare Consumer Coalitions to conduct information programs for beneficiaries. Coalitions would be nonprofit organizations whose board was composed primarily of Medicare beneficiaries.

Reimbursement. The Board would negotiate premiums with health plans, compute payments to plans (including geographic and risk adjusters), and make payments to plans. Plans would determine payments for services.

Beneficiary Cost-Sharing and Premiums. Beneficiaries would not pay Part B premiums. They would pay plan premiums if they chose higher cost plans subject

to higher premiums. There would be no beneficiary premium for plans costing 85% or less of the national weighted average (NWA) premium. For premiums between 85% and 100% of the NWA premium, beneficiaries would pay 80% of the excess over 85% of the NWA premium. For premiums equal to or exceeding 100% of the NWA premium, beneficiaries would pay 12% of the NWA premium plus the full amount by which the plan premium exceeds the NWA premium. *Only the costs of the core benefit package would count toward the computation*. If the only Medicare plans offered in an area are HCFA-sponsored plans, the beneficiary obligation for the standard plan could not exceed 12% of the NWA premium and the obligation for any high option plan could not exceed 12% of the NWA premium plus the amount by which the obligation for the high option plan exceeds the obligation for the standard plan. Beneficiary premiums would be collected in the same manner as Part B premiums are currently collected (i.e., as a deduction from social security checks).

Beneficiaries at or below 135% of poverty would pay zero premium for enrollment in the lowest cost high option plan in their area. (See low-income discussion.) All other beneficiaries enrolled in a high option plan would receive a discount on that portion of their premium attributable to the drug benefits (based on the actuarial value of the minimum benefit, i.e., $800 in 2003). The discount for persons with incomes between 135% and 150% of poverty would range from 50% phasing-down to 25%. The discount for persons with incomes over 150% of poverty would equal 25%. The amount of the discount would be treated as taxable income for persons over 135% of poverty.

The Board could permit reasonable variation in cost-sharing for private plans so long as the actuarial equivalence of cost-sharing is maintained. Plans could provide, as an additional benefit, lower cost sharing than otherwise specified under Medicare.

Beneficiary Protections. Plans and entities offering the plans would be required to meet requirements applicable to Medicare+Choice programs including those relating to the offering of Medicare benefits and protection for beneficiaries.

Cost-Control Mechanisms/Formularies. Entities could use cost control mechanisms customarily used in employer-sponsored plans, including formularies, tiered copayments, selective contracting with providers of drugs, and mail order pharmacies.

HCFA could ensure continued solvency of HCFA-sponsored plans through improvements in efficiencies and economies.

Relationship to Group Health Plans. Not specified.

Relationship to Medigap. Beginning January 1, 2003, only beneficiaries enrolled in HCFA-sponsored standard plans could purchase or renew Medigap policies.

Relationship to Medicaid/Assistance for Low-Income. Beneficiaries at or below 135% of poverty would pay zero premium for enrollment in the lowest cost high option plan in their area. If they enrolled in another plan, they would be liable for any additional premium over that otherwise applicable for the lowest cost high

option plan. The Board would establish an arrangement under which each state would make low-income eligibility determinations (with 50% federal matching).

States would be required to continue state contributions. This "maintenance of effort" requirement would require states to pay the following amounts for persons eligible for both Medicare and full Medicaid coverage: (1) the lesser of 12% of the NWA premium or the beneficiary obligation for the HCFA-sponsored standard plan, whichever is lower; (2) all coinsurance, deductibles, and cost-sharing imposed under the Medicare plan in which the beneficiary is enrolled; (3) any additional costs incurred in excess of stop-loss coverage for the core benefits; and (4) to the extent consistent with the state Medicaid plan, any additional costs in excess of the limit imposed for coverage of drugs under the plan. For the QMB-only population, state contributions would be limited to items #1 and #2, except that cost-sharing contributions would not apply for coverage of drugs. For other low-income persons, the state contribution would be limited to item #1. Federal matching would apply for these contributions.

