Order Code RL31084

CRS Report for Congress
Received through the CRS Web

Medicare: Selected Prescription Drug Proposals in the 107th Congress

Updated October 30, 2001

Jennifer O'Sullivan
Specialist in Social Legislation
Domestic Social Policy Division

Medicare: Selected Prescription Drug Proposals in the 107th Congress

Summary

Medicare, the nationwide health insurance program for the aged and disabled, does not cover most outpatient prescription drugs. On several occasions, the Congress has considered providing coverage for at least a portion of beneficiaries' drug costs. The issue received renewed attention in the 106th Congress. However, there was no consensus on how the coverage should be structured.

The issue has again received attention in the 107th Congress. The FY2002 Budget Resolution provides $300 billion over the FY2003-FY2011 period for a Medicare reserve fund for Medicare reform and prescription drug coverage. A number of bills have been introduced, though at this writing no bill has been introduced or acted on by any of the three committees of jurisdiction (House Ways and Means, House Energy and Commerce, and Senate Finance). Given the events of September 11, 2001, it is unclear what action, if any, the Congress will take on this issue this year.

The drug provisions of Medicare proposals introduced in both the 106th and 107th Congresses contain a number of common themes. In general, they would make coverage available to all Medicare beneficiaries on a voluntary basis. They would place a limit on the amount of federal spending for the new benefit, thereby requiring beneficiaries (or their supplementary insurance) to pay the remaining costs. Further, they would provide assistance for low-income persons. However, there are a number of significant differences between the bills. These include the degree of reliance and financial risk placed on the private sector versus the public sector, the scope of benefits, and the federal administrative structure.

It is generally agreed that if Congress were to enact a drug benefit, it would take several years before the program could be implemented. As an interim measure, President Bush announced June 14, 2001, the creation of a Medicare Prescription Drug Discount program. This program would provide for the endorsement by Medicare of qualified privately-administered prescription drug discount cards. Beneficiaries could obtain these cards either free or for a nominal enrollment charge; the card would provide access to discounts on prescription drugs. While this plan would not establish a Medicare drug benefit, it was designed to give seniors access to similar kinds of discounts as are available to the under age 65 population under private insurance plans. However, on September 6, 2001, a federal district court judge issued a temporary injunction against implementation of the card program.

This report provides a side-by-side comparison of *bills introduced in the 107th Congress that have received the most attention.* To date these are S. 358, introduced by Senators Breaux and Frist, and S. 1135, introduced by Senator Graham et al. This report is a companion report to CRS Report RL30819, *Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues*; that report includes a discussion of the major benefit design questions that would need to be addressed as the Congress develops a drug benefit. This report will be updated to reflect any legislative action.

Contents

List of Tables

Medicare: Selected Prescription Drug Proposals in the 107th Congress

Introduction

Medicare, the nationwide health insurance program for the aged and disabled, does not cover most outpatient prescription drugs. The absence of an adequate prescription drug benefit has been of concern to policymakers since the enactment of Medicare in 1965. On several occasions, the Congress has considered providing coverage for at least a portion of beneficiaries' drug costs. The issue received renewed attention in the 106th Congress. However, there was no consensus on how the coverage should be structured.

The issue has again received attention in the 107th Congress. A number of bills have been introduced, though at this writing no bill has been introduced or acted on by any of the three committees of jurisdiction (House Ways and Means, House Energy and Commerce, and Senate Finance). Given the events of September 11, 2001, it is unclear what action, if any, the Congress will take on this issue this year.

One of the key concerns in designing a drug benefit is the potential cost and how costs would increase over time. Another issue is the appropriate role of both the federal government and the private sector in assuming the financial risk of coverage and administering the benefit. Some observers suggest that a drug benefit should be added directly to Medicare while others recommend alternative approaches for assuring coverage for the target population. A further consideration is whether a major new benefit should be added until structural reforms are made to the Medicare program as a whole.[1]

It is generally agreed that if Congress were to enact a drug benefit this year, it would take several years before the program could actually be implemented. As an interim measure, President Bush announced June 14, 2001, the creation of a Medicare Prescription Drug Discount program. This program would provide for the endorsement by Medicare of qualified privately-administered prescription drug discount cards. Beneficiaries could obtain these cards either free or for a nominal enrollment charge; the card would provide access to discounts on prescription drugs. While this plan would not establish a Medicare drug benefit, it was designed to give seniors access to similar kinds of discounts as are available to the under age 65 population under private insurance plans. However, on September 6, 2001, a federal

---

[1]For a discussion of the major issues that would need to be addressed as Congress considers policy options, see: CRS Report RL30819, *Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues*, by Jennifer O'Sullivan.

district court judge issued a temporary injunction against implementation of the card program.

Legislation

106th Congress

A number of bills were introduced in the 106th Congress which would have established a prescription drug benefit for Medicare beneficiaries. Some measures added a new benefit to the Medicare program itself. Other proposals provided a new drug benefit through another federal or state program. Still other measures focused on private insurance coverage. Some other bills focused on the prices seniors pay for drugs.

The House passed the Medicare Rx 2000 Act (H.R. 4680, as amended) on June 28, 2000. The House bill relied on private insurance companies and other private sector entities to provide coverage. These entities were to be partially subsidized for assuming the risk of prescription drug costs. At a minimum, plans would have had to provide "qualified coverage." "Qualified coverage" was defined as "standard coverage" or coverage that was actuarially equivalent (i.e., had an equivalent dollar value). "Standard coverage" was defined as having: 1) a deductible ($250 in 2003), 2) then 50% cost-sharing up to an initial coverage limit (the next $2,100 in 2003, accounting for $1,300 in total out-of-pocket costs ($1,050 plus $250 deductible) and $2,350 total spending)); 3) then no coverage until the beneficiary had out-of-pocket costs of $6,000 ($7,050 in total spending; and 4) once the beneficiary reached the $6,000 catastrophic limit full coverage would be provided. Low-income seniors would receive assistance for premiums and costs not paid by the new benefit. The drug benefit and the Medicare+Choice program were to be administered by a new Medicare Benefits Administration.

Several other measures received considerable attention in the 106th Congress. These included proposals offered by President Clinton (S. 2342) and similar Democratic bills (S. 2541 and H.R. 4770), measures introduced by Senators Breaux and Frist (S. 1895 and S. 2807), and a bill introduced by Senators Graham and Robb. The Senate Finance Committee held a number of hearings but did not report a bill.[2]

107th Congress

Status of Legislation. The issue of prescription drug coverage has again received considerable attention in the 107th Congress. The FY2002 Budget Resolution provides $300 billion over the FY2003-FY2011 period for a Medicare

---

[2]For discussion of major bills considered in the 106th Congress see: CRS Report RL30584, *Medicare: Selected Prescription Drug Proposals in the 106th Congress*, by Jennifer O'Sullivan; and CRS Report RL30593, *Medicare: Side-by-Side Comparison of Selected Prescription Drug Bills*, by Jennifer O'Sullivan and Heidi Yacker.

reserve fund for Medicare reform and prescription drug coverage.[3] The three committees of jurisdiction have worked on bills which would address both drug coverage as well as other reform items. As of this writing, committee bills have not yet been introduced. Given the events of September 11, 2001, it is unclear what further action, if any, the Congress will take on this issue this year.

Several bills have been introduced. To date the two that have received the most attention are: 1) S. 358, the "Medicare Prescription Drug and Modernization Act of 2001 (Breaux and Frist, also known as "Breaux-Frist 2"); and 2) S.1135, the Medicare Reform Act of 2001 (Graham et al.). Both are similar, but not identical, to measures introduced in the 106th Congress.

Overview of Major Proposals

Proposals introduced in both the 106th and 107th Congresses contain a number of common themes. In general, they would make coverage available to all Medicare beneficiaries on a voluntary basis. They would have a limit on the amount of federal spending for the new benefit. Beneficiaries would be expected to assume specified costs of the new benefit in the form of premiums and cost-sharing charges. The bills generally would pay most or all of these charges for the low-income (generally persons below 135% of poverty). Other individuals would have a limit on out-of-pocket costs (a "catastrophic limit").

There are, however, a number of significant differences between the bills. These include the degree of reliance and financial risk placed on the private sector versus the public sector, the definition and scope of benefits, the federal administrative structure, and implementation of low-income subsidies.

