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Report for Congress

Medicare: Major Prescription Drug Provisions of Selected Bills

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Summary

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 has again received attention this year.

There are a number of issues driving the prescription drug debate. 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 single uniform drug benefit should be added directly to Medicare's other benefits. Others recommend offering benefits through private plans which could offer different benefit packages provided certain minimum standards were met. A further consideration is whether a major new benefit should be added until structural reforms are made to the Medicare program as a whole.

On June 28, 2002, the House passed the Medicare Modernization and Prescription Drug Act of 2002 (H.R. 4954). Under the bill, a new optional benefit would be established, effective January 1, 2005. The program would rely on private plans to provide drug coverage and to bear some 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. Low-income subsidies would be provided for persons with incomes below 175% of poverty. A new Medicare Benefits Administration (MBA) would be established within the Department of Health and Human Services (HHS) to administer the benefit and the M+C program. The House-passed bill is considerably different from the "House Democratic bill" (H.R.5019). Under the later bill, a single new benefit would be added directly to Medicare and be available nationwide. The benefit would be administered by contractors with the federal government assuming full financial risk, except for a small portion of the administrative payment.

Senator Daschle has announced that the Senate will consider prescription drug legislation prior to the August recess. Any bill approved by the Senate is expected to be substantially different from the House-passed bill. Two measures are currently under discussion. The first is the Medicare Outpatient Prescription Drug Act of 2002 (S. 2625 Graham et al.). This measure is similar in overall approach, but different in a number of details, to the House Democratic bill. According to some accounts, the Graham bill will be brought directly to the Senate floor, without prior committee action, prior to the August recess. Another Senate measure, the so-called "tripartisan proposal" may also be considered; however, as of this writing, this bill has not yet been introduced. This report will be updated to reflect any legislative action.

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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 has again received attention this year. On June 28, 2002, the House passed the Medicare Modernization and Prescription Drug Act of 2002 (H.R. 4954) by a vote of 221-208. Senator Daschle has announced that the Senate will consider prescription drug legislation prior to the August recess. Any bill approved by the Senate is expected to be substantially different from the House-passed bill.

There are a number of issues driving the prescription drug debate. 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 single uniform drug benefit should be added directly to Medicare's other benefits. Others recommend offering benefits through private plans which could offer different benefit packages provided certain minimum standards were met. 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 intended to give seniors access to similar kinds of discounts as are available to the under age 65

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[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.

population under private insurance plans. However, to date, implementation of the card program has been held up by court action.[2]

Legislation

A number of bills have been introduced in the 107th Congress which would establish a prescription drug benefit for Medicare beneficiaries. Some measures add a new benefit to the Medicare program itself while others would provide the benefit through private entities. Some other bills focus on the prices seniors pay for drugs.

As of this writing, a few measures are receiving the most attention. The first is the House-passed bill, the Medicare Modernization and Prescription Drug Act of 2002 (H.R. 4954). The second bill is the Medicare Rx Drug Benefit and Discount Act of 2002 (H.R.5019); this measure is commonly referred to as the House Democratic bill. The rule governing debate on H.R. 4954 did not allow for consideration of the Democratic bill. This was because the measure exceeded the 10-year (2003-2012) House-passed budget resolution figure of $350 billion for prescription drugs and Medicare modernization.

On the Senate side, two measures are currently under discussion. The first is the Medicare Outpatient Prescription Drug Act of 2002 (S. 2625 Graham et al.). According to some accounts, this measure will be brought directly to the Senate floor, without prior committee action, prior to the August recess. Another Senate measure, the so-called "tripartisan proposal" may also be considered; however, as of this writing, this bill has not yet been introduced.

Overview of Major Proposals

The major proposals under consideration 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 Other individuals would have a limit on out-of-pocket costs (a "catastrophic limit") once they reached a certain level of spending.

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.

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[2] For a discussion of the card program, see: 1) CRS Report RL31316, *President Bush's Proposed Medicare-Endorsed Drug Discount Card Program: Status and Issues*, by M. Angeles Villarreal; and 2) CRS Congressional Distribution Memorandum, *Medicare-Endorsed Prescription Drug Card Assistance Initiative – Summary of Proposed Regulations*, by Jennifer O'Sullivan, March 13, 2002.

