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Medicare Prescription Drug Provisions of S. 1, as Passed by the Senate, and H.R. 1, as Passed by the House

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Summary

On June 27, 2003, the Senate passed the Prescription Drug and Medicare Improvement Act of 2003 (S. 1) by a vote of 76-21. Later that same evening, the House passed the Medicare Modernization and Prescription Drug Act of 2003 (H.R. 1) by a recorded vote of 216 - 215 with 1 voting present.

Title I of both bills would add, effective January 1, 2006, a new prescription drug benefit for Medicare beneficiaries under a new Medicare Part D. Both bills would rely on private plans to provide the benefit and assume some of the financial risk. Both measures would be designed to assure access to plans in all areas; increased federal assistance would be authorized where necessary to encourage participation. The Senate bill, but not the House bill, would include a fallback mechanism in areas where private plans were not available. Under the fallback mechanism, Medicare would contract with a private plan to provide the benefit in the area; the plan would not be at financial risk, except for a small portion of management fees tied to performance.

Both S. 1 and H.R. 1 would require plans to provide "standard coverage" or "actuarially equivalent coverage" (i.e., a package with the same dollar value); however, the definition of standard coverage is quite different between the two. Both measures would provide additional assistance to the low-income. In addition, both bills would establish a temporary drug discount card endorsement program under which the Secretary would endorse card programs offered by prescription drug card sponsors meeting certain requirements; these programs would be discontinued after Part D was implemented.

There are considerable differences in the specifics of the prescription drug provisions in S. 1 and H.R. 1. These differences are at issue in a pending conference between the two Houses.

This report provides a side-by-side comparison of the Title I provisions of both bills. It will be updated as events warrant.

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In General

Provision	S. 1	H.R. 1
Title	Prescription Drug and Medicare Improvement Act of 2003.	Medicare Modernization and Prescription Drug Act of 2003
Summary	Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either "standard coverage" or "actuarially equivalent coverage." In 2006, "standard coverage" would have a $275 deductible, 50% cost-sharing for costs between $276 and $4,500, then no coverage until the beneficiary had out-of-pocket costs of $3,700 ($5,813 in total spending); and 10% cost-sharing thereafter. Individuals with incomes below 160% of poverty, who were not eligible for drug coverage under Medicaid, would receive assistance for a portion of the Part D premium and cost-sharing charges. (Medicaid enrollees with drug coverage would continue to receive drug benefits through Medicaid.) The bill 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. (A fallback mechanism would be provided in areas where private risk bearing plans were not available. Under the fallback mechanism, Medicare would contract with a private plan to provide the benefit in the area; the plan would not be at financial risk, except for a small portion of management fees tied to performance.) Coverage would be provided through Medicare Prescription Drug Plans (PDPs) or MedicareAdvantage plans (MAs, as established under Title II of the bill). Plans would determine payments and would be expected to negotiate prices. A new Center for Medicare Choices (CMC) would be established within the Department of Health and Human Services (HHS) to administer the Part D benefit and the new MA program (which would replace the existing Medicare+Choice program). **New Sections 1860D - 1860D-26 as added by Section 101 of the bill**.	Effective January 1, 2006, a new optional benefit would be established under a new Medicare Part D. Beneficiaries could purchase either "standard coverage" or "actuarially equivalent coverage". In 2006, "standard coverage" would have a $250 deductible, 20% cost-sharing for costs between $251 and $2,000, then no coverage until the beneficiary had out-of-pocket costs of $3,500 ($4,900 in total spending) when full coverage would be provided. (A higher catastrophic limit would apply for high-income beneficiaries). Low income subsidies would be provided for persons with incomes below 150% of poverty. Medicare Advantage (MA) organizations and Enhanced Fee-for-Service (EFFS) organizations (as established under Title II of the bill) would be required to offer plans that included qualified prescription drug coverage. An individual not enrolled in an MA or EFFS plan could enroll in a new prescription drug plan (PDP). The program would rely on these private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies would be provided to encourage participation. Plans would determine payments and would be expected to negotiate prices. A new Medicare Benefits Administration (MBA) would be established within the Department of Health and Human Services (HHS) to administer the Part D benefit and the new MA program (which would replace the existing Medicare+Choice program) and the new EFFS program. **New Sections 1860D-1 — 1860D-10 as added by Section 101 of the bill.**

Program Design

Provision	S. 1	H.R. 1
Beginning date	January 1, 2006. **New Section 1860D-1(a).**	January 1, 2006. **New Section 1860D-1**.
Benefits	"Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage." Both would require access to negotiated prices. In 2006, "standard coverage" would be defined as having a $275 deductible, 50% cost-sharing for drug costs between $276 and the initial coverage limit of $4,500, then no coverage until the beneficiary had out-of-pocket costs of $3,700 ($5,813 in total spending); and 10% cost-sharing thereafter. These amounts would be increased in future years by the percentage increase in 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 low-income provisions (but only with respect to the percentage of costs the individual is responsible for under such provisions), paid under Medicaid, or paid under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise could not be counted. Entities could offer more generous drug coverage, if approved by the Administrator, but only if they also offered a plan providing required coverage. **New Section 1860D-6**.	"Qualified coverage" would be either "standard coverage" or "actuarially equivalent coverage." In both cases, access would be provided to negotiated prices. In 2006, "standard coverage" would be defined as having a $250 deductible, 20% coinsurance for drug costs between $251 and $2,000 (accounting for $600 in total out-of-pocket costs, and then no coverage until the beneficiary had out-of-pocket costs of $3,500 ($4,900 in total spending); once the beneficiary reached the $3,500 catastrophic limit (with higher amounts for higher income beneficiaries) 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 or under a state pharmaceutical assistance program. 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. **Section 1860D-2(a-c, and e).**
Income-Related Catastrophic Limit	No provision	The annual out-of-pocket threshold would be increased for each enrollee whose adjusted gross income (AGI) exceeded a specified income threshold. (Individuals filing joint returns would each be treated separately with each person considered to have an AGI equal to one-half of the total.) The portion of income exceeding this income threshold ($60,000 in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows. First, the ratio of the annual out-of-pocket limit to the income limit would be calculated and expressed as a percent. For 2006, this would be $3,500 divided by $60,000 equaling 5.8%. This percentage would be multiplied by any excess income over $60,000, but not over $200,000, and added to the catastrophic limit. Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. **New Section 1860D-2(b)(4)**.