Financing Mechanism. No additional revenue source is specified. The plan would combine the Part A and Part B trust funds into a single Medicare Trust Fund. Income to the fund would include current payroll taxes, beneficiary premiums, general revenue contributions, and any additional fees imposed by the Board. The Board would annually report to Congress on the portion of expenses paid by general revenues, the first fiscal year when this percentage would exceed 40% (defined as programmatic insolvency), and the first fiscal year in which the fund would be unable to pay expenses. General revenue financing could not exceed 40% of expenses (not including administrative costs). The Board could impose assessments on plans for Board expenses.

Provision would be made to provide, prior to January 1, 2003, for initial capital for HCFA-sponsored plans. At the direction of the Board, such amounts as may be necessary would be transferred from the trust funds to cover initial capitalization, working capital, and a contingency reserve. These amounts would be kept in a separate account.

Voluntary Medicare Prescription Drug Plan Act of 2000 [S. 2319 (Bob Smith and Allard)]

General Approach. The bill establishes, under a new Part D, a voluntary Medicare prescription drug plan - Rx Option, effective January 1, 2001. A beneficiary enrolled in the Rx Option would be subject to a combined deductible ($675 in 2001) for Medicare Part A, Medicare Part B, and drug expenses. After the deductible is met the program would pay 50% of drug costs up to a specified annual maximum ($5,000 in 2001).

Persons Covered. Voluntary coverage would be offered to all beneficiaries who are enrolled in both Part A and Part B. Not included are persons enrolled in a Medicare+Choice plan or eligible for Medicaid drug benefits. An individual enrolling in Rx Option would be required to stay in the plan for at least 2 years (except that

they would be permitted to disenroll no later than the last day of the first full month following the month of election).

Scope of Benefits. After the beneficiary had met the combined deductible, the program would pay 50% of drug costs up to $5,000 in 2001. In future years the cap would be increased by the percentage increase in the prescription drug component of the consumer price index.

Administration of Benefits. The Secretary would contract with private entities to provide the benefit. Private entities would include insurers (including issuers of Medigap policies), pharmaceutical benefit managers, chain pharmacies, groups of independent pharmacies, and other private entities the Secretary determines are appropriate. Contracts could be awarded on a local, regional, or national basis. Drug benefits could only be offered through a contact with a private entity. No private entity could be excluded from offering benefits if it met all the requirements established by the Secretary.

The Secretary would establish a process for enrollment of individuals under the Rx Option that is based on the process for enrollment in Medicare+Choice.

Reimbursement. No provision

Beneficiary Cost-Sharing and Premiums. Beneficiaries enrolled in the Rx Option would be subject to the new combined deductible for Part A, Part B, and drug expenses. The deductible would be $675 in 2001, increased in future years by the percentage increase in the medical component of the consumer price index. This deductible would replace the existing Part A and Part B deductible for Rx Option enrollees. (Current Part A and B coinsurance rules would continue to apply.) Drugs would be subject to 50% cost-sharing up to the cap. There would be no premium for the Rx Option.

Beneficiary Protections. No provision

Cost Control Mechanisms/Formularies. No provision

Relationship to Group Health Plans. No provision

Relationship to Medigap. The NAIC would revise the existing standardized Medigap plans for persons enrolled in the RX Option so that policy holders are required to pay annual out-of-pocket expenses (other than premiums) in an amount equal to the combined deductible before the plan begins making payments. Medigap plans which currently cover some drug expenses (i.e. “H”, “I,” and “J”) could not duplicate coverage under the Rx Option. Persons enrolling in the Rx Optoion could only enroll in a plan meeting these requirements except in the case of the renewal of already existing policies.

Relationship to Medicaid/Assistance for Low-Income. No provision

Financing Mechanism. None specified. Senator Smith’s floor statements quote assessments from actuaries (including a former HCFA Chief Actuary) that the

legislation would be cost neutral to Medicare. (Part of the estimate is attributable to the fact that studies have shown that per capita Medicare costs are higher for persons with Medigap policies covering the Part A and B deductibles. This legislation would prohibit Medigap coverage of these deductibles for persons electing the Rx Option.)

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 one year delay in the implementation date and the establishment of a catastrophic prescription drug coverage reserve fund.).

Persons Covered. 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 (2003). 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 2003 and 2004, the Secretary would conduct a study concerning the feasibility of establishing an annual open enrollment period.