Private vs. Public Sector Responsibility. Virtually all proposals would place some measure of responsibility on the private sector for administration of a drug plan. It is the degree of reliance placed on the public versus the private sector that is one of the key areas of difference among the various proposals.

Last year's House-passed bill would have provided access to a drug-only benefit through private insurance companies and other entities who wished to offer the benefit. This year's Breaux-Frist 2 plan would also provide access to a drug benefit through private entities or Medicare+Choice plans. Under these proposals, most of the financial risk for the cost of covered benefits would be placed on the entities administering the benefit.

Under the House-passed bill, the Administrator of the new Medicare Benefits Administration would have administered the program in a manner such that eligible individuals would be assured access to at least two plans. If necessary to ensure access, the Administrator would have been authorized to provide financial incentives. The Breaux-Frist 2 bill specifically requires the Commissioner of a new Competitive

---

[3]For a further discussion of Medicare financing and other structural reform issues see: CRS Report RL31058, *Medicare Structural Reform: Background and Options,* by Jennifer O'Sullivan, Hinda Ripps Chaikind, and Sibyl Tilson.

Medicare Agency (CMA) to develop procedures for the provision of standard prescription drug coverage to each beneficiary residing in an area where there were no private entities providing coverage. The Commissioner could establish procedures that permitted partial risk-sharing arrangements if the Commissioner determined that this would generate bids in areas with no Medicare Prescription Plus plans or Medicare+Choice plans providing coverage. Under both bills, the private plans would be at risk for any costs in excess of federal subsidy payments and federal reinsurance payments. Reinsurance payments are made to cover a portion of the costs paid by plans for individuals exceeding the catastrophic out-of-pocket limit.

Under the Graham bill, the new benefit would be administered at the federal level like other Medicare benefits and the federal government would bear most of the financial risk of coverage. The actual operation of the benefit would be through contracts with private entities such as pharmaceutical benefit managers (PBMs). PBMs currently administer the drug benefit, including negotiating price discounts, for many private insurance plans. Under the Graham bill, a portion of the administrative fees for these entities would be put at risk; specifically, an adjustment would be made in administrative payments to ensure that entities complied with requirements relating to performance goals.

Scope of Benefits. Another key difference among proposals is the scope of benefits. Under the Graham bill there would be *one specific benefit* available to all enrollees nationwide. Conversely, under last year's House-passed bill and Breaux-Frist 2 there would be a *minimum* benefit level established. Under the House-passed bill and Breaux-Frist 2, the minimum benefit (referred to as "qualified coverage") would be either specified "standard coverage" or alternative coverage, provided it was actuarially equivalent to standard coverage and had the same limit on out-of-pocket spending.

Administration. Medicare is currently administered by the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS). Prior to June 14, 2001, this agency was known as the Health Care Financing Administration (HCFA). Several of the proposals would establish a new entity to administer the drug benefit at the federal level. Under the last year's House-passed plan, a new Medicare Benefits Administration (MBA) would have been established (outside of HCFA, but within HHS) to administer the drug benefit and Medicare+Choice. Under Breaux-Frist 2, a new Competitive Medicare Agency (outside of HHS) would be established to administer the drug benefit and Medicare+Choice; an independent Medicare Competition and Prescription Drug Advisory Board would be set up to advise the Commissioner of this agency. Under the Graham bill, the benefit would be administered by CMS; an advisory committee would be established to advise the Secretary on policies related to the drug benefit.

Low-Income. Under current law, some low income aged and disabled Medicare beneficiaries are also eligible for drug coverage under Medicaid. Those persons *entitled to full Medicaid protection* generally have prescription drug coverage. Some groups receive more limited Medicaid benefits. Qualified Medicare Beneficiaries (QMBs) are persons with incomes below poverty and resources below $4,000; these persons receive Medicaid assistance for Medicare cost-sharing and premium charges. Specified Low Income Beneficiaries (SLIMBs) meet the QMB

definition except that their income limit is above the QMB level; the SLIMB limit is 120% of poverty. QMBs and SLIMBs only receive drug benefits if they are also entitled to full Medicaid coverage. Under a temporary program, the SLIMB level can be extended to certain persons under 135% of poverty who are not otherwise eligible for Medicaid.

All of the major proposals would provide significant assistance to persons below 135% of poverty – in terms of premiums that would have to be paid for coverage and/or cost sharing once persons used benefits. The plans provide for no, or very limited, beneficiary liability for covered services for this population group. Some of the proposals would extend the low-income assistance protections to persons at slightly higher income levels. The proposals differ in what portion of the costs of low-income subsidies would be paid under the current federal-state Medicaid program and what portion would be fully paid by the federal government.

President Bush's Medicare Drug Discount Program

On July 12, 2001, the President announced the *President's Framework to Strengthen Medicare*. This document included the outlines for Medicare reform and prescription drug coverage. It did not include statutory language; instead the Administration intends to work with the Congress in developing legislation.

On the same day, the President announced a new national drug discount program for Medicare beneficiaries. The Administration intended to implement the program administratively; that is, no legislation would be requested. This discount program was viewed as an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, was enacted.

Implementation of the drug discount program is on hold. On July 17, 2001, the National Association of Chain Drug Stores and the National Community Pharmacy Association filed a suit against HHS stating that the Administration violated the Administrative Procedures Act in the way it established the program. On September 6, 2001, a federal district court judge issued a temporary injunction against implementation of the card program. The judge stated that HHS exceeded its authority in establishing the program and did not follow normal rulemaking procedures in implementing it. On October 9, 2001, the Justice Department filed a motion for a stay of the proceedings telling the court that HHS intended to publish a proposed rule for a new discount proposal that could differ from the original proposal. On October 11, 2001, the pharmacies asked the court to reject the stay. As of this writing, the Court has not ruled on the issue.

The drug discount program outlined by President Bush was intended to give seniors access to similar kinds of discounts as are available to the under age 65 population under private insurance plans. Under the discount plan, Medicare would endorse and promote qualified privately-administered prescription drug discount cards. Approved card sponsors (PBMs and similar entities) would make the cards available either free or at a one-time enrollment charge (not to exceed $25).

Beneficiaries could enroll in only one Medicare-endorsed card program at a time; they could change enrollment on a semi-annual basis.

Under the discount card proposal, approved card sponsors would be required to enroll all Medicare beneficiaries willing to participate. They would be required to provide a discount on at least one brand and/or generic drug in each therapeutic class. They would also be required to offer a national or regional pharmacy network, providing strong retail access. Applicants would be urged to include a mail-order service as part of their program; however, mail-order only plans would not be approved. Medicare would require approved card sponsors to publish the discounted prices. Approved plans could not charge fees to CMS for any activities related to the card program.

The discount program was to be a private program; it would not be financed by federal dollars. The federal oversight role was to be limited to annual certification of plans based on specified criteria including membership thresholds, pharmacy network thresholds, and the inclusion of all therapeutic classes in the discount program.

Card sponsors were to be required to participate in and help finance a Consortium to handle all enrollment and eligibility functions as well as publicize comparative information on the different discounted drug prices and quality enhancements available from various card sponsors. Under the proposal, the Consortium was to be required to implement a system, by October 1, 2001, to permit seniors to compare card programs on such factors as formulary content, networks and discounts. By October 1, 2002, the Consortium would be expected to help consumers comparison shop by providing them with the actual discounted prices associated with various card programs, including information on generic and formulary alternatives.

CMS intended to launch a major education campaign in the fall of 2001. On July 16, 2001, CMS published the requirements for endorsement of card sponsors. Medicare's endorsement was to be based on qualification requirements relating to experience, customer service, discounts, and access. The endorsement was to be for 14 months. CMS intended the first endorsement cycle to be effective November 1, 2001-December 31, 2002.

Applications for endorsement were due by August 27, 2001. CMS received 28 applications. However, the program is on hold following the preliminary injunction issued September 6, 2001. CMS reports that it is working with the Department of Justice to consider all legal options.

Summary of Major Proposals

Table 1 is a side-by-side comparison of *bills introduced in the 107th Congress that have received the most attention to date*. As noted earlier, no committee bills have been introduced to date. However, House committees are reportedly developing a bill modeled on H.R. 4680, the 106th Congress bill passed by the House on June 28, 2000. Therefore, this side-by-side also includes last year's bill. The summary is limited to the prescription drug provisions, though the bills may contain other Medicare provisions.