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Premiums	The plan sponsor would establish the premium amount, subject to approval by the Administrator. Monthly premiums would be uniform for all eligible beneficiaries in a plan, except that persons delaying Part D enrollment without other creditable drug coverage would be subject to higher premiums. The Administrator would calculate a monthly prescription drug coverage premium for each plan (including MA plans) and a monthly national weighted average premium. If the plan's monthly approved premium for standard coverage was equal to the national monthly weighted average premium for such coverage, the beneficiary would pay the applicable percentage of the monthly national average. If the plan's monthly approved premium was less than the national average the beneficiary would pay: (1) the applicable percentage of the monthly national average, *minus*, (2) the difference between the national average and the plan's premium. If the plan's monthly premium was greater than the national average, the beneficiary would pay: (1) the applicable percentage of the monthly national average, *plus* (2) the difference between the national average and the plan's premium. The applicable percentage for an area would be 30% divided by 100% minus a percentage equal to: total reinsurance payments that will be made in a year (including such payments to qualified retiree plans) divided by such reinsurance payments plus total payments that would be made to plans, including MA plans, in the year for standard coverage (or actuarially equivalent coverage). Premiums would be collected in the same manner as Part B premiums. The Administrator would establish procedures whereby the sponsor of employment-based retiree coverage could pay the premium. Premiums for a plan would not vary within a region. However, this requirement would not apply to enrollees who were enrolled in a plan pursuant to a contract between the plan and the employer or other group plan that provided employment-based retiree health coverage, if the premium amount was the same for all such enrollees under such agreement. **New Sections 1860D-5(g), 1860D-14, 1860D-15, and 1860D-17, and 1860D-18.**	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. 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 mechanism or otherwise. Reductions in Part B premiums attributable to enrollment in MA or EFFS plans could be used to reduce the premium otherwise applicable. **New Section 1860D-6(c)**.
Covered drugs	Covered outpatient drugs would include prescription drugs and biologicals covered under Medicaid, insulin (including syringes, and necessary medical supplies associated with the administration of insulin, as defined by the Administrator) and vaccines licensed under Section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition would	Similar provision except: (1) does not specifically mention syringes; (2) does not specify that if coverage were exhausted under Part B, payment could be made under Part D. **New Section 1860D-2(f).**

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	include any use of a covered outpatient drug for a medically accepted indication. Drugs which could be paid for under Medicare Part B would not be covered under Part D, except if Part B benefits were exhausted. A plan could elect to exclude a drug which would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed. A PDP or MA plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D. **New Section 1860D(a)(2).**	

Eligibility; Enrollment

Provision	S. 1	H.R. 1
Relationship to new Medicare options	In general, MA enrollees would obtain drug benefits through their MA plan. Other Part D enrollees would receive their drug coverage through enrollment in a PDP offered in the geographic area in which the beneficiary resided. MA enrollees in MSA plans would also receive drug coverage through enrollment in a PDP plan. MA enrollees in private fee-for-service plans would receive drug benefits through such plan if the plan provided qualified prescription drug coverage; otherwise they would enroll in a PDP. **New Section 1860D-1(a)**	The new MA organizations and EFFS organizations would be required to offer plans that included qualified prescription drug coverage. An individual enrolled in a MA Rx plan or EFFS Rx plan would obtain their drug coverage through the plan. An individual not enrolled in either an MA or EFFS plan could enroll in a new prescription drug plan (PDP). **New Section 1860D-1(a)**
Eligibility; enrollment	All individuals entitled to or enrolled in Part A and enrolled under Part B could elect to enroll in Part D, except for persons eligible for drug coverage under Medicaid. The Administrator of the new CMC would establish an enrollment process which would be similar to that for Part B. An initial open enrollment period would be established. For beneficiaries eligible as of November 1, 2005, this would be the 6-month period beginning November 1, 2005. Persons becoming eligible after this date would have an initial 7-month enrollment period similar to that established for Part B. Persons enrolling in Part D after their initial enrollment period would be subject to delayed enrollment penalties. 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 the other coverage. Creditable drug coverage would have to equal or exceed the value of standard coverage. It would include, subject to certain	All beneficiaries entitled to Medicare Part A or enrolled in Medicare Part B could elect to enroll in Part D through enrollment in an MA Rx plan or EFFS Rx plan, 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 October 2005; 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 lost other drug coverage. Persons electing coverage at the first opportunity and maintaining continuous coverage would be guaranteed the protection of community rating; otherwise they could be subject to late enrollment penalties. An individual would be considered to have had continuous prescription drug coverage if the individual established that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another plan):

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	conditions, drug coverage provided through a group health plan, state pharmaceutical assistance program, veterans programs, Medigap, and drug-only coverage through Medicaid for persons who were not dual eligibles. Special enrollment period would apply for persons losing creditable coverage. **New Sections 1860D(a)(3) and 1860D-2**	(1) qualified prescription drug coverage under a PDP or MA Rx or EFFS Rx plan; (2) Medicaid prescription drug coverage; (3) prescription drug coverage under a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP; (4) prescription drug coverage under a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP; (5) state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP; and (6) veterans coverage for prescription drugs, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified prescription drug plan. They could make such application if they could establish that they were not adequately informed that the coverage did not provide such level of coverage. **New Section 1860D-1**.
Plan enrollment	The Administrator would establish a process through which an eligible beneficiary who was not enrolled in an MA plan (except for an MSA plan or private-fee-for-service plan not offering qualified drug coverage) could enroll in a PDP serving the geographic area where the beneficiary resided. The beneficiary could make an annual election to change enrollment to another plan. A beneficiary in Part D who failed to enroll in a plan would be enrolled in a plan designated by the Administrator. The Administrator would use rules similar to the rules established for enrollment, disenrollment and termination of enrollment with MA plans. Included would be requirements relating to establishment of special election periods and application of the guaranteed issue and renewal provisions. The enrollment process established by the Administrator would ensure that beneficiaries who enrolled in the first open enrollment period (beginning November 2005) would be permitted to elect an eligible entity prior to January 1, 2006, in order to assure coverage was effective on that date. In general, persons enrolled in MA plans would receive drug coverage through their MA plans and be subject to their enrollment rules. Persons enrolled in MSA plans or private-fee-for-service plans not offering qualified drug coverage would be subject to Part D enrollment rules. **New Section 1860D-3**	Beneficiaries would enroll in an MA Rx plan, EFFS Rx plan or in a PDP. The Administrator would establish a process for the selection of a plan. The process would include: (1) conduct of annual coordinated election periods; (2) active dissemination of information to promote an informed selection among qualifying plans (in a manner consistent with and in coordination with the dissemination of information under MA; (3) coordination of elections through filing with an entity or sponsor in a manner consistent with that provided under MA; and (4) informing each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold. An MA Rx or EFFS Rx enrollee could only elect to receive drug coverage through the plan. Individuals electing qualified prescription drug coverage under a PDP plan or MA Rx or EFFS Rx plan could not be denied enrollment based on health status or other factors. MA provisions relating to priority enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors. Elections would take effect at the same time that elections take effect for MA plans. However, no election could take effect before January 1, 2006. **New Sections 1860D-1(c) and 1860D-5(a-c)**

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Information	The Administrator would be required to broadly disseminate information to beneficiaries regarding Part D coverage. Information activities would be similar to those performed for MA and be coordinated with such activities. Comparative plan information would include a comparison of benefits, monthly beneficiary obligation, quality and performance, beneficiary cost-sharing, consumer satisfaction surveys, and other information specified by the Secretary. **New Section 1860D-4**	The Administrator would be required to provide for the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Plans would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold. **New Section 1860D-5(b)**.