Scope of Benefits. 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; 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.

Reimbursement. 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 Cost-Sharing and Premiums. 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 are credited to the fund over for 2006-2010, with a total of $35 billion credited to the fund over the period. However, there are no specifics of how this fund would be used.

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. CBO estimates net 5-year costs at $34.5 billion and net 10-year costs at $149 billion.

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," the requirements for contact proposals from these entities are revised, and there is no provision for noncompetitive renewal of contracts; 3) 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 4) 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 (such as Medicare modernization) 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. 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. 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 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.

Reimbursement. 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 Cost-Sharing and Premiums. 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.

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 (and with resources not in excess of $4,000). The current federal/state matching rate would be used.

"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. No provision

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.

Summary of Bills to Add a Non-Medicare Benefit for the Medicare Population

Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 1999 [H.R. 2925 (Bilirakis, et al.)]

General Approach. The bill would amend the Public Health Service Act to establish two programs for Medicare beneficiaries — state prescription drug assistance and federal stop-loss drug protection. Under the state drug assistance program, federal matching funds would be provided to states who voluntarily set up prescription drug coverage programs for their low-income Medicare population; coverage would be available for persons not eligible for drug coverage under the state's Medicaid program. The federal stop-loss protection would limit Medicare beneficiaries out-of-pocket liability for drugs; initially the annual limit would be set at $1,500. These two plans are described separately below.

Low-Income Assistance Program: Persons Covered. The state drug assistance program would cover low income persons in states that chose to set up a program. Low income persons are defined as persons: (1) eligible for Medicare Part A and/or Part B; (2) not eligible for drug coverage under the state's Medicaid program; (3) whose income falls below the level set by the state which must be between 120% and 200% of poverty; and (4) at the option of the state, has resources below a level set by the state (which could not be lower than $4,000 for an individual, $6,000 for a couple).

Low-Income Assistance Program: Scope of Benefits. The "scope and quality" of drug benefits under the state assistance program would be set by the state but could not be less than that offered under one of the following: (1) the state's Medicaid program; (2) the standard Blue Cross/Blue Shield plan under FEHBP; (3) the coverage available to state employees; (4) coverage available to enrollees in the state's largest HMO (as defined by its commercial non-Medicaid enrollment); or (5)

other benchmark coverage that the Secretary determines, upon application by the state, provides comprehensive outpatient drug coverage. The term "scope and quality" means the extent of drugs covered (including any exclusions or limitations and the application of any formulary (including exceptions to the formulary) and provisions to assure access to and quality of covered drugs. The term does not include cost sharing requirements. State programs would be prohibited from imposing any maximum annual lifetime or other durational limits. State programs could not impose any preexisting condition exclusion.

The state drug assistance programs could not include coverage for items currently covered under Medicare, items for which coverage is not available under Medicaid, or drugs used for assisted suicide.

Low-Income Assistance Program: Administration of Benefits. A state would be eligible for assistance if it submitted to the Secretary a plan which included a written document that outlined how the state intended to use the federal funds and the procedures to be used to provide for outreach to low-income beneficiaries. Further, the state would have to provide a certification by the chief executive officer of the state that the state drug assistance program is consistent with the specific requirements of the bill.

A state would be required to provide assurances to the Secretary that: (1) it would collect data, maintain records and furnish reports as specified by the Secretary in order to enable the Secretary to monitor state program administration and compliance and to evaluate and compare state programs; (2) it would afford the Secretary access to records and information for the purposes of review and audit; and (3) it would assess and report to the Secretary annually on state program operation.

The Secretary could not impose conditions in addition to those specified under the bill for state drug assistance programs.

The Secretary would pay each state that submitted a drug assistance plan an amount for each quarter (beginning on or after October 1, 1999) equal to the sum of: (1) the enhanced federal match for expenditures for low-income beneficiaries with family incomes below 150% of poverty; (2) the federal matching rate that applies under the state's Medicaid program for expenditures for other low income beneficiaries covered under the state's program; and (3) the enhanced matching rate for expenditures related to outreach and other administrative activities (except that assistance for administrative expenses cannot exceed 20% of the total federal contribution in the first year or 10% in subsequent years). The enhanced matching rate is 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 x 40)]. In no case could the federal rate exceed 85%.