The summary highlights the major features of the bills. The first items provide a broad overview (Title, General Approach, Previous Versions, and Effective Date). This is followed by beneficiary coverage items (Eligible Populations, Program Enrollment, Plan Enrollment, and Information for Beneficiaries). Next is a discussion of benefits (Nature of Benefits, Scope of Benefits, Premium, Deductible, Cost-Sharing, and Updates to Deductible and Cost-Sharing Amounts). The next items relate to drugs (Drug Pricing and Payment, Access to Negotiated Prices, and Covered Drugs). The next items relate to administration (New Federal Agency, Federal Advisory Body, Federal Administration, Definition of Eligible Entity, Establishment of Plans/Benefits, Access, Federal Payments to Plans or Benefit Administrators, and Assumption of Risk). This is followed by plan requirements (Plan Requirements, Cost Controls/Formularies, Beneficiary Protections, and Pharmacies). The next items relate to existing programs which supplement Medicare benefits (Relationship to Medicare+Choice, Relationship to Private Plans, and Relationship to Medigap). Then the low-income provisions are reviewed (Low-Income Subsidies and Relationship to Medicaid). Finally, other administrative and financing items are outlined (Reports, Accounting Mechanism, Financing, and CBO Cost Estimate).

Table 1. Side-by-Side Comparison of Selected Prescription Drug Bills Introduced in the 107th Congress and H.R. 4680, the House-passed bill from the 106th Congress

Title

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Medicare Prescription Drug and Modernization Act of 2001	Medicare Reform Act of 2001	Medicare Rx 2000 Act

General Approach

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner of the newly established Competitive Medicare Agency (CMA) would be required to establish a Prescription Drug and Supplemental Benefit program under Title XXII of the Social Security Act. Eligible beneficiaries would voluntarily enroll and receive access to covered outpatient drugs and, in certain cases, other supplemental benefits through enrollment in either a Medicare Prescription Plus plan offered by a private entity or a Medicare+Choice plan. At a minimum, drug coverage would be standard coverage or actuarially equivalent coverage. The entities would assume most of the risk of benefit costs. All persons would receive a minimum of a 25% discount on that portion of their premium related to qualified prescription drug coverage. Persons with incomes below 135% of poverty would receive a 100% discount. All current Medicare benefits would be guaranteed and be unaffected by the new program. (The bill also includes provisions that establish the CMA, modify the Medicare+Choice program, and establish Medicare Consumer coalitions.)	A new voluntary benefit would be established under a new Part D. The benefit would be administered by the Secretary of Health and Human Services (HHS). Enrolled beneficiaries would obtain coverage through either a Medicare+Choice plan or through enrollment in a plan offered by an eligible entity under contract with HHS. The federal government would bear most of the financial risk of coverage. A specified benefit would be available to all enrollees nationwide. Medicaid would cover Part D premiums, coinsurance, and deductibles for persons with incomes below 135% of poverty. (The bill also includes other Medicare provisions; these would expand coverage of preventive benefits, create an independent panel to make coverage decisions, set up a demonstration program to improve Medicare+Choice, provide for management improvements to the traditional Medicare program, and income-relate the Part B premium.)	A new optional benefit would be established under a new Part D. The bill would rely on private plans to provide coverage and to bear most of the financial risk for drug costs; federal subsidies would be provided to encourage participation. Coverage would be provided through prescription drug plans (PDPs) or Medicare+Choice (M+C) plans. Beneficiaries could purchase either a standard plan or an actuarially equivalent plan. Individuals with incomes below 135% of poverty would have a premium subsidy equal to 100% of the value of standard drug coverage. A new Medicare Benefits Administration (MBA) would be established within HHS to administer the benefit and the Medicare+Choice program. (The bill also includes provisions that would establish the MBA, modify the Medicare+Choice program, modify the Medicare coverage and appeals provisions, and establish a demonstration project for disease management for severely chronically ill beneficiaries).

Previous Versions

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
This bill, is frequently referred to as "Breaux-Frist 2". It is similar, but not identical to S. 2807 (Breaux and Frist) from the 106th Congress which was also known as Breaux-Frist 2. "Breaux Frist 1" (S. 357 in the 107th Congress, S. 1895 in the 106th Congress) provides for more extensive Medicare reforms.	The drug portion of this bill is similar to S. 10 (Daschle), though there are a number of differences between the two bills. S. 10 is very similar, but not identical to, S.Amdt. 3598 (Robb) to H.R. 4577, submitted on June 22, 2000 (106th Congress) and not agreed to on the same date by a 44-53 roll call vote. The Senate amendment was very similar, but not identical to S. 2758, the Medicare Outpatient Drug Act (the MOD Act) introduced on June 20, 2000, by Senators Graham, Bryan, Robb, et.al.	This is the 106th Congress bill which was passed by the House June 28, 2000.

Effective Date

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
January 1, 2004	January 1, 2004	January 1, 2003

Eligible Populations

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
All Medicare beneficiaries enrolled in both Parts A and B who elected to enroll.	All Medicare beneficiaries (enrolled in Part A, Part B, or both) who elected to enroll.	All beneficiaries enrolled in Part B who elected to enroll in a Medicare+Choice plan with prescription drug coverage or in a PDP.

Program Enrollment

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would establish an enrollment process which would be similar to that established for Medicare Part B. Beneficiaries would have a *one-time* enrollment opportunity. For current beneficiaries this would be the 6-month period beginning November 2003; for future beneficiaries it would be the same 7-month period applicable for initial Part B enrollment. A special enrollment period would be established for persons involuntarily losing other drug coverage under Medicaid, a group health plan, Medigap, a state pharmaceutical assistance program, or veterans coverage; persons would be required to enroll within 63 days of losing other coverage.	The Secretary would establish an enrollment process which would be similar to that for Medicare Part B (including provisions deeming persons enrolled when they first become eligible). An individual's initial enrollment opportunity would generally occur when an individual first became eligible for Medicare. The Secretary would establish an initial open enrollment period for current enrollees. Late enrollment penalties, similar to those applicable under Part B, would apply for persons who did not enroll during their initial enrollment period. Late enrollment penalties would not apply in cases where an individual was 1) previously covered under a group health plan (including a qualified retiree prescription drug plan) which provided coverage at least equal to the value of Part D coverage; and 2) such coverage terminated, or ceased to provide or reduced the value of coverage below the Part D level within the previous 60 days. Late enrollment penalties would also not apply for persons losing their eligibility for drug coverage under Medicaid, a state pharmaceutical assistance program, or veterans coverage within the previous 60 days.	The Administrator of the new MBA would establish an enrollment process. An initial election period would be established. For current Part B beneficiaries this would be the 6-month period beginning November 2002; for future beneficiaries it would be the same 7-month period applicable for initial Part B enrollment. Special election periods would apply for persons who involuntarily lose other drug coverage. A one-time enrollment period would be established for Part A-only beneficiaries. (Such persons could not enroll in a Medicare+Choice plan unless they also enroll in Part B.) Persons electing coverage at the first opportunity and maintaining continuous coverage would be guaranteed the protection of community rating. Persons who delayed enrollment (and who did not maintain alternative drug coverage through such sources as Medicaid, group health plans, or state programs) could be subject to increased premiums or a pre-existing condition exclusion.

Plan Enrollment

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would establish a process, consistent with that established for Medicare+Choice, for individuals to make an annual election to enroll in a Medicare Prescription Plus Plan offered by an entity serving their geographic area.	The Secretary would establish a process through which beneficiaries enrolled in Part D, but not in a Medicare+Choice plan, would make an annual election to enroll in a plan offered by an eligible entity. The rules would be similar to, and coordinate with, those for Medicare+Choice enrollment.	The Administrator, acting through the new Office of Beneficiary Assistance would be required to establish and maintain a plan election process consistent with that now provided for the election of Medicare+Choice plans. The process would include the conducting of annual coordinated election periods, the active dissemination of comparative plan information, and the coordination of elections.