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.

The House-passed bill would provide access to a drug-only benefit through private insurance companies and other entities who wished to offer the benefit. A portion of the financial risk for the cost of covered benefits would be placed on the entities administering the benefit. In general, 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 incurring high costs.) The Administrator of the new Medicare Benefits Administration would administer the program in a manner such that eligible individuals would be assured access to at least two plans. If necessary to ensure access, the Administrator would be authorized to provide financial incentives in addition to the federal subsidy and reinsurance payments.

Under the House Democrat and Graham bills, 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 both bills, 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 House Democrat and Graham bill there would be *one specific benefit* available to all enrollees nationwide. Conversely, under the House-passed bill there would be a *minimum* benefit level established. Under the House-passed bill, the minimum benefit (referred to as "qualified coverage") would be either specified "standard coverage" or alternative coverage, provided it was actuarially equivalent (i.e., had the same dollar value) 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).[3] Several of the proposals would establish a new entity to administer the drug benefit at the federal level. Under the House-passed plan, a new Medicare Benefits Administration (MBA) would be established (outside of CMS, but within HHS) to administer the drug benefit and Medicare+Choice. Under the House-passed and 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.

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[3] Prior to June 14, 2001, this agency was known as the Health Care Financing Administration (HCFA).

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 discussed in this report would provide assistance to persons below 150% of poverty – in terms of premiums that would have to be paid for coverage and/or cost sharing once persons used benefits. As such, the bills would pick up some of the costs now paid by Medicaid for the dual eligible population. Both House plans provide for no, or very limited, beneficiary liability for covered services for this population group. The Graham bill only provides premium assistance for persons between 135% and 150% of poverty. 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.

Summary of Major Proposals

The following table is a side-by-side comparison of bills introduced in the 107th Congress that have received the most attention to date. These are the House-passed bill, the House Democratic bill, and the Graham bill. *The summary is limited to the Medicare prescription drug provisions*. Both House bills contain additional Medicare provisions.[4] The House Democratic bill also contains drug-related amendments to the Federal Food Drug and Cosmetic Act and the Public Health Service Act. The Graham bill is limited to Medicare prescription drug provisions.

The summary highlights the *major* features of the bills. The first items provide a broad overview (title and summary). This is followed by an overview of program design (benefits, premiums, eligibility, and relationship to Medicare+Choice). The next section reviews administration and financial risk (federal administration, administration of benefit, establishment of plan/benefit, plan enrollment, federal payments to plans, assumption of financial risk, and access). The next items relate to pricing and cost controls (drug pricing and payment, access to negotiated prices, and cost controls/formularies). The next item discusses beneficiary protections.

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[4] For a summary of the provisions of the House-passed bill, see CRS Report RL31462, *Major Provisions of the Medicare Modernization and Prescription Drug Act of 2002, H.R. 4954, as Passed by the House*, by Jennifer O'Sullivan, Hinda Ripps Chaikind, and Sibyl Tilson.

Then the low-income subsidy provisions are reviewed. This is followed by a discussion of the relationship between the new program and existing programs which supplement Medicare benefits (Medicaid, private plans, and Medigap). The last item discusses the drug card and the transitional low-income assistance program in the House-passed bill.

Side-by-Side Comparison of Major Medicare Drug Provisions of Selected Bills

In General

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Title	Medicare Modernization and Prescription Drug Act of 2002	Medicare Rx Drug Benefit and Discount Act of 2002	Medicare Outpatient Prescription Drug Act of 2002
Summary	Effective January 1, 2005, a new optional benefit would be established under a new Part D. The program would rely on private plans to provide coverage and to bear some 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. Low income subsidies would be provided for persons with incomes below 175% of poverty. A new Medicare Benefits Administration (MBA) would be established within the Department of Health and Human Services (HHS) to administer the benefit and the M+C program.	Effective January 1, 2005, a new optional benefit would be established under a new Part D. The program would be administered by the Secretary of Health and Human Services (HHS); the Secretary would enter into contracts with pharmacy contractors who would administer the program on a regional or national basis. Coverage would be provided through M+C plans for M+C enrollees. The federal government would assume financial risk except that a limited percentage of the administrative payment would be adjusted to ensure that the contractor pursued performance requirements. A single benefit would be available nationwide. Assistance would be provided for low-income persons with incomes below 175% of poverty. The Secretary would be required to negotiate contracts with drug manufacturers that specified the maximum prices that could be charged to program enrollees.	Effective January 1, 2004, a new optional benefit would be established under a new Part D. The program would be administered by the Secretary of Health and Human Services (HHS); the Secretary would enter into contracts with eligible entities, which could include pharmacy benefit managers, health plans, and retail pharmacy delivery systems. The eligible entities would administer the benefit on a regional basis. Coverage would be provided through M+C plans for M+C enrollees. The federal government would assume financial risk, but a percentage of the management payments could be tied to performance requirements of the contracted entity. A single benefit would be available nationwide. Persons with incomes below 150% of poverty would receive assistance.