Low-Income Assistance Program: Reimbursement. The state would be required to provide low-income assistance to each eligible person who applied for coverage. States would be required to provide the assistance as a premium subsidy for persons enrolled in a Medicare+Choice or group health plan that provides qualified prescription drug coverage. The amount of the subsidy would would equal

the portion of the premium attributable to furnishing drug coverage. For other persons, the state could select any method for the provision of, or payment for, qualified coverage, provided it is separate from Medicaid.

Low-Income Assistance Program: Beneficiary Cost-Sharing and Premiums. A state drug assistance program could not impose a premium, enrollment fee, or deductible for drug coverage. No copayments or coinsurance charges could be imposed for persons whose family income was below 120% of poverty. For persons with higher incomes, cost-sharing could not exceed the greater of $5 per prescription unit or 20% coinsurance. In the aggregate, cost-sharing could not exceed an annual limit; the limit would be $1,500 in 2000. This limit would be increased in future years by the percentage increase in per capita expenditures for prescription drugs over the period July 1999 to July of the year prior to the year in question.

Low-Income Assistance Program: Beneficiary Protections. No provision.

Low-Income Assistance Program: Cost/Control Mechanisms/Formularies. The Secretary could not require states to use any particular formulary or pricing structure. States would be prohibited from using the Medicaid rebate system or any other federal rebate system.

Low-Income Assistance Program: Relationship to Group Health Plans. Low-income persons enrolled in group health plans with qualified drug coverage would have a premium subsidy payment made in their behalf.

Low-Income Assistance Program: Relationship to Medigap. Medicare beneficiaries provided low-income assistance would be permitted to drop a Medigap policy which includes drug coverage and be able to purchase another policy offered by the insurer. Beneficiaries who lose low-income prescription drug assistance would be permitted to restore Medigap coverage that included prescription drug coverage. In addition, the Secretary would establish a 6-month open enrollment period when all beneficiaries would be able to obtain a Medigap policy with prescription drug coverage.

Low-Income Assistance Program: Relationship to Medicaid/Assistance for Low-Income. See above.

Low-Income Assistance Program: Financing. No provision.

Federal Stop-Loss Protection: Persons Covered. The federal stop-loss protection program would be available for persons enrolled in Part A and/or B who have qualified Medicare prescription drug coverage. Qualified coverage is defined as drug coverage meeting the following requirements: (1) the deductible cannot exceed $500 in a year; (2) cost-sharing (in the form of copayments, coinsurance, or both) could not exceed 50% of the payment amount for the drug; (3) there is an annual per beneficiary limit of not more than $1,500 on out-of-pocket expenses; and (4) the entity offering the coverage has entered into an agreement with the entity administering stop-loss protection under which it agrees to provide for the information necessary to establish eligibility for program payments. Plans meeting

these requirements could be Medicare+Choice plans, Medigap policies, or group health plans.

Federal Stop-Loss Protection: Scope of Benefits. The federal stop-loss program would pay the costs of providing benefits under a qualified Medicare prescription drug coverage plan once a beneficiary had incurred out-of-pocket expenses exceeding a specified amount. This amount would be $1,500 in 2000. It would be increased in future years by the percentage increase in per capita expenditures for prescription drugs over the period July 1999 to July of the year prior to the year in question.

Federal Stop-Loss Protection: Administration of Benefits. The Secretary would enter into contracts with one or more carriers or other qualified entities to operate the stop-loss program. The program would make the stop-loss payments to the entity providing the qualified Medicare prescription drug coverage.

Federal Stop-Loss Protection: Reimbursement. No provision.

Federal Stop-Loss Protection: Beneficiary Cost-Sharing and Premiums. No cost sharing would be required once the beneficiary hit the stop-loss coverage threshold.

Federal Stop-Loss Protection: Beneficiary Protections. No provision.

Federal Stop-Loss Protection: Cost/Control Mechanisms/Formularies. The Secretary, carrier, or other qualified entity would not be authorized to deny or limit payment under the plan. However, the Secretary, carrier or entity could compute costs taking into account discounts or other rebates related to the provision of drug coverage.