Relationship to Medicare+Choice

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
A Medicare+Choice enrollee would obtain benefits through the Medicare+Choice plan if the plan provided qualified drug coverage. A Medicare+Choice plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage and the plan complied with the beneficiary protections required for Medicare Prescription Plus plans. Medicare+Choice plans would be required to compute and publish: a) a premium for drug benefits that is separate from other coverage; b) the ratio of the actuarial value of standard drug coverage to the actuarial value of drug coverage offered under the plan; and c) the portion of the premium attributable to standard benefits. Medicare+Choice organizations would be permitted to reduce the amount of premiums charged.	Medicare+Choice plans would be required to offer Part D drug benefits. Enrollees electing the drug benefit would receive these benefits through the plan. Capitation payments to the plans would be adjusted accordingly with a separate calculation made for Part D benefits. Medicare+Choice enrollees could not be required to pay deductible or coinsurance charges that exceed those specified under Part D.	A Medicare+Choice enrollee would obtain benefits through the Medicare+Choice plan if the plan provided qualified drug coverage. A Medicare+Choice plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage and the plan complied with the beneficiary protection requirements for PDP sponsored plans. Medicare+Choice plans would be required to compute and publish: a) a premium for drug benefits that is separate from other coverage; b) the ratio of the actuarial value of standard drug coverage to the actuarial value of drug coverage offered under the plan; and c) the portion of the premium attributable to standard benefits. Medicare+Choice organizations would be permitted to reduce the amount of premiums charged.

Information for Beneficiaries

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would establish a process, similar to that established for Medicare+Choice to broadly disseminate information. The information activities would be coordinated with other required information activities, including those for Medicare+Choice. The Commissioner could establish Medicare Consumer Coalitions (nonprofit entities primarily composed of beneficiaries) to help provide information to beneficiaries; such sums as may be necessary would be authorized for this purpose.	The Secretary would conduct activities to broadly disseminate information regarding drug coverage. To the extent practicable, this information would be made available 30 days prior to a beneficiary's first enrollment period. Information would include comparative information for each eligible entity on: 1) benefits provided, including prices beneficiaries will be charged, preferred pharmacies used, formularies, and appeals processes; 2) quality and performance; 3) beneficiary cost-sharing; 4) results of consumer satisfaction surveys; and 5) additional information as determined by the Secretary. The information activities would be coordinated with other required information activities including those for Medicare+Choice. The Secretary could contract with Medicare Consumer Coalitions (nonprofit entities made up primarily of beneficiaries) to conduct information activities; such sums as may be necessary would be authorized for this purpose.	The required active dissemination of plan information, including information on price and quality, would be conducted in a manner consistent with and in coordination with the dissemination of information regarding Medicare+Choice plans.

Nature of Benefits

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)

"Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage" (i.e., having an equivalent dollar value). Plans could offer more generous drug coverage; they could also offer supplemental non-drug benefits. If an entity offered more generous coverage, it would also be required to offer a Medicare Prescription Plus plan in the area meeting minimum coverage criteria only.	A specified benefit would be available to all enrollees nationwide.	"Qualified coverage" would be either standard coverage or actuarially equivalent coverage. Plans could offer more generous drug coverage, if approved by the MBA Administrator.

Scope of Benefits

S. 358 ("Breaux-Frist 2")	**S. 1135 (Graham et al.**	**H.R. 4680 (106th Congress - Thomas et al.)**

"Standard coverage" would be defined as having a deductible ($250 in 2004), 50% cost-sharing up to the initial coverage limit (the next $2,100 in 2004 (accounting for $1,300 in total out-of-pocket costs and $2,350 total spending)), then no coverage until the beneficiary had out-of-pocket costs of $6,000 ($7,050 in total spending); once the beneficiary reached the $6,000 catastrophic limit full coverage would be provided. Plans could offer a package that was actuarially equivalent to the standard package, subject to certain conditions, including having a limit on out-of-pocket costs the same as that under standard coverage. A Medicare Prescription Plus plan could provide more generous drug benefits. It could also offer coverage of non-drug benefits. If these non-drug benefits included coverage of any Medicare cost-sharing charges and related charges specified as core benefits under Medigap, the plan would have to cover at least all such charges that would be covered under Medigap Plan A. If an entity offered more generous coverage, it would also be required to offer a Medicare Prescription Plus plan in the area meeting qualified coverage criteria only. Further, the Commissioner would have to find that the benefits were not designed to result in favorable selection of beneficiaries.	The benefit would be subject to a deductible ($250 in 2004), 50% coinsurance until beneficiary out-of-pocket costs reached a specified level ($3,500 in 2004), and then 25% coinsurance until out-of-pocket costs reached the out-of-pocket limit ($4,000 in 2004).	"Standard coverage" would be defined as having a deductible ($250 in 2003), 50% cost-sharing up to the initial coverage limit (the next $2,100 in 2003 (accounting for $1300 in total out-of-pocket costs and $2,350 total spending)) then no coverage until the beneficiary had out-of-pocket costs of $6,000 ($7,050 in total spending); once the beneficiary reached the $6,000 catastrophic limit full coverage would be provided. Plans could offer a package that was actuarially equivalent to the standard package, subject to certain conditions including having a limit on out-of-pocket costs the same as that under standard coverage. Plans could also offer additional drug coverage.

Premium

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
A plan would be required to charge a uniform premium for individuals enrolled in the plan in the same service area. Beneficiaries would pay the premium amount (less any discount) in the same manner as Part B premiums are paid (generally as a deduction from an individual's social security check). All beneficiaries would receive a discount of at least 25% of the value of standard coverage. (The low income would receive a larger discount, see below.) This discount would be included as taxable income to the beneficiary.	Beneficiaries would pay a monthly premium equal to 50% of estimated average per capita program costs; premiums paid by former employers would equal two-thirds of the total. The remaining 50% would be paid by the federal government. Premiums would be collected in the same way as Part B premiums; for most persons this is a deduction from social security checks. Higher income persons would receive a lower government premium contribution. Individuals with adjusted gross incomes between $75,000 and $100,000 and couples with adjusted gross incomes between $150,000 and $200,000 would have the government premium contribution reduced from 50% to 25%, calculated on a sliding scale basis. (These income amounts would be adjusted for inflation as measured by the consumer price index for years after 2004.) All beneficiaries would receive a minimum 25% government subsidy.	The plan sponsor would establish the premium amount. The premium for a prescription drug plan could not vary among individuals enrolled in the plan in the same service area, unless the individuals were subject to penalties for late enrollment. Premiums would be paid to the plans.

Deductible

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
In 2004, the deductible for standard coverage would be $250.	The benefit would be subject to an annual deductible ($250 in 2004). An entity could waive the deductible for generic drugs if: 1) the Secretary determined that the waiver was tied to performance goals established by the Secretary; and 2) it would not result in an increase in federal costs. Any coinsurance paid with respect to such a generic drug would be credited toward the deductible applicable for other drugs.	In 2003, the deductible for standard coverage would be $250.

Cost-Sharing

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
"Standard coverage" would be defined as having 50% cost-sharing up to the initial coverage limit (the next $2,100 after the $250 deductible in 2004, accounting for total spending of $2,350), and full coverage after an annual limit in out-of-pocket spending ($6,000 in 2004). Thus in 2004, the beneficiary would pay the first $250, $1,050 of the next $2,100 (with the plan paying the other $1,050), and all costs for drug spending between $2,350 and $7,050. The plan would pay in full for all costs over $7,050 ($6,000 in out-of-pocket costs). Out-of-pocket costs counting toward the limit would include costs paid by a state program but not those covered as benefits under other third-party coverage.	In 2004, beneficiary cost-sharing would equal 50% of costs until out-of-pocket costs totaled $3,500. At this point, beneficiary cost-sharing would be reduced to 25%. There would be no cost sharing once out-of-pocket costs reached $4,000. Thus, assuming no waiver of the deductible, the beneficiary would pay 100% of the first $250, 50% of the next $6,500 ($6,750 total, $3,500 total out-of-pocket), and 25% of the next $2,000 ($8,750 total, $4,000 total out-of-pocket). The program would pay any remaining costs. Entities could reduce cost sharing if the Secretary determined that the reduction was tied to performance goals and such reduction would not increase federal costs. Entities could also require higher cost-sharing for drugs not on their formulary (see below), except that higher cost-sharing would not be permitted if the drug was determined to be medically necessary (based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence) to prevent or slow the deterioration of, or improve or maintain, the health of an eligible beneficiary.	"Standard coverage" would be defined as having 50% cost-sharing up to the initial coverage limit (the next $2,100 after the $250 deductible in 2003, accounting for total spending of $2,350), and full coverage after an annual limit in out-of-pocket spending ($6,000 in 2003). Thus in 2003, the beneficiary would pay the first $250, $1,050 of the next $2,100 (with the plan paying the other $1,050), and all costs for drug spending between $2,350 and $7,050. The plan would pay in full for all costs over $7,050 ($6,000 in out-of-pocket costs). Out-of-pocket costs counting toward the limit would include costs paid by another person including a state program or other third-party coverage.