Administration; Financial Risk

Provision	S. 1	H.R. 1
Federal administration	The new CMC would administer the new Part D drug benefit and the new MA program. (The Centers for Medicare and Medicaid Services (CMS) would retain responsibility for the traditional fee-for-service program.) A Medicare Competitive Policy Advisory Board would be established within the Center. The Administrator of the Center would: (1) establish a process for beneficiaries to enroll in Part D and a process for beneficiaries to enroll in plans; (2) broadly disseminate information on plans; (3) establish a process for determining the actuarial value of drug coverage; (4) provide for the development of national standards for the drug card or other technology; (5) establish additional Part D standards by January 1, 2005, and periodically review such standards; (6) establish risk adjusters; (7) calculate monthly national average premiums; (8) establish service areas; (9) negotiate contracts with plan sponsors; (10) make payments to plans; and (11) administer subsidy provisions. The Administrator would be authorized to provide information about eligible beneficiaries to eligible entities with contracts under Part D. Such information would be provided as the Administrator determined necessary to facilitate enrollment with such entities and for only so long and to the extent necessary to carry out this objective. The Administrator would be authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether out-of-pocket costs were being reimbursed by insurance or other third-party arrangement. **New Sections 1860D-1(a); 1860D-2(a and b), 1860D-3(a)(c), 1860D-6(c and e), 1860D-7(g, and h), 1860D-10, 1860D-11, 1860D-13(b), 1860D-14, 1860D-15, 1860D-16, and 1860D-19.**	The new MBA would administer the new Part D drug benefit and the new MA and EFFS programs. (CMS would retain responsibility for the traditional fee-for-service program.) A Medicare Policy Advisory Board would be established within the MBA. The Administrator of the MBA would: (1) establish processes for beneficiaries to make Part D elections and enroll in plans; (2) establish a process for determining the actuarial value of drug coverage; (3) in consultation with an advisory task force, develop standards relating to the electronic prescription drug program; (4) review bids and negotiate contracts with plan sponsors; (5) make low-income subsidy payments and implement a plan coordinating Part D and Medicaid; and (6) administer direct and reinsurance subsidy payments. The Administrator, in order to provide efficient marketing, could provide information to sponsors and organizations about eligible enrollees. The Secretary, in conjunction with the Secretary of the Treasury, would coordinate the implementation of the income-related catastrophic limit. **New Sections 1860D-1(b), 1860D-2(b and e) 1860D-3(c and d),1860D-4(b, c, and d), 1860D-5, 1860D-6, 1860D-7(d and e), and Section 1860D-8 (a, d, and g). New Section 1809 as added by Section 801**.

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Noninterference	In carrying out the duties with respect to the drug program and the MA program, the Administrator could not, to the extent possible, interfere in any way with negotiations between eligible entities, MA organizations, hospitals, physicians, other entities or individuals furnishing items or services under Medicare (including contractors), and drug manufacturers, wholesalers, or other suppliers of covered drugs. **New Section 1808 as added by Section 301.**	In carrying out the duties with respect to the drug program, the Administrator would be specifically barred from: (1) requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs; (2) interfering in any way with negotiations between PDP sponsors and MA organizations and EFFS organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; or (3) otherwise interfere with the competitive nature of providing such coverage through such sponsors and organizations. **New Section 1809 as added by Section 801**.
Administration of benefit	The benefit would be administered by an MA organization or PDP entity. A PDP entity would be an entity certified under Part D as meeting the Part D standards and requirements. In general, an entity 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. Alternatively it could meet solvency standards established by the Administrator for entities not licensed by the state. An "eligible entity" would be any risk bearing entity that the Administrator determined to be appropriate to provide eligible beneficiaries with benefits under a Medicare Prescription Drug Plan. Eligible entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers (including insurers that offered Medigap policies), other risk bearing entities, or any combination of these. This requirement would not preclude state pharmacy assistance programs from becoming qualified entities if they met the requirements). **New Section 1860D(a) and 1860D-7(a, c, d, and e).**	Similar provision for PDPs, MAs, and EFFSs, except eligible entities are not specified. **New Section 1860D-4(a, c, and d)**
Contracts	PDP entities would be required to enter into a contract with the Administrator under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. Contracts would be for 2 years. MA contract requirements relating to protections against fraud and abuse, beneficiary protections, intermediate sanctions, and termination procedures would apply to contracts with PDPs. The Administrator would establish additional standards by January 1, 2005, and periodically review such standards. **New Section 1860D-7(b, f, and h) and Section 1860D-13(f)**	PDP sponsors would be required to enter into a contract with the Administrator under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. Contracts would be for at least 1 year. Many of the contract requirements applicable to MA plans would be incorporated by reference including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rata user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20% of the maximum fee permitted for an MA or EFFS plan. **New Section 1860D-4(b)**

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Relationship to state laws	Standards established for Part D would supersede any state law and regulation to the extent such law or regulation was inconsistent with such standards and in the same manner those standards were superseded for MA plans. Standards specifically superseded include those relating to benefits (including requirements relating to cost-sharing and the structure of formularies), premiums, requirements relating to inclusion or treatment of providers, coverage determinations (including related grievance and appeals processes), and requirements relating to marketing materials and summaries and schedules of benefits for a plan. States would be prohibited from imposing a premium or similar tax with respect to premiums paid to the Administrator for PDPs and any payments made by the Administrator to eligible entities offering such a plan. **New Section 1860D-7(h)**	The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the Administrator. **New Section 1860D-4(e).**
Service areas	The Administrator would be required to establish by April 15, 2005, and periodically review, service areas in which plans could offer benefits. The Administrator would establish service areas so that they maximized the availability of plans to eligible beneficiaries and minimized the ability of entities offering plans to favorably select beneficiaries. The Administrator would establish at least 10 service areas which would have to include at least one state. States could not be divided so that portions of a state were in different service areas. To the extent possible, multi-state metropolitan statistical areas (MSAs) would be in a single service area. MSAs could be divided, where necessary, to establish service areas of such size and geography as to maximize plan participation. The Administrator could conform service areas to those established for preferred provider organizations under MA. **New Section 1860D-10.**	The Administrator would designate at least 10 service areas in the U.S., consistent with EFFS regions, to the extent practicable. **New Section 1860D-4(d)(5).**
Risk adjusters	The Administrator would be required to establish a method for adjusting premium payments to plans to take into account variations in costs based on the differences in actuarial risk of different enrollees being served. Any risk adjustment would be designed in a budget neutral manner. The Administrator could take into account similar methodologies used to adjust payments for MA organizations. The Administrator would be required to publish such risk adjusters not later than April 15 each year (beginning in 2005) to be used for computing payments to plans for standard coverage. **New Section 1860D-11**	Direct subsidy payments could be risk adjusted, to the extent the Administrator determined it appropriate to avoid risk selection. The adjustment would be based on factors specified by the Administrator and be designed to be budget neutral. **New Section 1860D-8(c)**.