Federal Stop-Loss Protection: Relationship to Group Health Plans. See above.

Federal Stop-Loss Protection: Relationship to Medigap. See low-income program, above.

Federal Stop-Loss Protection: Relationship to Medicaid/Assistance for Low-Income. See low-income program, above.

Federal Stop-Loss Protection: Financing. No provision.

Medicare Low-Income Prescription Drug Assistance Act of 2000 [H.R. 4235 (Foley)]

General Approach. The bill requires the Secretary of HHS to establish a voluntary program, beginning in 2002, for low-income Medicare beneficiaries. Low-income individuals are defined as singles with incomes under $30,000 and couples with incomes under $60,000. Beneficiaries would pay a $20 monthly premium and

have payments made to the pharmacy for drugs, subject to a $10 or $20 copayment and an annual maximum payment of $1,500.

Persons Covered. Persons enrolled in Medicare Part B with incomes under $30,000 ($60,000 for a couple) would be able to enroll in the program. These levels would be annually adjusted to reflect changes in average beneficiary income.

Scope of Benefits. In general, coverage would be extended to outpatient prescription drugs meeting FDA criteria. Drugs currently covered under Medicare would not be included.

Administration of Benefit. The Secretary would be required to establish one or more periods of voluntary enrollment meeting certain criteria. There would be an initial enrollment period at the beginning of the program and an initial enrollment period for individuals meeting first meeting eligibility requirements after the program begins. Special enrollment periods could be established to take into account loss of other drug coverage. Generally, individuals could only disenroll on an annual basis. Enrollment and disenrollment periods would be designed to avoid adverse selection.

The Secretary would enter into agreements, under terms and conditions deemed appropriate, with States, carriers, and other private entities to operate the program including making eligibility determinations, enrolling individuals, and paying of claims.

Reimbursement. Payments would be made to the pharmacy.

Beneficiary Cost-Sharing and Premiums. Beneficiaries would pay a $20 monthly premium. Premiums would be collected in the same way as Part B premiums; for most persons this would be a deduction from social security checks. Beneficiaries would also pay a copayment equal to $20 per prescription ($10 for generic drugs). The Secretary could adjust these amounts to reflect changes in benefit costs. Beneficiaries would pay all costs once the program paid $1,500 per year.

Beneficiary Protections. No provision.

Cost-Control Mechanisms and Formularies. No provision.

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision.

Relationship to Medicaid/Assistance for Low-Income. See description above. No provision relating to Medicaid.

Financing Mechanism. No provision.

Healthy Seniors Act of 1999 [S. 1837 (Baucus)]

General Approach. The bill provides low-income individuals with assistance, beginning in FY2000, to meet out-of-pocket drug costs. Payment would be made

equal to 100% of such costs for persons below 100% of poverty; partial assistance would be available on a sliding scale basis for persons under 175% of poverty. The program would be administered through Medicaid.

Persons Covered. Persons covered would be individuals, enrolled in Medicare Part B, with incomes under 175% of poverty but not otherwise eligible for Medicaid drug benefits in the state.

Scope of Benefits. Covered drugs would be those available under the state's Medicaid program.

Administration of Benefits. The benefit would be administered through the state's Medicaid program. The Federal matching rate would be 100%. However, states would be required to maintain the level of state expenditures for Medicare beneficiaries that existed under any state-funded prescription drug program or Medicaid in 1999.

Reimbursement. The program would be administered through Medicaid; presumably Medicaid rules would apply.

Beneficiary Cost-Sharing and Premiums. There is no premium. Program payment would be made equal to 100% of out-of-pocket costs for persons below 100% of poverty, 75% of such costs for persons with incomes between 100% and 125% of poverty, 50% of such costs for persons with incomes between 125% and 150% of poverty, and 25% of such costs for persons with incomes between 150% and 175% of poverty. Beneficiaries would be liable for that portion of out-of-pocket costs not met by the program.

Beneficiary Protections. The program would be administered through Medicaid; presumably Medicaid rules would apply.