Program Design

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Benefits	"Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage." In 2005, "standard coverage" would be defined as having a $250 deductible, 20% cost-sharing for drug costs between $251 and $1,000, 50% cost-sharing for drug costs between $1,001 and the initial coverage limit of $2,000, and then no coverage until the beneficiary had out-of-pocket costs of $3,700 ($4,800 in total spending); once the beneficiary reached the $3,700 catastrophic limit full coverage would be provided. The dollar amounts would be increased in future years by the percentage increase in the average per capita expenditures for covered drugs for the year ending the previous July. Out-of-pocket costs counting toward the limit would include costs paid by the individual (or by another individual such as a family member), paid on behalf of a low-income individual under the subsidy provisions, or paid under Medicaid. Any costs for which the individual was reimbursed by insurance or by another third-party payment arrangement could not be counted. Plans could offer more generous drug coverage, if approved by the MBA Administrator.	There would be a single nationwide benefit. In 2005, there would be a $100 deductible, 20% coinsurance and a limit on out-of-pocket spending (including cost-sharing for drugs covered under Part B) of $2,000. In addition, once an enrollee met the stop-loss limit, they would not have to pay any cost-sharing for drugs covered under Part B. These dollar amounts would be increased in future years by the percentage increase (projected in advance by the Secretary, for the year involved) in per capita program expenditures. Coinsurance would be applied differently for preferred and non-preferred medicines. For preferred medicines coinsurance would equal 20% or a lower percentage established to encourage appropriate use of preferred medicines. For nonpreferred medicines the coinsurance would be 20% of the price for the lowest cost preferred medicine within the same therapeutic class plus an amount equal to the amount by which the price of the nonpreferred drug exceeded the lowest price preferred drug. The extra payments for nonpreferred drugs would not be considered countable cost-sharing for purposes of meeting the deductible or stop-loss limit.	There would be a single nationwide benefit with no deductible. Cost-sharing would be based on tiered copayments. Each drug would fall into one of four classes: generic, preferred brand name, non-preferred brand name, and non-formulary. In 2004, enrollees would pay $10 for each prescription filled with a generic drug, $40 for each prescription filled with a preferred brand name drug, and $60 for each prescription filled with a non-preferred brand name drug. For non-formulary drugs, an entity could charge a copayment higher than $60. Non-preferred and non-formulary drugs deemed medically necessary would be treated as brand-name preferred drugs. An enrollee would not pay for any prescriptions once the enrollee incurred out-of-pocket costs for the year of $4,000 (regardless of who paid the costs). For each year after 2005, the copayments and out-of-pocket limit would be increased by the annual increase in prices (reflecting both price inflation and changes in therapeutic mix) as determined by the Secretary for the year ending the previous July. An eligible entity could charge lower copayments if such reduction was tied to performance requirements and would not increase overall program costs. For generic and preferred brand name drugs, the enrollee would pay the negotiated price minus $5 if such amount was less than the respective copayment.