Updates to Deductible and Coverage Limits

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)

The annual dollar amounts would be increased by the increase in average per capita aggregate expenditures for drugs by Medicare beneficiaries for the year ending the previous July.	The dollar amounts would be increased in future years (beginning in 2005) by the percentage increase in average per capita expenditures under the program in the preceding year over such expenditures in 2004.	The annual dollar amounts would be increased by the increase in average per capita aggregate expenditures for drugs by Medicare beneficiaries for the year ending the previous July.

Drug Pricing and Payment

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The entity would determine payments and would be expected to negotiate discounts.	The contracting entity's bid would include a proposal for the estimated prices for covered drugs and projected annual increase in prices. The entity would be expected to negotiate discounts.	The PDP sponsor would determine payments and would be expected to negotiate discounts.

Access to Negotiated Prices

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Both standard and actuarially equivalent coverage would have to provide beneficiaries access to negotiated prices, even when the plan was under no obligation to pay for the benefits. The entity or Medicare+Choice plan would issue a drug discount card.	Plans would provide that beneficiaries would have access to negotiated prices (including applicable discounts) regardless of the fact that no or only partial benefits are paid because of the application of the deductible or coinsurance.	Both standard coverage and actuarially equivalent coverage would have to provide beneficiaries access to negotiated prices (including applicable discounts) even when no benefits may be payable because the beneficiary has reached the initial coverage limit.

Covered Drugs

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
In general, coverage would be extended to outpatient prescription drugs meeting FDA criteria, biological products, and insulin. Drugs currently covered under Medicare would continue to be covered under the basic program. Drugs excluded under Medicaid would not be covered, except those for smoking cessation.	In general, coverage would be extended to outpatient prescription drugs meeting FDA criteria, biological products, and insulin. Prescription drugs and biological products meeting the criteria but also available over-the-counter would also be covered. Drugs currently covered under Medicare would continue to be covered under the basic program. Drugs excluded under Medicaid would not be covered, except those for smoking cessation. All therapeutic classes of covered outpatient drugs would be covered.	In general coverage would be extended to outpatient prescription drugs, meeting FDA criteria, biologicals, and insulin. Drugs excluded under Medicaid would not be covered except those for smoking cessation or those specified by the MBA Administrator. Drugs currently covered under Medicare would continue to be covered under the basic program.

New Federal Agency

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An independent agency, the Competitive Medicare Agency would be set up in the executive branch outside of HHS. The Agency would administer the Medicare Prescription Drug and Supplemental Benefit Program under the new Title XXII and the Medicare+Choice program. (HHS would retain responsibility for the traditional fee-for-service program.) The head of the Agency would be a Commissioner appointed by the President, with the advice and consent of the Senate, for a 6-year term. The Commissioner and the Secretary of HHS would consult on an ongoing basis to ensure coordination of programs and would exchange data as appropriate. The Commissioner would prepare an annual budget for the agency that would be submitted to the President and Congress without revision, together with the President's budget for the Agency. The Commissioner would serve as a member of the Board of Trustees of the Medicare trust funds.	Not applicable.	The new MBA, within HHS, would administer the new Part D drug benefit and the Medicare+Choice program. (HCFA, now CMS, would retain responsibility for the traditional fee-for-service program.) The head of the MBA would be an Administrator appointed by the President, with the advice and consent of the Senate, for a 5-year term. The Secretary of HHS would assure appropriate coordination between the Administrator and the Administrator of HCFA (now CMS). The Administrator would serve as a member of the Board of Trustees of the Medicare trust funds.

Federal Advisory Body

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An independent 7-member Medicare Competition and Prescription Drug Advisory Board would be set up to advise the Commissioner on policies related to the new program and Medicare+Choice. Three members would be appointed by the President (no more than two from the same party), two by the President pro tempore of the Senate (each from a different party) and two by the Speaker of the House (each from a different party). The Board would submit reports to the Commissioner and the Congress as determined appropriate. It would be required to submit reports directly to Congress; no officer or agency could require that they be submitted to any federal officer or agency for prior review or approval.	A 19-member Medicare Prescription Drug Advisory Committee would be established to advise the Secretary on policies related to development of: 1) guidelines for implementation and administration of the benefit; 2) standards for contracting entities for their Pharamacy and Theurapeutic (P&T) committees; 3) standards for entities for determining if a drug is medically necessary to prevent or slow the deterioration of, or improve or maintain, the health of an eligible beneficiary; 4) standards for defining therapeutic classes and adding new classes to the formulary; 5) procedures to evaluate bids from eligible entities; and 6) procedures to ensure that contracting entities are in compliance with Part D requirements. The Committee membership would be representative of physicians (nine members), pharmacists (four members), Centers for Medicare and Medicaid Services (one member), actuaries, pharmacoeconomists, researchers and appropriate experts (four members), and emerging drug technologies (one member).	A 7-member Medicare Policy Advisory Board would be set up within the MBA to advise the Administrator on policies related to the new program and Medicare+Choice. Three members would be appointed by the President, two by the Speaker of the House, and two by the President pro tempore of the Senate. The Board would submit reports to the Administrator and the Congress as determined appropriate. It would be required to submit reports directly to Congress; no officer or agency could require that they be submitted to any federal officer or agency for prior review or approval.

Federal Administration

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would establish a Prescription Drug and Supplemental Benefit Program. The Commissioner would establish a program enrollment process and a process through which beneficiaries would enroll, on an annual basis, in a Medicare Prescription Plus plan. The Commissioner of the new agency would have responsibility for: 1) coordinating determinations of beneficiary eligibility and enrollment under Title XVIII and the new drug program with the Commissioner of Social Security; 2) entering into and enforcing contracts with entities for the offering of Medicare Prescription Plus plans; 3) disseminating comparative information regarding benefits and quality; 4) dissemination of appeals rights information; and 5) establishing a Medicare beneficiary education program. The Commissioner would also establish processes for determining the actuarial value of prescription drug coverage and for determining the annual percentage increase in coverage limits. The Commissioner would also administer the low-income cost sharing subsidy. The Commissioner would review proposed plans based on information submitted by eligible entities and approve or disapprove the proposal. The Commissioner would have the same authority to negotiate terms and conditions of premiums and other terms of the plans as the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits plans.	The Secretary would: 1) establish a Part D enrollment process for beneficiaries; 2) establish an annual process for beneficiary enrollment with eligible entities; and 3) conduct information activities. The Secretary would establish a competitive bidding process for the award of contracts to eligible entities to administer and deliver the drug benefit. At least 10 different coverage areas would be established. The Secretary would consider the comparative merits of each bid based on past performance and other factors. At least two contracts would be awarded in each area unless only one entity met the bidding requirements. Each contract would be awarded for 2-5 years. The Secretary would approve marketing material and application forms. The Secretary could not award a contract unless the entity agreed to comply with terms and conditions specified by the Secretary including those relating to: 1) quality and financial standards; 2) procedures to ensure proper utilization and avoidance of adverse drug reactions; 3) patient protections; 4) procedures to control fraud, abuse, and waste; and 5) submission of reports; 6) approval of marketing material and application forms; and 7) maintenance of records.	The Administrator, acting through the new Office of Beneficiary Assistance, would be required to establish a plan election process including the dissemination of comparative information. The Administrator would be responsible for entering into contracts with a PDP sponsor; the contract could cover more than one plan. The Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans. The Administrator would be required to take into account reinsurance subsidy payments and the adjusted community rate for covered benefits in negotiating the terms and conditions regarding premiums. The Administrator could not require that a particular formulary be used, institute a price structure for drugs, or interfere in negotiations between PDP sponsors and Medicare+Choice organizations with drug manufacturers, wholesalers or other suppliers of drugs. The Administrator would establish processes for determining the actuarial value of prescription drug coverage and for determining the annual percentage increase in coverage limits. The Administrator would provide a process for administration of the subsidy program including periodic reimbursement to the PDP sponsor or Medicare+Choice organization of the subsidy amount.