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Submission of bids	Entities would submit bids to the Administrator on an annual basis. The bid would contain information on proposed plans including benefits, actuarial value of the qualified prescription drug coverage, the service area for the plan, and the monthly premium. Premium information would have to include an actuarial certification of the basis for the premium, the portion of the premium attributable to benefits in excess of standard coverage, and the reduction in bids attributable to reinsurance payments. Entities would also be required to provide information on whether the entity planned to use any funds in the plan stabilization reserve fund that were available to the entity for the purpose of stabilizing or reducing the monthly premium. Service areas covered by the bid could either be the entire area of one of the service areas established by the Administrator or the entire area covered by Medicare. Entities could submit separate bids for multiple service areas, provided each bid was for a single service area. **New Section 1860D-12**	Each PDP sponsor would be required to submit specified information to the MBA Administrator in the same manner information was submitted by MA organizations. Required information would include information on qualified drug coverage provided; actuarial value of the coverage; and bid and premium for coverage. The Administrator could not approve the premium unless it accurately reflected: (1) the value of benefits provided; and (2) the 73% federal subsidy for standard benefits. **New Section 1860D-6(a)**.
Plan approval	The Administrator could not approve a plan unless the premium, for both standard coverage and for any additional benefits, accurately reflected the actuarial value of the benefits less the actuarial value of reinsurance payments and any stabilization funds used. Each bid submitted by an entity for a qualified plan would have to reasonably and equitably reflect the cost of benefits provided under that plan. The Administrator would have the authority to negotiate the terms and conditions of the proposed monthly premiums and other terms and conditions of proposed plans. The Administrator could disapprove, or limit enrollment in, a proposed plan based on costs to beneficiaries, the quality of coverage and benefits, the adequacy of the plan network, average aggregate projected costs of covered drugs, and other factors determined appropriate by the Administrator. The Administrator could approve a plan only if it provided the required benefits and was not designed to result in a favorable selection of beneficiaries. **New Section 1860D-12(a-c)**.	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 Administrator would be required to take into account subsidy payments for covered benefits in negotiating the terms and conditions regarding premiums. **New Section 1860D-4(b)**
Federal payments to plans	The Administrator would pay each entity offering a drug plan an amount equal to the full monthly approved premium, with appropriate risk adjusters. Payments to plans would be adjusted to account for differences in actuarial risk of different enrollees being served. **Reinsurance payments** would be made on behalf of: (1) persons enrolled in a PDP; (2) MA plan (except for MSA plan or private fee-for-service plan not providing qualified coverage); (3) persons eligible for but not enrolled in Part D and covered under a qualified retiree plan; (4) persons eligible for but not enrolled in Part D and covered under a qualified state pharmaceutical	The federal government would pay direct subsidies and reinsurance payments to PDPs, MA Rx and EFFS Rx plans which would equal 73% of the value of standard coverage. **Direct subsidies** would be equal to 43% of the national weighted average monthly bid amount for standard coverage. Each year, the Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts (i.e., amounts for standard coverage) for each drug plan (not including those offered by private-fee-for service entities) adjusted to add back the

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	assistance program. Qualified retiree plans and state pharmaceutical assistance programs would have to provide coverage at least equal to the actuarial value of standard coverage. Reinsurance payments would be made to plans in the case of individuals whose spending exceeded the out-of-pocket limit. Payments to plans would equal 80% (65% in the case of persons in a state pharmaceutical assistance program) of allowable drug costs exceeding the limit. Administrative costs, and costs for coverage in excess of the standard benefit would not be included. Payment methods would be determined by the Administrator. Any plan sponsor that was not an employer would be required to redistribute reinsurance payments to employers contributing to the plan maintained by the sponsor; the payments would be allocated proportionately among all employers contributing to the plan. **New Section 1860D-16(a) and 1860D-20**.	value of reinsurance subsidies. **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 2006); and (2) 80% for costs over the out-of-pocket limit (in general, $3,500 in 2006). 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. **New Section1860D-8**.
Assumption of financial risk	A portion of total payments to plans would be subject to risk. Entities would be required to notify the Administrator for each year (beginning in 2007) of the total actual costs the entity incurred in providing standard coverage in the preceding year. Total actual costs would reflect total payments made to pharmacies and other entities for coverage net of the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity. The notification would not include spending for administrative costs, amounts spent for coverage in excess of standard coverage, or amounts for which the entity subsequently received reinsurance payments. **Risk corridors**, defined as specified percentages above and below a target amount would be established. The target amount would be defined as the total of plan premiums minus a percentage (negotiated between the Administrator and the entity) for administrative costs. No payment adjustment would be made if allowable costs were between the first threshold lower limit and the first threshold upper limit for the year, i.e., if the plans were within the first risk corridor. A portion of any plan spending above or below these levels would be subject to risk adjustments. If allowable costs exceeded the first threshold upper limit, then payments would be increased. If allowable costs were below the first threshold lower limit, payments would be reduced. During 2006 and 2007, plans would be at full risk for drug spending within 2.5% above or below the target. Plans would be at risk for 25% of spending exceeding 2.5% (first threshold upper limit) and below 5.0% of the target (second threshold upper limit). That is, their payments would equal 75% of the allowable costs for spending in this range. They would be at risk for 10% of the spending exceeding 5% of the target. That	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. **New Section 1860D-4(a)**.

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	is their payments would equal 90% of the allowable costs for spending in this range. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 10% of any amounts below 5% of the target. A special transition corridor would be established in the first 2 years. The Administrator would make a payment adjustment if the Administrator determined that 60% or more of all participating plans (including MA plans) representing at least 60% of covered beneficiaries had allowable costs that were more than 2.5% above the target. Risk corridor payments would equal 90% of any spending greater than 2.5% of the target but below 5% of the target. For 2007-2011, plans would be at full risk for drug spending within 5.0% above or below the target level. Plans would be at risk for 50% of spending exceeding 5.0% and below 10.0% of the target level. They would be at risk for 10% of the spending exceeding 10% of the target level. **New Section 1860D-16(b)**	
Stabilization fund	The Administrator would be required to establish a stabilization reserve fund, within the Prescription Drug Account. If the target amount for a plan for any year 2006-2010 exceeded applicable costs by more than 3% for the year, the entity would pay the Administrator the amount of such excess; the Administrator would deposit such amount in the fund on behalf of the entity. Applicable costs would be defined as the sum of allowable costs and the amount by which monthly payments were reduced through application of the risk corridor provisions. At appropriate intervals, the Administrator would notify a participating entity of the balances in any of its stabilization accounts. Beginning in 2008, entities would be permitted to use account funds to stabilize or reduce plan premiums. The accounts would expire after 5 years. Any amounts not used by an eligible entity or that was deposited for use by an entity that no longer had a Part D contract would revert to the use of the Prescription Drug Account. **New Section 1860D-16(c)**	No provision.
Access	The Administrator would approve at least two contracts to offer a drug plan in an area. Contracts would be awarded for 2 years. If the Administrator determined that at least two plans were not going to be available in the subsequent year, the Administrator would reduce the amount of risk required by plans in a region. This would be achieved by adjusting the percentages applicable to risk corridors established under the bill. Alternatively, the reinsurance percentage could be increased. The Administrator could not provide for the full underwriting of	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 one of which was a PDP) in their area of residence. The requirement would not be satisfied if only one PDP sponsor or one MA or EFFS 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