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
			For non-preferred drugs, the enrollee would pay the negotiated price if such amount was less than the copayment.
Premiums	The plan sponsor would establish the premium amount, subject to approval by the Administrator. 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. However, PDP sponsors would be required to permit each enrollee to pay premiums through withholding from social security checks in the same manner Part B premium payments are withheld or through an electronic funds transfer.	Premiums would be set at $25 per month for 2005. This amount would be increased in future years by the percentage increase, (projected in advance by the Secretary, for the year involved) in per capita program expenditures. Enrollees would pay premiums through withholding from social security checks in the same manner Part B premium payments are withheld. Late enrollment penalties, calculated in the same manner as such penalties are calculated for Part B, would be applied to persons who did not enroll during their initial enrollment period or during a special enrollment period established due to involuntary loss of other drug coverage.	Premiums would be set at $25 per month for 2004. This amount would be increased in future years by the percentage increase, (projected in advance by the Secretary, for the year involved) in average per capita program expenditures. Enrollees would pay premiums through withholding from social security checks in the same manner Part B premium payments are withheld. Late enrollment penalties, calculated in a similar manner as such penalties are calculated for Part B, would be applied to premiums for persons who did not enroll during their initial enrollment period or during a special enrollment period established due to involuntary loss of other drug coverage.
Eligibility	All beneficiaries enrolled in Medicare Part A or Part B could elect to enroll in Part D through enrollment in a M+C plan with prescription drug coverage or in a PDP. The Administrator of the new MBA would establish an enrollment process. An initial election period would be established. For current beneficiaries this would be the 6-month period beginning November 2004; 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. Persons electing coverage at the first opportunity and maintaining continuous	All beneficiaries enrolled in Medicare Part A or eligible to enroll in Part B could elect to enroll in Part D. An initial enrollment period would be established. For current beneficiaries this would be the 7-month period beginning August 1, 2004; for future beneficiaries it would be the same 7-month period applicable for initial Part B enrollment. Special enrollment periods would apply for persons who involuntarily lost other drug coverage (including coverage offered by former employers); these persons would not be subject to late enrollment penalties.	All individuals enrolled in Part A or Part B could elect to enroll in Part D. The Secretary would establish an enrollment process. An initial enrollment period would be established. For current beneficiaries, this would be a period of time determined by the Secretary before January 1, 2004, so that Part D coverage was effective as of such date. For future beneficiaries, the enrollment procedures would be similar to those used for Part B. Eligible beneficiaries with creditable drug coverage could elect to continue to receive such coverage, not enroll in Part D, and subsequently enroll in Part D without penalty if they involuntarily lost their

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	coverage would be guaranteed the protection of community rating; otherwise they could be subject to late enrollment penalties.		other coverage; special enrollment periods would apply for this group.
Relationship to Medicare+Choice	An M+C enrollee would obtain benefits through the M+C plan if the plan provided qualified drug coverage. An M+C plan could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage.	M+C organizations would be required offer plans with drug coverage that was at least actuarially equivalent to Part D benefits. An M+C enrollee would be required to obtain Part D drug benefits through the plan.	M+C organizations would be required to offer Part D drug benefits. M+C enrollees would receive coverage through their M+C plan.

Administration; Financial Risk

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Federal Administration	The new MBA, within HHS, would administer the new Part D drug benefit and the M+C program. (The Centers for Medicare and Medicaid Services (CMS), would retain responsibility for the traditional fee-for-service program.) A Medicare Policy Advisory Board would be established within the MBA.	The Secretary (through CMS) would administer the benefit. A newly created Medicare Prescription Medicine Advisory Committee would advise the Secretary.	The Secretary (through CMS) would administer the benefit. A newly created Medicare Prescription Drug Advisory Committee would advise the Secretary. The Secretary could contract with Medicare Consumer Coalitions (nonprofit entities whose board members were primarily Medicare beneficiaries) to conduct information activities.
Administration of benefit	The benefit would be administered by a M+C plan or PDP. A PDP plan sponsor would be an entity certified under Part D as meeting the Part D standards and requirements. In general, a PDP sponsor would have to be licensed under state law as a risk bearing entity eligible to offer health benefits or health insurance coverage in each state in which it offered a prescription drug plan.	The benefit would be administered by pharmacy contractors serving on a regional or national basis. The benefit could be administered on a partial regional basis, if determined appropriate by the Secretary. The Secretary would determine regions and assure that there were at least 10 in the U.S. Coverage would be provided through M+C plans for M+C enrollees. Contractors would be required to meet Part D requirements. They would be authorized to enter into participation	The benefit would be administered by M+C plans or by eligible entities serving on a regional basis. The benefit could be administered on a partial regional basis, if determined appropriate by the Secretary. An entity could submit a single bid to provide coverage in multiple regions. The Secretary would determine regions and assure that there were at least 10 in the U.S. Entities would be required to meet Part D requirements. They would be authorized to enter into participation