Definition of Eligible Entity

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An eligible entity would be any risk-bearing entity the Commissioner determined to be appropriate to administer the benefit including a pharmaceutical benefit management company; a wholesale or retail pharmacist delivery system; an insurer (including an insurer that offers Medigap policies); another entity, or any combination of these.	An eligible entity would be any entity the Secretary determined to be appropriate to administer the benefit including: a pharmacy benefit management company (PBM); retail pharmacy delivery system; health plan or insurer; a state (through mechanisms established under a Medicaid state plan); any other entity approved by the Secretary; or any combination of such entities if the Secretary determined that the combination increased the scope or efficiency of the provision of benefits and was not anticompetitive.	A PDP plan sponsor would be an entity certified under Part D as meeting the Part D standards and requirements.

Establishment of Plans/Benefits

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Each entity intending to offer a plan would be required to submit to the Commissioner information on benefits provided, actuarial value of the coverage, monthly premium to be charged for the coverage, and the service area for the plan. The entity would have to include an actuarial certification of the actuarial basis for the premium, the portion of the premium attributable to benefits in excess of the standard coverage, and the reduction in the premium resulting from reinsurance subsidies. The Commissioner would review the submitted information for purposes of conducting negotiations with the plan. Plans could not be elected by beneficiaries unless the Commissioner had entered into a contract with the plan sponsor; the contract could cover more than one plan. The Commissioner could approve a service area only if the Commissioner found that it was not designed so as to discriminate based on health status, economic status, or prior receipt of health care of eligible beneficiaries. Further, the benefit package could not be designed so as to lead to favorable selection of beneficiaries.	An entity's bid (which could include multiple areas) would include: 1) a proposal for the estimated prices for covered drugs, projected annual increase in prices, including differentials between formulary and nonformulary prices, if applicable; 2) the amount the entity would charge the government for administering the benefit; 3) a statement regarding whether the entity would waive the deductible for generic drugs and how the waiver is tied to performance goals; 4) a statement of whether there would be any coinsurance reduction and how that is tied to performance goals; 5) a detailed description of performance goals; 6) a detailed description of access to pharmacy services including whether the entity would use a preferred pharmacy network, and if so, whether the entity would offer access outside the network and what the coinsurance would be; 7) the procedures for modifying a formulary, if one is used; 8) a detailed description of any ownership or shared financial interests with other entities involved in delivering the drug benefit; 9) a description of the entity's estimated marketing and advertising expenditures; and 10) other information deemed necessary by the Secretary. Eligible entities would be required to offer drugs on a regional basis, except that the Secretary could permit coverage on a partial regional basis if the region was at least the size of the commercial service area of the entity and the area was not smaller than a state.	Each PDP sponsor would be required to submit to the MBA Administrator information on the qualified drug coverage to be provided, the actuarial value of the coverage, and the monthly premium to be charged for the coverage. The PDP sponsor would have to include an actuarial certification of the actuarial basis for the premium, the portion of the premium attributable to benefits in excess of the standard coverage, and the reduction in the premium resulting from reinsurance subsidies. The Administrator would review the submitted information for purposes of conducting negotiations with the plan. Plans could not be elected by beneficiaries unless the Administrator had entered into a contract with the plan sponsor; the contract could cover more than one plan. A PDP sponsor could not establish a service area in a manner that would discriminate based on health or economic status of potential enrollees. The Administrator could terminate the contract of a PDP sponsor or Medicare +Choice plan offering drug coverage if the entity purposely engaged in activities designed to result in favorable selection by eligible beneficiaries.

Access

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would develop procedures for the provision of standard prescription drug coverage to each beneficiary residing in an area where there were no Medicare Prescription Plus plans or Medicare+Choice plans providing coverage. The Commissioner could establish procedures that permit partial risk-sharing arrangements (that is the government would share some of the costs) if the Commissioner determined that this would generate bids in areas with no Medicare Prescription Plus plans or available Medicare+Choice plans providing qualified drug coverage.	The Secretary would develop procedures for the provision of covered drugs to each eligible beneficiary that resides in an area not covered by a contract. The Secretary would also develop procedures to ensure that each beneficiary that resides in different areas in a year is provided benefits throughout the year.	The Administrator would assure that all eligible individuals would have a choice of enrollment in at least two qualifying plan options (at least one of which was a PDP) in their area of residence. (The requirement would not be satisfied if only one PDP sponsor or Medicare+Choice organization offered all the qualifying plans in the area). If necessary to ensure such access, the Administrator would be authorized to provide financial incentives, including the partial underwriting of risk, for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan (including offering such plan on a regional or nationwide basis). However, the MBA Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and Medicare+Choice organizations. The Administrator would be required to report to Congress annually on the exercise of this authority.

Federal Payments to Plans and Benefit Administrators

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The Commissioner would pay to each eligible entity the full amount of the premium for each beneficiary minus administrative costs levied on the plan. The Commissioner would provide a process for notifying eligible entities of low-income persons eligible for reduced cost-sharing and for reimbursement of the amount of such reductions. The Commissioner would provide for reinsurance payments to Medicare Prescription Plus plans, Medicare+Choice plans providing qualified prescription drug coverage, and qualified retiree drug plans. In 2004, the reinsurance payment would cover 80% of costs exceeding $7,050 (the point at which beneficiary out-of-pocket payments cease). This amount would be increased in future years by the percentage increase in average per capita aggregate expenditures for drugs by Medicare beneficiaries for the year ending the previous July. The payment method would be determined by the Commissioner and could use an interim payment system based on estimates.	The Secretary would establish procedures for making payments to eligible entities.	The Administrator would provide for reinsurance payments to PDP sponsors, Medicare+Choice plans providing qualified prescription drug coverage, and qualified retiree drug plans. In 2003, reinsurance payments would be provided for individual drug costs exceeding $1,250. The percentage of costs subject to reinsurance payments would be 30% for costs above $1,250 but not above $1,350, 50% of costs above $1,350 but not above $1,450, 70% of costs above $1,450 but not above $1,550, and 90% of costs above $1,550 but not above $2,350. Reinsurance, not to exceed 90% would also be provided for costs over $7,050 (total spending amount for beneficiaries reaching the out-of-pocket limit). These amounts would be increased in future years by the percentage increase in average per capita aggregate expenditures for drugs by Medicare beneficiaries for the year ending the previous July. The Administrator would proportionately adjust the payments so that total reinsurance payments made during the year equaled 35% of total payments to be made by qualifying plans for standard coverage during the year. The payment method would be determined by the Administrator and could use an interim payment system based on estimates.

Assumption of Risk

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The entity would be required to assume full financial risk for the cost of covered benefits except: 1) as covered by federal reinsurance payments for high cost enrollees; and 2) as provided for under any partial risk sharing arrangements developed by the Commissioner to encourage bids (see Access, above). The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.	A portion of an entity's *administrative fees* would be put at risk. An adjustment would be made in payments for administration to ensure that the entity complies with requirements related to: 1) quality service (including sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member support services and timely action with regard to appeals); 2) quality clinical care (including notification to prevent adverse drug reactions and specific clinical suggestions to improve health); and 3) control of Medicare costs (including generic substitution, price discounts and other factors that do not reduce access to necessary drugs). The Secretary would determine the percentage of payments that would be tied to performance goals; however, the percentage could not be set at a level that jeopardized the ability of an eligible entity to administer and deliver the benefits in a quality manner.	The PDP sponsor would be required to assume full financial risk on a prospective basis for the cost of covered benefits except: 1) as covered by federal reinsurance payments for high cost enrollees; or 2) as covered by federal incentive payments (for encouraging sponsors to expand service areas for existing plans or to establish new plans). The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

Plan Requirements

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An entity would have to be licensed as a risk-bearing entity in each state in which it offered a Medicare Prescription Plus plan. Alternatively it could meet solvency and other standards established for entities not licensed by the state. It would also have to meet beneficiary protection requirements (see below). An entity's contract with the Commissioner could cover more than one Medicare Prescription Plus plan. The Commissioner would establish standards for eligible entities. As is the case for Medicare+Choice, the standards established for plans would supersede state laws to the extent they were inconsistent. The following state standards would be specifically preempted: benefit requirements, requirements relating to inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).	Entities would have to meet specified requirements including those relating to quality and financial standards, beneficiary protections (see below), and procedures to control fraud and abuse. The entity would be required to submit annual reports on: 1) prices that the entity is paying for drugs; 2) prices enrolles will be charged; 3)administrative costs; 4) utilization of benefits; and 5) marketing and advertizing expenditures.	A PDP sponsor would have to be licensed as a risk-bearing entity in each state in which it offered a prescription drug plan. Alternatively it could meet solvency standards established by the MBA Administrator for entities not licensed by the state. It would also have to meet beneficiary protection requirements (see below). Many of the plan requirements would be comparable to those imposed under Medicare+Choice. As is the case for Medicare+Choice, standards established for plans and plan sponsors would supersede state laws to the extent they were inconsistent. The following state standards would be preempted: benefit requirements, requirements relating to inclusion or treatment of providers, coverage determinations (including related appeals and grievance processes), and establishment and regulations of premiums. States could not impose premium taxes on plan premiums.