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	financial risk for any entity and could not provide for the underwriting of any financial risk for a public entity. The Administrator would seek to maximize the assumption of financial risk to ensure fair competition among plans. The authority would be used only so long as, and to the extent necessary, to assure access. The authority could not be used if two or more qualified bids were submitted in an area by qualified entities. **New Section 1860D-13(d)**	(beyond subsidy payments), 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. Additionally, the Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and MA and EFFS organizations. **New Section 1860D-5(d).**
Fallback	Not later than September 1 of each year, beginning in 2005, the Administrator would make a determination as to whether there were two approved bids. If not, the Administrator would enter into an annual contract with an entity to provide Part D enrollees in the area with standard coverage (including access to negotiated prices) for the following year. The Administrator could enter into only one contract for each such area. A single entity could be awarded contracts for more than one such area. The Administrator could not enter into such a contract if the Administrator received two or more qualified bids after exercise of the authority to reduce risk for entities. Entities would be required to meet beneficiary protection requirements. Beneficiary premiums for a fallback plan would be set at the premium amount that would apply if the plan premium equaled the national weighted average premium for the area, as adjusted for geographic differences in drug prices. The contract with the plan would provide for payments to the plans for the negotiated costs of covered drugs and payment of prescription management fees tied to performance management fees established by the Administrator. Performance requirements established by the Administrator would include the following; (1) the entity contained costs to the Prescription Drug Account and to beneficiaries; (2) the entity provided quality clinical care; and (3) the entity provided quality services. The fallback plan would not be permitted to engage in any marketing or branding of the contract. An entity that submitted a bid to be a qualified risk-bearing entity could not submit a bid to be a fallback plan. In the case of an area with only one competitively bid contract, the plan (at the plan's option) could be offered under the rules established for risk-bearing plans. Beneficiaries could enroll with such plan or with the fallback plan. **New Section 1860D-13(e)**.	No provision.

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Pharmacies	An entity would be required to establish a point-of-service method of operation under which the plan would provide access to any or all pharmacies not participating in the network and could charge beneficiaries, through adjustments in cost sharing, the additional costs associated with this option. This additional cost sharing would not count toward the program's cost-sharing requirements or benefit limits. Entities would be required to permit enrollees to receive benefits (which could include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order; a differential amount (which would not count toward the catastrophic limit) could be paid by enrollees. **New Section 1860D-5(b)**.	PDP plan sponsors and entities offering an MA Rx or EFFS Rx plan would be required to permit the participation of any pharmacy meeting the plan's terms and conditions. A PDP and an MA Rx or EFFS Rx plan could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Administrator to the plan. PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to secure participation in its network of a sufficient number of pharmacies that dispensed drugs directly to patients (other than by mail order) to assure convenient access. The Administrator would establish convenient access rules which would be no less favorable to enrollees than those established by the Secretary of Defense for the TRICARE Retail Pharmacy program. Sponsors would permit enrollees to receive benefits (which could include a 90-day supply of drugs or biologicals) through a community pharmacy rather than through mail-order, with any difference in charge paid by the enrollee. Pharmacies could not be required to accept insurance risk as a condition of participation. PDP sponsors would be required, when establishing fees for pharmacists, to take into account the costs associated with the medication therapy management program. **New Section 1860D-3(c).**

Requirements for MA and EFFS Organizations

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Organization requirements	MA enrollees would obtain drug benefits through their MA plan (except for MSA enrollees and enrollees in private fee-for-service plans not offering drug coverage). Other Part D enrollees would receive their drug coverage through enrollment in a PDP offered in the geographic area in which the beneficiary resided. Part C requirements relating to MA would be applied (unless otherwise specified) as if: (1) any reference to an MA plan included a reference to a Medicare Prescription Drug plan; (2) any reference to a provider-sponsored organization included a reference to an eligible entity, (3) any reference to a contract included a reference to a drug plan contract, and (4) any reference to Part C included a reference to Part D. **New Section 1860D(b)**.	Beginning January 1, 2006, a MA organization could not offer a coordinated care MA plan unless either that plan or another plan offered by the organization in the area included qualified drug coverage. It could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a MA plan offering such coverage. The organization would be required to meet beneficiary protections outlined in the new Section 1860D-3, including requirements relating to information dissemination and grievance and appeals. The organization would also be required to submit the same information

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		required of PDP sponsors when submitting a bid. The Administrator could waive such requirements to the extent the Administrator determined they were duplicative of requirements otherwise applicable to the organization or plan. MA organizations providing qualified drug coverage would receive low-income subsidy payments, and direct and reinsurance subsidies. A single premium would be established for drug and nondrug coverage. The same requirements would be applicable to an EFFS organization. **Section 102**
Requirements for fee-for-service plans	No provision.	MA private fee-for-service plans would not be required to negotiate prices or discounts; however, to the extent a plan did so, it would be required to meet related Part D requirements. If such a plan provided access to all pharmacies without charging additional copayments, it would not be required to meet the any willing pharmacy requirement. The drug utilization management program requirement would not apply to such plans. If the plan provided coverage for drugs purchased from all pharmacies without entering into contracts or agreements, the requirement for public disclosure of pharmaceutical prices of the lowest cost equivalent generic drugs would not apply. **Section 102**

Pricing; Cost-Controls

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Drug pricing and payment	The PDP sponsor and MA organizations would determine payments and would be expected to negotiate discounts. **New Sections 1860D-5(b) and 1860D-12.**	Similar provisions. **New Section 1860D-2(d) and 1860D-6.**
Access to negotiated prices	Eligible entities would be required to have in place procedures to ensure that beneficiaries were not charged more than the negotiated price of a covered drug. The procedures would include the issuance of a card or other technology that could be used by a beneficiary to assure access to negotiated prices for which coverage was not otherwise provided under the plan. The PDP or MA organization would be required to disclose to the Administrator the extent to which manufacturer discounts or rebates, or other price concessions or direct or indirect remunerations were made available to the sponsor or organization and passed through	Both standard coverage and actuarially equivalent coverage would have to provide beneficiaries access to negotiated prices (including applicable discounts) even when no benefits were payable because the beneficiary had reached the initial coverage limit. The PDP sponsor or MA or EFFS entity would be required to disclose to the Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions were made available to the sponsor or organization and passed through to enrollees through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Administrator under the same