Cost-Control Mechanisms and Formularies. The program would be administered through Medicaid; presumably Medicaid rules would apply.

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision.

Relationship to Medicaid/Assistance for Low-Income. See above.

Medigap Proposals

DrugGap Insurance for Seniors Act of 1999 [S. 1725 (Jeffords)]

This bill provides for changes to Medigap policies and development of new DrugGap supplemental policies. The bill directs the National Association of Insurance Commissioners (NAIC) to modify the current standard Medigap plans and to include some drug coverage, however limited, in each plan. In addition, there would be three new drug-only DrugGap policies as follows: (1) standard DrugGap benefit having a low deductible (not to exceed $250), coinsurance not to exceed 20%, and a $5,000 maximum benefit; (2) a low-cost standard DrugGap benefit with a higher deductible (not to exceed $750), coinsurance not exceeding 30% and a $5,000 maximum benefit; and (3) stop-loss DrugGap policy covering out-of pocket costs exceeding $5,000 (or, for a person with one of the standard DrugGap packages, exceeding the maximum benefit). DrugGap policies could use formularies provided all therapeutic classes of drugs were covered and beneficiaries were guaranteed access to off-formulary drugs when necessary and appropriate. DrugGAP policies could use generic substitution. Policyholders would be assured access to the same prices as negotiated by the plan. Policies could not duplicate other Medigap policies that an individual had.

A beneficiary meeting the following requirements would be eligible to receive assistance for the purchase of a standard DrugGAP policy *plus* a stop-loss DrugGAP policy: (1) income below 50 percentage points above the state's Medicaid eligibility level but not exceeding 200% of poverty; (2) no drug coverage under either an employer plan or Medicare+Choice plan; and (3) not eligible for Medicaid drug coverage. States would administer the program and compute state weighted average premiums. They would make payments on behalf of qualified beneficiaries: (1) equal to the lesser of the state weighted average premium for the policy or the full quoted premium; plus (2) for related out-of-pocket expenses as the state determines appropriate. Payments for such costs would be made from the Part B trust fund (but would not be used in the calculation of the Part B premium). Maintenance of state effort would be required.

Seniors Security Act of 2000 [S. 2237 (Craig)]

The Seniors Security Act of 2000 (SSA 2000) provides income tax deductions, beginning in 2000, for premiums for Medigap insurance policies and Medicare+Choice plans containing drug benefits. The deduction for all persons (not just those that itemize) would equal 100% of the amount paid for a Medigap policy or a Medicare+Choice plan with a drug benefit with an annual actuarial value equal to or greater than $500. The minimum value would be adjusted in future years to reflect changes in Medicare per capita drug expenditures. The deduction would not be available to individuals eligible for employer-sponsored coverage. (The bill also provides for deductions for long-term care insurance.)

The Secretary of HHS would establish procedures for Medigap issuers and Medicare+Choice plans to demonstrate that the annual actuarial value exceeds the minimum value. The procedures established would be based on: 1) a standardized set

of utilization and price factors, and a standardized population that is representative of all enrollees and calculated based on projected use if all enrollees have coverage; 2) apply the same principles and factors in comparing different packages; and 3) not take into account the method of delivery or the means of cost control. The Medigap issuer or organization offering the Medicare+Choice plan would be required to set forth the value in an actuarial report meeting specified criteria.

SSA 2000 authorizes the development of additional standardized Medigap policies by the National Association of Insurance Commissioners (NAIC). New packages covering prescription drugs could not provide first-dollar coverage for drugs and could provide stop-loss coverage (that limits beneficiary out-of-pocket spending in a year). Packages could provide for the use of formularies. The Secretary would establish special open enrollment periods for persons with existing Medigap coverage to enroll in a new plan. For individuals enrolled in a Medigap policy with drug coverage the period would be 180 days from the time the new coverage first became available. For persons enrolled in a Medigap policy without drug coverage, the period would be 63 days. The bill permits an issuer to cancel one of these new policies provided certain criteria are met. The bill also permits the sale of non-duplicative Medigap policies to an individual. The Medicare Payment Advisory Commission (MedPAC) would be required to report by June 1, 2000, on issues related to design of prescription drug benefit policies.