Cost Controls/Formularies

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An entity offering a Medicare Prescription Plus plan or Medicare+Choice plan could use cost control mechanisms customarily used in employer-sponsored health care plans that offer coverage for outpatient prescription drugs. These include formularies, tiered copayments, selective contracting with providers of outpatient prescription drugs, and mail order pharmacies. Entities using formularies would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily all drugs within such categories and classes). Entities would have a process for beneficiaries to appeal denials of coverage based on application of the formulary.	Contracting entities could employ mechanisms to provide benefits economically including formularies, alternative distribution methods, and generic drug substitution. They could use mechanisms to encourage beneficiaries to select cost-effective drugs or less costly means of receiving drugs including use of pharmacy incentive programs, therapeutic interchange programs, and disease management programs. They could also encourage pharmacy providers to inform beneficiaries of price differences between generic and nongeneric drugs and to provide medication therapy management programs. Any formulary would have to comply with standards established by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee. The entity would be required to use a pharmacy and therapeutics committee to develop and implement the formulary. The formulary would be required to include at least two drugs from each therapeutic class (unless only one drug was available in the class) unless clinically inappropriate, and a generic substitute (if available) if more than two drugs were available in a class and it was not clinically inappropriate. Further, the contracting entity would be required to develop procedures for modification of the formulary and to disclose to current and prospective beneficiaries related information. Entities would be required to cover nonformulary drugs when determined medically necessary (based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence) to prevent or slow the deterioration of, or improve or maintain, the health of an eligible beneficiary.	Plans would be allowed to have formularies restricting coverage to certain drugs. Plans electing to use a formulary would be required to establish a pharmaceutical and therapeutic committee (that included at least one physician and one pharmacist) to develop the formulary. The formulary would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes). An enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the therapeutically similar drug that was on the formulary was not as effective for the enrollee or had significant adverse effects for the enrollee.

	Entities could require higher cost-sharing for nonformulary drugs except when such nonformulary drug is determined medically necessary. They could educate prescribing providers, pharmacists, and beneficiaries about the medical and cost benefits of formulary drugs. Further, they could request prescribing providers to consider a formulary drug prior to dispensing of a nonformulary drug so long as the requirement did not unduly delay provision of the drug.	

Beneficiary Protections

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
An entity offering a Medicare Prescription Plus plan would be required to disclose in a clear, accurate and standardized form to each enrollee information on access to covered outpatient drugs, formulary provisions, cost-sharing requirements and grievance and appeals procedures. Beneficiaries would have the right to obtain more detailed information on request. Plans would also be required to furnish beneficiaries information on benefits provided. Further, plans would be required to provide access to negotiated prices, even when the plan is under no obligation to pay for the benefits. Plans would be required to establish cost and drug utilization management, quality assurance, and fraud and abuse control programs. Entities would be required to have meaningful procedures for resolving grievances and protecting confidentiality and accuracy of enrollee records. Further they would be required to provide enrollees access to expedited coverage determinations and a procedure for reconsideration and appeals of benefit denials; these requirements would be the same as those applicable for Medicare+Choice plans. Entities would also assure that premiums charged are the same for all individuals enrolled in a plan.	Contracting entities would be required to comply with requirements relating to: 1) quality; 2) drug utilization review procedures to ensure proper utilization and compliance, and avoidance of adverse drug reactions; 3) procedures to guarantee patient confidentiality and timely transfer of records; and 4) procedures for working with the Secretary to deter medical errors related to the provision of drugs. Entities would be required to ensure that covered drugs are accessible and convenient to beneficiaries by 1) offering services 24 hours a day and 7 days a week for emergencies; and 2) if a pharmacy network is used, the network complies with standards. The entity would be required to have procedures to assure that charges for drugs do not exceed the negotiated price and the retail pharmacy dispensing the drug does not charge the beneficiary more than the beneficiary's obligation. The entity would also be required to have procedures to determine if a non-formulary drug is medically necessary (based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence) to prevent or slow the deterioration of, or improve or maintain, the health of an eligible beneficiary. Further, entities would have to have procedures (comparable to those applicable for Medicare+Choice) to ensure timely internal and external review and resolution of denials of coverage and complaints. Beneficiaries would be provided with information on appeals procedures at the time of enrollment.	A PDP sponsor would be required to disclose in a clear, accurate and standardized form to each enrollee information on access to covered outpatient drugs, formulary provisions, cost-sharing requirements and grievance and appeals procedures. Beneficiaries would have the right to obtain more detailed information on request. A PDP sponsor would also be required to furnish beneficiaries information on benefits that have been provided. Further, plans would be required to provide access to negotiated prices, even when the plan is under no obligation to pay for the benefits. PDP sponsors would be required to have in place: 1) an effective cost and drug utilization management program; 2) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including a medication therapy management program; and 3) a program to control fraud, abuse, and waste. Medication therapy management programs would have to be developed in cooperation with licensed pharmacists and physicians. PDP sponsors would be required to maintain meaningful procedures for hearing and resolving grievances and protecting the confidentiality and accuracy of enrollee records. Further, they would be required to meet requirements for expedited coverage determinations, reconsiderations, and appeals; these requirements would be the same as those applicable for Medicare+Choice plans.

		PDP sponsors would provide that each pharmacy or other dispenser of drugs would inform the beneficiary at the time of purchase of the price differential between the prescribed drug and the lowest cost generic drug that is therapeutically and pharmaceutically equivalent and bioequivalent.

Pharmacies

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
No provision.	The entity would be required to ensure than any retail pharmacy that it contracts with meets minimum quality and technology standards. If the entity uses a preferred pharmacy network, the network would be required to meet minimum access standards; in establishing the standards, the Secretary would take into account reasonable distances to pharmacy services in both urban and rural areas.	PDP sponsors would be required to secure participation of a sufficient number of pharmacies (which could include mail order pharmacies) to make access to covered benefits convenient for enrollees.

Relationship to Private Plans

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Qualified retiree prescription drug plans would be eligible for reinsurance payments. Qualified coverage would be defined as employment-based retiree health coverage meeting certain requirements. The sponsor of the plan would be required to annually attest to the Commissioner (and to provide such other assurances as required by the Commissioner) that coverage met the requirements for qualified prescription drug coverage. The sponsor and the plan would have to maintain and provide access to records needed to ensure the adequacy of coverage and accuracy of payments made.	The Secretary would be authorized to develop an Employer Incentive Program under which employers and other sponsors of employment-based retiree coverage that is at least equivalent to that under the new Part D would receive incentive payments. Such payments would be made in behalf of beneficiaries who obtained drug coverage under the sponsors plan rather than Medicare. The incentive payment would equal two-thirds of the premium amount the beneficiary would otherwise pay if the individual were enrolled in Part D. Plan sponsors would be required to provide certain assurances and information to the Secretary.	Qualified retiree prescription drug plans would be eligible for reinsurance payments. Qualified coverage would be defined as employment-based retiree health coverage meeting certain requirements. The sponsor of the plan would be required to annually attest to the Administrator (and to provide such other assurances as required by the Administrator) that coverage met the requirements for qualified prescription drug coverage. The sponsor and the plan would have to maintain and provide access to records needed to ensure the adequacy of coverage and accuracy of payments made.