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	to enrollees through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Administrator under the same conditions currently required for Medicaid. **New Section 1860D-5(b) and 1860D-6(e)**	conditions currently required for Medicaid. **New Section 1860D-2(d)**.
Cost-controls; formularies	Entities could use a variety of cost control mechanisms including formularies, tiered copayments, selective contracting with drug providers, and mail order pharmacies. Plans electing to use a formulary would be required to establish a pharmacy and therapeutic committee (that included at least one academic expert, at least one practicing physician, and at least one practicing pharmacist) to develop and review the formulary. The committee would base clinical decisions on the strength of scientific evidence and standards of practice. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been provided to beneficiaries, physicians, and pharmacists. 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 treatment of the same condition for the individual or had adverse effects for the individual. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable for a preferred drug if the prescribing physician determined that the preferred drug was not as effective for treatment of the same condition for the individual or had adverse effects for the individual. 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). For purposes of defining therapeutic categories and classes, the Administrator would use the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, the DRUGEX Information System, and American Medical Association Drug Evaluations, and other recognized sources, as determined appropriate by the Administrator. **New Section 1860D-5(b, d and e) and 1860D-6(a).**	Similar formulary provision, except: (1) pharmacy and therapeutic committee not required to have an academic expert; (2) the only reference cited for the purpose of establishing classes of drugs would be standards published in the United States Pharmacopeia-Drug Information; (3)any change in the preferred or tier cost-sharing status of a drug could take effect only after appropriate notice to beneficiaries and physicians; and (4) plans would be required to provide for periodic evaluation and analysis of treatment protocols and procedures in connection with the formulary. **New Section 1860D-3(c, e and f)**

Requirements

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Beneficiary protections	Plans would be required to comply with a number of beneficiary protections including those related to: (1) guaranteed issue and community-rated premiums; (2) information disclosure; (3) assuring the participation of a sufficient number of pharmacies that dispensed drugs directly to patients to assure convenient access; (4) a cost and drug utilization management program including medication therapy management; (5)programs to control fraud and abuse; (6) provisions for hearing and resolving grievances and handling appeals; including independent review of coverage denials and appeals; (7) safeguarding the privacy of medical records; and (8) conduct of consumer satisfaction surveys. Pharmacies or other dispensers would be required to assure that beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that was therapeutically equivalent and bioequivalent and that is available at the pharmacy or other dispenser. **New Section 1860D-5**	Plans would be required to comply with a number of beneficiary protection provisions including those related to: (1) guaranteed issue and community-rated premiums; (2) non-discrimination; (3) information disclosure; (4) assuring the participation of a sufficient number of pharmacies that dispensed drugs directly to patients to assure convenient access; (5) issuance of a card so beneficiaries could assure access to negotiated prices when coverage was not otherwise available under the plan; (6) a cost and drug utilization management program including medication therapy management; (7) effective 2007, an electronic prescription drug program that provided for electronic transfer of prescriptions and provision of information to the prescribing health professional; (8) programs to control fraud and abuse; (9) provisions for hearing and resolving grievances and handling appeals; and (10) safeguarding the privacy of medical records. Each PDP sponsor and entity offering a MA Rx or EFFS Rx plan would ensure that each pharmacy or other dispenser informed enrollees at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent. **New Sections 1860D-1(c), 1860D-2(d), 1860D-6(b), and 1860D-3**.
Standards for electronic prescribing; Electronic Prescription Program	A new Part D in Title XI of the Social Security Act would be established. It would require the development or adoption of standards for transactions and data elements for such transactions, to enable the electronic transmission of medication history, eligibility, benefit and other prescription information. In developing the standards, the Secretary would be required to consult with representatives of physicians, hospitals, pharmacists, standard setting organizations, pharmacy benefit managers, beneficiaries, information exchange networks, technology experts, and representatives of the Departments of Veterans Affairs and Defense and other interested parties. Patients could request a written prescription and not be charged for such request. The standards would accommodate the electronic transmittal of information among prescribing and dispensing professionals at the point of care. The information that could be transmitted using the standards would include: information on the drugs prescribed for the patient; cost-effective alternatives (if any) to the drug prescribed; information	PDP sponsors would be required, beginning in 2007, to have an electronic prescription drug program. The program would have to be consistent with national standards developed by the Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases) and for provision of information to the prescribing health professional. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive realtime basis. The standards would be compatible with those established for the administrative simplification program established under Title XI of the Social Security Act. The Administrator would establish an advisory task force to provide recommendations to the Administrator on standards including recommendations relating to: (1) range of available computerized prescribing software and hardware and their costs to develop and implement; (2) extent to which such standards and systems reduced medication errors and could be readily implemented by physicians, pharmacies, and hospitals; (3) efforts to develop uniform standards and a

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	on eligibility and benefits (including the drugs included in the applicable formulary and any requirements for prior authorization); information on potential drug interactions; and other information to improve the quality of care and to reduce medical errors. The standards would be designed so that, to the extent practicable, they did not impose an undue administrative burden on the practice of medicine, pharmacy, or other health professions. The standards developed or adopted by the Secretary would be consistent with federal regulations concerning the privacy of individually identifiable health information and compatible with administrative simplification standards. The Secretary would adopt standards for the exchange of appropriate and necessary information among prescribing and insurance entities and other necessary entities. The Secretary would have to adopt the standards by January 1, 2006, and would be permitted to modify them, but only in a manner that minimized the disruption and cost of compliance. Individuals or entities that transmitted or received prescriptions electronically would be required to comply with the standards. Entities covered by the standards would have 24 months to comply. Small health plans, as defined by the Secretary, would have an additional 12 months to comply. A new Section 1180A would authorize the Secretary to award grants to health care providers to implement electronic prescription programs. There would be authorized to be appropriated such sums as may be necessary for each of fiscal years 2006, 2007, and 2008. **Section 121.**	common software platform for the secure electronic transmission of information; (4) efforts to develop and promote universal connectivity and interoperability for the secure exchange of information; (5) cost of implementing such systems in hospital and physician office settings and pharmacies; and (6) implementation issues as they relate to administrative simplification requirements and current federal and state prescribing laws and regulations and their impact on implementation of computerized prescribing. The Administrator would be required to establish the task force by April 1, 2004. It would be required to submit recommendations to the Administrator by January 1, 2005. The Administrator would be required to promulgate national standards by January 1, 2006. **New Section 1860D-3(d)(3).**

Financing

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In general	A separate account, known as the Prescription Drug Account, would be established within the Part B Trust Fund. Funds in this Account would be kept separate from other funds within the Trust Fund. Payments would be made from the Account to eligible entities and MA plans and sponsors of qualified retiree plans, and for low-income subsidies, reinsurance payments, and administrative expenses. Appropriations would be made to the Account equal to the amount of payments and	A Medicare Prescription Drug Trust Fund would be created. Low-income subsidies, direct subsidies, reinsurance payments, and federal administrative costs would be paid from this fund. Funds would be transferred to state Medicaid programs attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the

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	transfers made from the Account. **New Section 1860D-25.**	fact that Medicaid became the secondary payer of drug benefits for the dual eligibles. General revenues would be appropriated to cover remaining costs. **New Section 1860D-9**.