Financing Measure

Medicare Prescription Drug Coverage Act of 1999 [H.R. 886 (Frank, et al.), S. 696 (Wellstone)]

The bill provides for the transfer of federal estate tax revenues to the Federal Hospital Insurance Trust Fund under Medicare (Part A of the program). It establishes an Outpatient Prescription Drug Account in the Trust Fund to receive such revenues and to pay for outpatient prescription drugs furnished under the program. Within 180 days of enactment, the Secretary would be required to submit a plan to Congress providing for the full coverage of outpatient prescription drugs for Medicare beneficiaries. The report is to include a determination of whether the estate tax revenues are sufficient to fund this drug benefit.

Measures Directed Toward Amounts Seniors Pay For Drugs

Prescription Drug Fairness for Seniors Act [H.R. 664 (Allen, et al.), S. 731 (Kennedy, et al.)]

The bill would require each participating manufacturer of a covered outpatient drug to make available for purchase by each pharmacy quantities of covered drugs equal to the aggregate amount of the drug sold or distributed by the pharmacy to Medicare beneficiaries. (Covered drugs are those which are covered by Medicaid.)

Participating manufacturers are defined as any manufacturer of drugs or biologicals that enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States. The manufacturers would be required to make the drug available at a price equal to the lower of: (1) the lowest price paid for the drug by *any agency or department of the United States*; or (2) the manufacturer's "best price" for the drug as that term is defined under Medicaid.

The bill directs the Secretary to implement the requirements as expeditiously as practicable and in a manner consistent with the obligations of the United States.

Making Affordable Prescriptions Available for Seniors Act [H.R. 723 (Kennedy, et al.)]

The bill would establish a pharmacy assistance program under the Public Health Service Act. The assistance would be provided in the manner the Secretary determined to be the most cost effective including indemnification, vouchers, coupons, or direct provider reimbursement through the Medicaid claims payment system. No cash payment could be made to an eligible person before presentation of a receipt or other invoice. Persons eligible for the benefit would be persons over age 65 with no other drug coverage whose income did not exceed 175% of poverty. The assistance could not exceed $500 per person per year.

The Secretary could impose an enrollment fee of up to $15 per year. The Secretary would be required to develop copayment requirements and could establish deductibles to control program expenses. Copayment amounts (limited to $10 per prescription) could vary to promote the purchase of generic drugs and could be based on a sliding income scale.

Manufacturers would be required to pay the Secretary 7% of gross sales receipts as a condition of approval for new drugs. This requirement would apply in cases where the drug manufacturer submits with the application the results of research carried out by the National Institutes of Health, or under an agreement under the Stevenson-Wydler Technology Innovation Act of 1980. The Secretary could waive this requirement if he or she determined that to do so was in the public interest.

Tax Provisions

Taxpayer Refund and Relief Act of 1999 [H.R. 2488 (Archer, et al.)]

This tax bill, *vetoed by the President* September 23, 1999, included provisions related to the deduction of medical expenses; these provisions were described as a placeholder for subsequent congressional action.

Current tax law limits deductions for medical expenses to those that exceed 7.5% of adjusted gross income. H.R. 2488 would have specified that this income threshold would not apply to prescription drug insurance coverage for Medicare beneficiaries

if certain reforms were enacted. Specifically, the threshold would not apply when all the following conditions were met:

- Low-income federal assistance is available to enable persons with incomes below 100% of poverty to purchase a drug-only Medigap policy or coverage through integrated comprehensive plans. Federal assistance would be phased-out for persons with incomes between 135% and 150% of poverty.
- At least one authorized Medigap policy is a drug-only policy.
- Coverage for outpatient prescription drugs for beneficiaries is provided only through integrated comprehensive health plans which offer current Medicare covered services and maximum limitations on out-of-pocket spending. Plans offered by HCFA would have to compete on the same basis as private plans.
- The tax code allows deductions for a drug, which is not currently a prescribed drug, but which was a prescribed drug in the year purchased or during the 2 preceding years.

Seniors Security Act of 2000 [S. 2237 (Craig)]

See discussion under Medigap proposals, above.