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
		agreements with pharmacies who comply with program requirements.	agreements with pharmacies who comply with program requirements.
Submission of bids	Each PDP sponsor would be required to submit to the MBA Administrator information on the qualified drug coverage to be provided including the premium. The Administrator could not approve the premium unless it accurately reflected: 1) the value of benefits provided; and 2) the 67% federal subsidy for standard benefits. PDP plan sponsors would be required to enter into a contract with the Administrator; 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 the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans.	The Secretary would enter into contracts with pharmacy contractors to administer the benefit. The Secretary would accept competitive bids from entities. The bid would include: a proposal for the estimated drug prices and projected annual increases in prices, a statement regarding what it would charge the Secretary to administer the benefit, a description of access to pharmacy services, a detailed description of performance requirements, and a detailed description standards the entity would use in selecting preferred medications. The Secretary would award, on a competitive basis contracts for 2-5 year terms. At least two contracts would be awarded per area unless only one entity submitted a bid meeting minimum standards. The Secretary would consider the comparative merits of each bid.	The Secretary would enter into contracts with eligible entities to administer the benefit; entities would include pharmacy benefit management companies, retail pharmacy delivery systems, health plans or insurers, states, or any other entity or combination of entities. The Secretary would accept competitive bids from entities. The bid would include: a proposal for estimated drug prices and projected annual increases in prices, a statement regarding what it would charge the Secretary to administer the benefit, a description of access to pharmacy services, a description of performance requirements, and a description of standards the entity would use in modifying the formulary. The Secretary would award, on a competitive basis contracts for 2-5 year terms. At least two contracts would be awarded per area unless only one entity submitted a bid meeting minimum standards. The Secretary would consider the comparative merits of each bid.
Plan enrollment	Beneficiaries would enroll a M+C plan with prescription drug coverage or in a PDP.	Each individual would select (and could change the selection on a periodic basis) the pharmacy contractor to administer the benefit for such individual.	Eligible beneficiaries not enrolled in a M+C plan would make an annual election to enroll in a Medicare Prescription Drug Plan. A default option would be selected by the Secretary for enrollees that failed to select an entity.
Federal payments to plans	The federal government would pay direct subsidies and reinsurance payments to PDPs, M+C plans, and qualified retiree	The Secretary would pay each pharmacy contractor for the administration of benefit and for the negotiated prices (less cost-	The Secretary would pay each eligible entity for the management of the benefit and for the negotiated cost (less cost

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	plans which would equal 67% of the value of standard coverage. Direct subsidies would be equal to 37% of the value of standard coverage provided under the plan. Reinsurance payments would be equal to 30% of the value of standard coverage. Reinsurance payments would be provided for: 1) 30% of an individual's allowable drug costs between $1,001 and $2,000 (in 2005); and 2) 80% for costs over the out-of-pocket limit ($3,700 in 2005). The Administrator would proportionately adjust payments so that total reinsurance payments for the year equaled 30% of total payments by qualifying plans for standard coverage during the year. The Administrator could adjust direct subsidy payments in order to avoid risk selection.	sharing, plus a reasonable dispensing fee) for prescription drugs used by enrollees. The Secretary would include in the contract with a pharmacy contractor incentives for cost and utilization management and quality improvement; the contract could provide financial incentives to encourage greater program savings. The Secretary would provide for performance standards for contractors which could include monetary bonuses if the standards were met and penalties if they were not met.	sharing) of prescription drugs used by enrollees. A percentage of the management payment (as determined by the Secretary) would be tied the entity's performance, including controlling costs, providing quality clinical care, and providing quality service. The Secretary could reduce payments to reflect rebates and price concessions obtained by the entity from manufacturers. Agreements between eligible entities and participating pharmacies would provide for payment of a reasonable dispensing fee.
Assumption of financial risk	Plans would be required to assume full financial risk on a prospective basis for covered benefits except: 1) as covered by federal direct subsidy payments or reinsurance payments for high cost enrollees; or 2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish new plans. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.	The federal government would assume financial risk for the cost of benefits except that a limited percentage (to be determined by the Secretary) of the administrative payment would be adjusted to ensure that the contractor pursues performance requirements; the Secretary could not establish a percentage that would jeopardize the ability of the contractor to administer the benefits in a quality manner.	The federal government would assume financial risk for the cost of benefits except that a percentage (to be determined by the Secretary) of the administrative payment would be adjusted to ensure that the contractor pursued performance requirements. The percentage could be up to 100%. The Secretary could not establish a percentage that would jeopardize the ability of the contractor to administer the benefits in a quality manner.
Access	The Administrator would assure that all eligible individuals residing in the U.S. would have a choice of enrollment in at least two qualifying plan options (at least	The Secretary would develop procedures for the provision of Part D benefits to persons residing in areas not covered by a contract. The Secretary would also	The Secretary would develop procedures for the provision of Part D benefits to persons residing in areas not covered by a contract. The Secretary would also