Low-Income

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Persons eligible for subsidies	Medicaid beneficiaries eligible for medical and drug benefits under their state Medicaid program (including the medically needy) would continue to receive drug benefits through Medicaid. Persons meeting the definition of QMB, SLMB, or QI-1, and not eligible for Medicaid medical and drug benefits would receive their drug benefits through Part D. The definition of income would be tied to that currently used for the QMB, SLIMB, and QI-1 programs (100% federal poverty level for QMB, 120% for SLIMB and 135% for QI-1, subject to certain exclusions). The current definition of assets ($4,000 for an individual, $6,000 for a couple) would apply (States may, however, waive the assets tests). Coverage would also be extended to persons below 160% of the federal poverty level not meeting the definition of dual eligible, QMB, SLIMB, or QI-1; no assets tests would apply for this group. Beginning January 1, 2009, to the extent a state had not already eliminated application of an assets test, it would be required to permit individuals to make a self-declaration that assets did not exceed $10,000 for an individual or $20,000 for a couple. In subsequent years, these amounts would be increased by the increase in the consumer price index. By January 1, 2005, the Secretary would submit a report to Congress on recommendations for a voluntary option for dual eligibles to enroll in Part D drug plans. **New Section 1860D-19 and Section 104(e)**	Beneficiaries with incomes below 150% of poverty and assets below a specified threshold would be eligible for low-income subsidies. The definition of income would be tied to that currently used for the QMB, SLIMB, and QI-1 programs. In 2006, the definition of resources would be three times that used for the supplemental security income program (i.e., $6,000 for an individual, $9,000 for a couple, subject to certain exclusions). In future years, this resource level would be increased by the annual increase in the consumer price index. **New Section 1860D-7(a).**
Subsidy benefit	**QMBs**: Beneficiaries would have 100% premium subsidy for premiums provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average). The benefit package would be defined as having a zero deductible, cost-sharing of 2.5% instead of 50% for costs below the initial coverage limit ($4,500 in 2006); 5.0%	**Income at or below 135% of poverty (and assets below threshold):** Beneficiaries would have a Part D premium subsidy equal to 100% of the value of standard drug coverage provided under the plan. Beneficiary cost-sharing for spending up to the initial coverage limit ($2,000 in 2006) would be reduced to an amount not to exceed $2 for a multiple source or generic drug and $5 for a non-preferred drug. No deductible would be imposed. PDPs

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	instead of 100% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit ($3,700 in 2006), and 2.5% instead of 10% cost-sharing for costs above the catastrophic limit. **SLIMBs and QI-1s**: Beneficiaries would the same premium subsidy as QMBs. The benefit package would be defined as having a zero deductible, 5.0% cost-sharing for costs below the initial coverage limit; 10.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 2.5% cost-sharing for costs above the catastrophic limit. **Persons with incomes below 160% of poverty, not otherwise eligible for low-income benefits**: These persons would have a sliding scale premium subsidy ranging from 100% of the premium at 135% of poverty to 0% at 160% of poverty with no additional premium costs provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average). The benefit package for this population would be defined as having a $50 deductible in 2006 (indexed in subsequent years by the annual percentage increase in average per capita Medicare drug expenditures), 10.0% cost-sharing for costs below the initial coverage limit; 20.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 10.0% cost-sharing for costs above the catastrophic limit. **All groups**: Plans could waive or reduce cost-sharing otherwise applicable. **New Section 1860D-19**	could not charge individuals receiving cost-sharing subsidies more than $5 per prescription. (The dollar amounts for cost-sharing charges would be increased in future years by the percentage increase in beneficiary drug costs). **Income between 135% and 150% of poverty (and assets below threshold):** Beneficiaries would have a sliding scale premium subsidy ranging from 100% of the value of standard coverage at 135% of poverty to 0% of such value at 150% of poverty. **Both groups:** PDPs could reduce to zero the cost-sharing otherwise applicable for generic drugs. No coverage would be provided for costs between the initial coverage limit ($2,000 in 2006) and the catastrophic limit ($3,500 in 2006); however, subsidy payments would count toward the out-of-pocket limit. **New Section 1860D-7(a-c)**.
Administration of subsidy	The Administrator would implement a process to notify the eligible entity or MA plan that the individual was eligible for a cost-sharing subsidy and the amount of the subsidy. The entity would reduce the applicable cost-sharing and submit information to the Administrator on the amount of the reduction. The Administrator would periodically and on a timely basis reimburse the entity or organization for the amount of the reductions. **New Section 1860D-19**	The Administrator would provide a process whereby the Administrator would notify the PDP sponsor or MA Rx or EFFS Rx entity that an individual was eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy. The Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of the reductions. **New Section 1860D-7(d)**
Relationship to Medicaid	States would be required to make low-income eligibility determinations for low-income subsidies. States would be required, for purposes of the transitional prescription drug card assistance program (see below), to establish eligibility standards consistent with that program; establish procedures for providing presumptive eligibility determinations (similar	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. States, as a condition of receiving federal Medicaid assistance, would be required to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the Administrator of

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	to that which currently apply for low-income pregnant women and children); make eligibility determinations for the card program; and communicate to the Secretary information on eligibility determinations or discontinuations. For purposes of the low-income subsidies for the new Part D program, states would be required, beginning November 2005, to make eligibility determinations; inform the Administrator of cases where eligibility was established, and otherwise provide the Administrator with any information required to carry out Part D. States would be required to enter agreements with the Commissioner of Social Security to use all social security field offices in the state as information and enrollment sites for making eligibility determinations. As part of the eligibility determination process, states would also be required to screen for eligibility for Medicare cost-sharing assistance under the QMB, SLIMB, and QI-1 programs. If a state elected to use negotiated prices for a drug under its Medicaid program, the Medicaid rebate requirements would not apply for that drug. Any prices negotiated by a PDP plan, MA plan, or qualified retiree program would be exempted from Medicaid's determination of "best price" for purposes of the Medicaid drug rebate program. **Section 104 (b and d) and New Section 1860D-6(e)**.	cases where eligibility has been established, and otherwise provide the Administrator with information that may be needed to carry out Part D. If a state elected to use negotiated prices for a drug under its Medicaid program, the Medicaid rebate requirements would not apply for that drug. Further, the bill would 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. **Section 103 and Section 1860D-2(d**).
Matching payments	The federal government would pay an enhanced matching rate for administrative costs associated with making eligibility determinations for *both* the transitional and Part D programs. The rate would be 75% for the period January 1, 2004-September 30, 2005, 70% for fiscal year 2006, 65% for FY2007, and 60% beginning in FY2008. Beginning November 1, 2005, the rate would be 100% for purposes of making eligibility determinations for low-income subsidies. In addition, states would be entitled to enhanced matching for the costs associated with designing, developing, acquiring and installing improved eligibility determination systems, including hardware and software, for low-income subsidy programs. The enhanced rate would be 90% for fiscal years 2004, 2005, and 2006. The systems would be required to comply with any standards established by the Secretary for improved eligibility systems. Further, the systems would have to be compatible with the standards established under the administrative simplification provisions of Title XI of the Social Security Act. **Section 104(b)**	There would be a federal phase-in of increased costs associated with low-income eligibility determinations. In 2005, the federal matching rate would be increased by 6-2/3% and in 2006 by 13-1/3%. In each subsequent year, the percent would be increased by 6-2/3 percentage points (but in no case could the rate exceed 100%). Beginning in 2019, the federal matching rate would be 100%. There would also be a federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles (i.e., persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006-2020 period, the federal matching rate for these costs would be increased to cover 100% of what would otherwise be state costs. **Section 103.**