Relationship to Medigap

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
No Medigap policy that provided coverage for prescription drugs could be sold to an individual after January 1, 2004, unless it replaced a policy for an individual that included drug coverage. Individuals enrolled in the new Title XXII program who terminated enrollment in a Medigap policy with prescription drug coverage or another policy with drug coverage would be guaranteed enrollment in a Medigap non-drug policy if enrollment occurred within 63 days of the termination of prior coverage.	The three of the 10 standardized Medigap plans offering drug coverage would have to be revised to complement, not duplicate Part D. The revised drug packages could not offer coverage for the Part D deductible or for more than 90% of the Part D coinsurance.	No Medigap policy that provided coverage for prescription drugs could be sold to an individual after January 1, 2003, unless it replaced a policy for an individual that included drug coverage. Individuals enrolled in a plan under the new Part D program who terminated enrollment in a Medigap policy with prescription drug coverage or another policy with drug coverage would be guaranteed enrollment in a Medigap non-drug policy if enrollment occurred within 63 days of the termination of prior coverage.

Low-Income Subsidies

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Low-income persons would receive a discount on their premiums (based on the value of standard coverage). Individuals with incomes below 135% of poverty (and assets below $4,000) would have a discount equal to 100% of the value of standard drug coverage provided under the plan. Beneficiary cost-sharing for such individuals would be nominal. For individuals between 135% and 150% of poverty, there would be a sliding scale discount on their premiums ranging from 100% of such value at 135% of poverty to 25% of such value at 150% of poverty. There would be no cost-sharing subsidy for this group. The maximum amount of cost-sharing subsidy that could be provided for an enrollee under 135% of poverty could not exceed 95% of the maximum amount of cost-sharing that could be incurred for standard coverage. Beneficiary cost-sharing for these persons would be nominal as determined by the Commissioner. A plan could waive or reduce the amount of cost-sharing otherwise applicable.	Medicaid would cover Part D premiums, coinsurance, and deductible for persons below 135% of poverty. (Coinsurance and deductible amounts would be based on drug payment amounts determined under Part D not Medicaid.) Beneficiaries between 135% and 150% of poverty would pay a reduced Part D premium, calculated on a sliding scale basis.	Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135% of poverty (and assets below $4,000) would have a subsidy equal to 100% of the value of standard drug coverage provided under the plan. Beneficiary cost-sharing for such individuals would be nominal. For individuals between 135% and 150% of poverty, there would be a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. There would be no cost-sharing subsidy for this group. The maximum amount of cost-sharing subsidy that could be provided for an enrollee under 135% of poverty could not exceed 95% of the maximum cost-sharing that could be incurred for standard coverage. Beneficiary cost-sharing for these persons would be nominal as determined by the MBA Administrator. A plan could waive or reduce the amount of cost-sharing otherwise applicable.

Relationship to Medicaid

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
The new Title XXII coverage would be primary to any drug benefits under Medicaid. States would be required to make eligibility determinations for low- income subsidies; there would be a 5 year phase-in of increased matching rates for this activity so that there would be full federal funding beginning in 2008. Dual eligibles (i.e., persons eligible for Medicare and full Medicaid benefits, including drugs) would have their low-income subsidy costs picked up by Medicaid. Over a 5 year period the federal matching rate for these costs would be increased to cover 50% of what would otherwise be state costs. (For example, if the regular state matching rate for Medicaid costs was 40%, the state matching rate for low income subsidies would be 20% after 5 years.) States would be required to maintain Medicaid benefits as a wrap around to Medicare benefits for dual eligibles; states could require that these persons elect Title XXII drug coverage.	Low-income subsidies would be provided through Medicaid. The current federal-state matching rate would apply for those below 120% of poverty. The federal matching rate would be 100% for those between 120% and 135% of poverty. The federal matching rate would be 100% for premiums for those between 135% and 150% of poverty.	The new coverage would be primary to any drug benefits under Medicaid. States would be required to make eligibility determinations for low-income subsidies; there would be a 5-year phase-in of increased matching rates for this activity so that there would be full federal funding beginning in 2007. Dual eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs) would have their low-income subsidy costs picked up by Medicaid. Over a 5-year period the federal matching rate for these costs would be increased to cover 100% of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap around to Medicare benefits for dual eligibles; states could require that these persons elect Part D drug coverage.

Reports

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
By January 1, 2003, the Commissioner would be required to submit a report on permitting Part B only individuals to enroll. The Commissioner would be required to submit an annual report on the administration of the new drug benefit and Medicare+Choice. The annual reporting requirements for the Board of Trustees of the Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B) trust funds would be expanded. The Board would be required to submit a combined report on the two trust funds as well as the Medicare Prescription Drug Account. The report would include information on total amounts obligated from the general revenues of the Treasury in the past year for benefits; a historical overview of spending; 10-year and 50-year projections; and overall spending from general revenues in relation to GDP growth. A report on the effectiveness of Medicare Consumer Coalitions (if the Commissions were established) would be due by December 31, 2004.	HHS would be required to report, within 2 years of enactment, on the feasibility and advisability of: 1) establishing a uniform format for pharmacy benefit cards; and 2) development of systems to electronically transfer prescriptions.	A State Pharmaceutical Assistance Transition Commission (representative of each state with a state pharmaceutical assistance program) would be established to develop a detailed proposal for addressing transitional issues facing such programs. The proposal would be consistent with protecting the interests of program participants and the financial interests of the states. The Commission would be required to submit a report on the proposal to the President and Congress by July 1, 2001. By March 31 of each year, the Administrator would submit a report to Congress and the President on the administration of the drug program and Medicare+Choice during the previous fiscal year. The new Medicare Policy Advisory Board, within MBA, would submit reports to the Congress and the Administrator as it deemed appropriate. Within 90 days, the Administrator would submit an analysis of the reports' recommendations to the Congress and the President. The annual reporting requirements for the Board of Trustees of the Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B) trust funds would be expanded. The Board would be required to submit a combined report on the two trust funds. The report would include information on total amounts obligated from the general revenues of the Treasury in the past year for benefits; a historical overview of spending; 10-year and 50-year projections; and overall spending from general revenues in relation to GDP growth.

Accounting Mechanism

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
A Medicare Prescription Drug Account would be created within the Part B trust fund. Funds provided under the new Title XXII to the Account would be kept separate from all other funds within Part B. Program costs would be paid from the Account. The Commissioner could levy on Medicare Prescription plans and Medicare+Choice plans providing qualified drug coverage an assessment to pay the estimated expenses of the Commissioner for administering the new Title XXII. The assessments would be deposited in the Medicare Prescription Drug Account.	A Prescription Drug Account would be created within the Part B trust fund. Funds provided under the new program to the Account would be kept separate from all other funds within Part B. Program costs would be paid from the Account.	A Medicare Prescription Drug Account would be created within the Part B trust fund. Funds provided under Part D to the Account would be kept separate from all other funds within Part B. Reinsurance payments, low-income subsidy payments, and payments for administrative expenses would be made from the account.

Financing

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Appropriations would be made from the general fund to cover program costs exceeding premium collections and other fees. Appropriations for administrative expenses of the Competitive Medicare Agency would be authorized on a biennial basis. Such funds as may be necessary would be authorized to be appropriated out of the Trust Funds to carry out the purposes of the Agency.	Appropriations would be made from the general fund to cover program costs exceeding premium collections.	Appropriations would be made from the general fund to cover program costs. (The FY2001 budget resolution earmarked up to $40 billion over 5 years for a drug benefit. Federal funds for the subsidies and reinsurance payments would fall within this limit. The remaining costs would be paid by beneficiaries through premiums.)

CBO Cost Estimate

S. 358 ("Breaux-Frist 2")	S. 1135 (Graham et al.)	H.R. 4680 (106th Congress - Thomas et al.)
Not available. However, on June 11, 2001, CBO presented an updated estimate of S. 2807, "as introduced by Senators Breaux and Frist and modified in discussion with staff." This bill from the 106th Congress is similar to S. 358 from this Congress. The CBO's updated estimate of S. 2807, which presumes an implementation date of 2004, is $175.9 billion for the FY2002-2011 period.	Not available. However, on June 11, 2001, CBO presented an updated estimate of S.Amdt. 3598 to H.R. 4577 from the 106th Congress; the drug provisions of this bill (S. 1135) are similar to that amendment though there are a number of differences between the two versions. The CBO's updated estimate of the amendment, which presumes an implementation date of 2004, is $318.2 billion for the FY2002-2011 period.	On June 11, 2001, CBO presented an updated estimate of H.R. 4680. The CBO's updated estimate, which presumes an implementation date of 2004, is $156.9 billion for the FY2002-FY2011 period.