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	one of which was a PDP) in their area of residence. The requirement would not be satisfied if only one PDP sponsor or M+C 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. The assistance would be available only so long as, and to the extent necessary, to assure the guaranteed access. However, the Administrator could never provide for the full underwriting of financial risk for any PDP sponsor, nor could the Administrator provide for any assumption of financial risk for a public PDP sponsor offering a nationwide drug plan. Additionally, the Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and M+C organizations.	develop procedures to assure that beneficiaries residing in more than one area in a year were provided benefits throughout the year.	develop procedures to assure that beneficiaries residing in more than one area in a year were provided benefits throughout the year.

Pricing; Cost Controls

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Drug pricing and payment	The PDP sponsor would determine payments and would be expected to negotiate discounts.	The Secretary would be required to negotiate contracts with drug manufacturers that specify the maximum prices that may be charged to program enrollees. The Secretary would be required to take into account the goal of developing breakthrough medicines.	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 prices.

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Access to negotiated prices	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 had reached the initial coverage limit.	The contract between the Secretary and the pharmacy contractor would require the contractor to negotiate contracts with manufacturers that provide for maximum prices that are lower than those negotiated by the Secretary, if applicable. The reduction would be passed on to beneficiaries and the Secretary would hold the contractor accountable for meeting performance requirements with respect to price reductions and limiting price increases.	Plans would provide that beneficiaries would have access to negotiated prices
Cost controls/formularies	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 practicing physician and one practicing pharmacist) to develop and revise 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). Plans could offer tiered cost-sharing for drugs included within a formulary and lower cost-sharing for preferred drugs in the formulary. 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 formulary drug was not as effective for the individual or had adverse effects for the individual.	Preferred medicines (which would have lower cost sharing) would be designated by the Secretary or the pharmacy contractor for a therapeutic class. Pharmacy contractors would be required to have in place procedures to treat, on a case-by-case basis, non-preferred medicines as preferred medicines if the preferred medicine was determined not to be as effective for, or to have significant adverse effects on, the enrollee. The procedures would require that determinations be based on professional medical judgment, medical condition of the enrollee and medical evidence. The Secretary, directly or through contracts with pharmacy contractors, would employ mechanisms to provide services appropriately and efficiently; mechanisms could include: 1) price negotiations; 2) reduction in coinsurance below 20% for preferred medicines; 3) methods to reduce medication errors and encourage appropriate use of medications;	Entities would be required to use cost control strategies that could include alternative methods of distribution, preferred pharmacy networks, generic substitution, therapeutic interchange, disease management programs, medication therapy management, and informing beneficiaries of price differences between generic and brand name drugs. Entities would be required to establish formularies. The formulary would be developed by a pharmacy and therapeutics committee in accordance with standards developed by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee. All brand name drugs in the formulary would be designated preferred or non-preferred. The formulary would have to include: 1) all generic covered drugs, 2) at least one preferred brand name drug for each therapeutic class, and 3) at least one non-preferred brand name drug for each therapeutic class (if there is more than one brand name drug available). Entities

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
		and 4) permitting pharmacy contractors, as approved by the Secretary, to make exceptions to the cost-sharing provisions for nonpreferred medicines, to secure best prices for enrollees. Price negotiations would be conducted in such a manner so that: 1) there was at least one contract for a medicine in each therapeutic class; 2) if more than one medicine was available in a class, there were contracts for at least two medicines in the class unless determined clinically inappropriate; and 3) if more than two medicines were available in a class, there were contracts for at least two medicines in a class and a contract for a generic substitute, unless determined clinically inappropriate.	would have to have procedures to treat non-preferred and non-formulary drugs as preferred brand-name drugs if the preferred drug was determined not to be as effective for the enrollee in preventing or slowing the deterioration of, or improving or maintaining the health of the enrollee or to have a significant adverse effect for the enrollee.

Requirements

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Beneficiary protections	Plans would be required to comply with a number of beneficiary protection provisions including those related to: 1) community-rated premiums; 2) non-discrimination; 3) information disclosure; 4) assuring the participation of a sufficient number of pharmacies; 5) issuance of a card so beneficiaries could assure access to negotiated prices when coverage is not otherwise available under the plan; 6) a cost and drug utilization management program including medication therapy management and an electronic prescription drug program that provides	The Secretary would establish standards and programs for quality and other standards including those related to: 1) access (including 24-hour/7-day a week access, on-line review to evaluate for medicine therapy problems, and adherence of any preferred pharmacy network to minimum access standards); 2)assuring compliance of pharmacies with negotiated prices; 3) enrollee counseling; 4) education of providers, pharmacists, and enrollees; and 5) provision of cost data to the Secretary. Pharmacy contractors would be required to have in place	The Secretary could not award a contract to an entity unless the entity: 1) met quality and financial standards; 2) had in place drug utilization review procedures to ensure appropriate utilization of drugs and avoidance of adverse drug reactions; 3) ensured 24hour/7-day a week access to drugs; 4) ensured that pharmacies would not overcharge enrollees; 5) had procedures for determining if non-formulary and non-preferred drugs were medically necessary; 6) had an appeals process for enrollees; 7) had procedures to safeguard the privacy of medical records;

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	for electronic transfer of prescriptions and provision of information to the prescribing health professional; and 7) provisions for hearing and resolving grievances and handling appeals.	procedures to ensure timely procedures for internal and external review of denials of coverage and other complaints.	and 8) had procedures to deter medical errors and ensure that contracted pharmacies have such procedures.

Low-Income subsidies

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Subsidies	Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes at or below 150% 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. Individuals with incomes between 150% and 175% of poverty would have a sliding scale premium subsidy ranging from 100% of such value at 150% of poverty to 0% of such value at 175% of poverty. For both groups, beneficiary cost-sharing for spending up to the initial coverage limit ($2,000 in 2005) would be reduced to an amount not to exceed $2 for a multiple source or generic drug and $5 for a non-preferred drug. PDPs could not charge individuals receiving cost-sharing subsidies more than $5 per prescription. PDPs could reduce to zero the cost-sharing otherwise applicable for generic drugs.	Persons meeting the definition of qualified Medicare beneficiaries (QMBs, persons with incomes below 100% of poverty and assets below $2,000), and persons meeting the QMB definition except that their incomes were between 100% and 150% of poverty, would have their Part D premiums, deductibles, and countable cost sharing paid by Medicaid. Persons meeting the QMB definition except that their incomes were between 150% and 175% of poverty would have their Part D deductibles and countable cost-sharing paid by Medicaid; their Part D premiums would be reduced on a sliding scale basis ranging from 100% of the premium at 150% of poverty to 0% at 175% of poverty.	Persons meeting the definition of qualified Medicare beneficiaries (QMBs, i.e., persons with incomes below 100% of poverty), and persons meeting the QMB definition except that their incomes were between 100% and 135% of poverty, would have their Part D premiums and copayments paid by Medicaid. Enrollees between 135% and 150% of poverty would pay a reduced Part D premium, calculated on a sliding scale basis. In determining QMB qualification for payment of Part D premiums and copayments, asset requirements would not apply.

Relationship to Other Coverage

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Relationship to Medicaid	States would be required to make eligibility determinations for low-income subsidies; there would be a phase-in of the federal assumption of associated administrative costs. (Alternatively, the eligibility determinations could be made by the Social Security Administration.) There would also be a federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles. 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. The bill would also exempt any prices negotiated by a PDP, Medicare+Choice plan, or qualified retiree program from Medicaid's determination of "best price" for purposes of the Medicaid drug rebate program.	Medicaid costs associated with paying Part D cost-sharing charges for persons with incomes above 100% of poverty would be paid by the federal government.	The current federal-state matching rate would apply for Medicaid costs associated with paying Part D premiums and cost-sharing for those below 120% of poverty. The federal matching rate would be 100% for those between 120% and 150% of poverty.
Relationship to private plans	Qualified prescription drug plans offered by employers to retirees would be eligible for direct subsidies and reinsurance payments. At a minimum, qualified retiree coverage would have to meet the requirements for qualified prescription drug coverage.	The Secretary would make payments to retiree health plans offering coverage that was not less than Part D coverage. Payments would equal two-thirds of the estimated average per capita government contribution for Part D enrollees.	The Secretary would make payments to retiree health plans offering coverage that was not less than Part D coverage. Payments would equal two-thirds of the estimated average per capita government contribution for Part D enrollees.
Relationship to Medigap	Effective January 1, 2005, the issuance of new Medigap policies with prescription drug coverage would be prohibited unless 1) the policies replaced another policy with drug coverage; or 2) policies met requirements for two new standardized policies *for all Medicare services*. The first new policy would have the following	The bill would modify current requirements for standardized Medigap policies. Effective January 1, 2005, an appropriate number of such polices would have to provide coverage for medicines which complemented, but did not duplicate, Part D benefits.	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 more than 90% of the Part D copayments. Effective January 1, 2004, the issuance of any of the old standardized policies with

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	benefits (notwithstanding other provisions of law relating to core benefits): 1) coverage of 50% of the cost-sharing otherwise applicable (except coverage of 100% cost-sharing applicable for preventive benefits); 2) no coverage of the Part B deductible; 3) coverage of all hospital coinsurance for long stays (as in current core package); and 4) a limitation on annual out-of-pocket costs of $4,000 in 2005 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: 1) coverage would be provided for 75%, rather than 50%, of cost-sharing otherwise applicable; and 2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible. The bill would require plans to sell any of the Plans A through Plan G to individuals who enroll in Part D within 63 days and who were covered until then by Medigap policy H, I, or J.		drug coverage would be prohibited. The bill would guarantee issuance, during the period established by the Secretary for Part D enrollment, of the benefit package the Secretary determined most comparable to the old standardized drug policy held by the policyholder.

Drug Card

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
Discount Drug Card Program	The provision would require the Secretary to endorse prescription drug discount programs meeting certain requirements and to make available information on such programs to beneficiaries. The program: 1) would have to pass on to enrollees discounts on drugs, including discounts negotiated with manufacturers; 2)could not be limited to mail order drugs; 3) would have to provide pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions; 4) would have to provide information to enrollees that the Secretary identified as being necessary to provide for informed choice by beneficiaries among endorsed programs; 5) would have to safeguard individually identifiable information in accordance with the Health Insurance Portability and accountability Act (HIPAA); and 6) would have to meet requirements the Secretary found necessary to participate in the transitional low-income assistance program (see below). A beneficiary could only be enrolled in one endorsed program at a time. Annual enrollment fees could not exceed $25.	No provision	No provision
Transitional Low-Income Assistance Program	The bill would provide for the implementation of a transitional prescription drug assistance program, until the Part D program was implemented, for Medicare beneficiaries with incomes under 175% of poverty who did not have drug coverage under Medicaid, Medigap,		

Provisions	H. R. 4954	H.R. 5019 (Rangel et al.)	S. 2625 (Graham et al.)
	group health insurance, or federally-supported health care programs under the Department of Defense, Veterans Administration, Federal Employees Health Benefits program, or the Indian Health Care Improvement Act. Individuals eligible for assistance would have to be enrolled under a prescription drug discount card program (or an alternative state program approved by the Secretary). Appropriations totaling $300 million in FY2003, $2.1 billion in FY2004, and $500 million in FY2005 would be available. Funds would be allotted among the states based on the proportion of Medicare beneficiaries with incomes below 175% of poverty. The assistance would be in the form of a discount in addition to that available under the discount card program. States could continue to provide assistance under their own pharmaceutical assistance programs.		