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Part B premiums	Beginning January 1, 2006, states agreeing to provide a drug benefit to their dual eligible population that was at least equivalent to minimum standards would be relieved of their responsibility to pay Medicare Part B premiums for persons with incomes between the level established for the supplemental security income program and 100% of the federal poverty level. A state would be required to meet all current law coverage standards for dual eligibles under Medicaid, including nominal cost-sharing requirements. States would have to provide beneficiary protections equivalent to those provided under Part D. States could not place a limit on the number of prescriptions for dual eligibles. Appropriate transfers would be made from the Treasury to the Part B trust fund. **Section 104(b)**.	No provision.
Part A cost-sharing	If on the date of enactment, a state provided medical assistance to aged and disabled persons up to 100% of poverty, it would be entitled to have the federal government assume the costs for Medicare Part A cost-sharing. The Part A costs would be assumed so long as the state maintained the expanded coverage. The provision would apply effective January 1, 2006. Appropriate transfers would be made from the Treasury to the Part A trust fund. **Section 104(b)**.	No provision.
Territories	Residents of the territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, provided they formulated a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The aggregate amount available would be $37.5 million for the last three quarters of FY2006, and $50 million for FY2007. In subsequent fiscal years, the aggregate amount would be the amount available the previous year, increased by the percentage increase in prescription drug spending. The Secretary would be required to report to Congress on the application of the law in the territories. **Section 103(b).**	Similar provision except for funding. The aggregate amount available would be $25 million in 2006, increased in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. **Section 103(d)**.
QI-1 program	The QI-1 program would be extended through December 2008 with total annual allocations of $400 million through fiscal year 2008 and $100 million for the first quarter of fiscal 2009.	No provision.

Provision	S. 1	H.R. 1
Cost-sharing for persons with specified diseases	The cost-sharing specified under the low-income subsidy provisions would be modified for persons diagnosed with cancer. The cost-sharing specified under new Section 1860D-19 would apply except for the following changes. The QMB population would have a full premium subsidy for at least one drug plan available in the area where the beneficiary resided. For the SLIMB and QI-1 population, there would be no premium for any plan whose premium was at or below the monthly national average premium. For other persons below 160% of poverty, the premium would be only a percentage of the premium otherwise applicable. Persons with incomes above 160% of the poverty line would have, in 2006, the same cost-sharing otherwise specified under the bill. The same provisions would apply for persons diagnosed with cardiovascular disease, cancer, diabetes, or Alzheimer's disease. **Sections 108 and 109.**	No provision.

Relationship to Retiree Plans

Provision	S. 1	H.R. 1
Payments toward out-of-pocket limit	Payments made by retiree plans for cost-sharing charges would not count toward out-of-pocket limit. **New Section 1860D-6(c)(4)(C)**	Similar provision. **New Section 1860D-2(b)(4)(C)**.
Subsidies	Reinsurance subsidy payments, equal to 80% of costs above the catastrophic limit, would be made to qualified retiree drug plans. A qualified plan would be defined as employment-based retiree health coverage provided based on an individual's status as former employees or labor union members. The sponsor would have to attest that coverage had at least the same actuarial value as standard coverage and would have to maintain such records as the Administrator required for audits and other oversight activities. Payment could not be made for an individual unless: the individual was covered under the retiree plan, entitled to enroll under Part D but elected not to. In addition, any plan sponsor that was not an employer would be required to redistribute reinsurance payments to employers contributing to the plan maintained by the sponsor; the payments would be allocated proportionately among all employers contributing to the plan. The Administrator would also make direct payments to sponsors of qualified retiree prescription drug	Special subsidy payments would be made to a "qualified retiree prescription drug plan." A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The Administrator would have to determine that coverage had at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless: the individual was covered under the retiree plan, entitled to enroll under a PDP or MA Rx or EFFS Rx plan but elected not to. Subsidy payments would equal 28% of allowable costs over the $250 deductible but not over $5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.) Nothing would preclude an individual covered under an employment-based retiree plan

Provision	S. 1	H.R. 1
	plans for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would equal the direct subsidy percent of the monthly national average premium for the year, as adjusted by risk adjusters. The direct subsidy percent would be 100% minus the applicable percent. The applicable percentage for an area would be 30% divided by: (1) 100%, minus (2) a percentage equal to total reinsurance payments that would be made in a year divided by such amount plus total payments that would be made to plans in the year for standard coverage. **New Sections 1860D-20 and 21.**	from enrolling in a PDP plan or MA or EFFs plan or having the employment-based plan paying the premium. Employment-based supplemental coverage would be considered the primary payor for purposes of the Medicare secondary payment provisions. **New Section 1860D-8(f)**
Enrollment	Sponsors of employment-based retiree coverage that offered a prescription drug plan would be permitted to restrict enrollment in the plan to eligible beneficiaries enrolled in such coverage. Sponsors could not offer enrollment in a Medicare Prescription Drug plan based on the health status of beneficiaries. **New Section 1860D-26.**	No provision.

Relationship to State Pharmaceutical Assistance Programs

Provision	S. 1	H.R. 1
Payments toward out-of-pocket limit	Payments made by state pharmaceutical assistance programs for cost-sharing charges would count toward out-of-pocket limit. **New Section 1860D-6(c)(4)(C)**	Similar provision. **New Section 1860D-2(b)(4)(C)**.

Provision	S. 1	H.R. 1
Subsidies	**Reinsurance subsidy payments**, equal to 65% of costs above the catastrophic limit, would be made to qualified state pharmaceutical assistance programs. The state would have to attest that coverage had at least the same actuarial value as standard coverage and that the actuarial value of subsidies was at least equal to the low-income subsidies under Part D. The program would have to be in effect on the date of enactment, be sponsored and financed by the state, and provide coverage for drugs for persons meeting income and resource-related qualifications. Payment could not be made for an individual unless the individual was covered under the state program, entitled to enroll under Part D but elected not to. The Administrator would also make **direct payments** to sponsors of qualified state pharmaceutical assistance programs for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would be calculated in the same way that such payments were calculated for retiree plans (see above). Further, the Administrator would provide for additional payments in behalf of each person who would otherwise qualify for a low-income subsidy, if the individual were enrolled in Part D. The payment would equal the amount the Administrator estimated would have been paid under the subsidy provisions, but in no case more than the average payment made under the subsidy provisions for an individual in the same income group. **New Sections 1860D-20, 1860D-22, 1860D-22.**	No provision.
Coordination	Entities offering a drug plan or an MA organization offering a MA plan could enter into an agreement with a state pharmaceutical assistance program (including one established under a Section 1115 waiver) to coordinate coverage. **New Section 1860D-26.**	No provision.

Relationship to Medigap

Provision	S. 1	H.R. 1
Relationship to Medigap	Effective January 1, 2006, Medigap drug policies could not be sold, issued or renewed for Part D enrollees. Persons who had such policies could obtain Medigap coverage without drug benefits. Beneficiaries who sought to enroll during the Part D open enrollment period established for current beneficiaries would be guaranteed issuance of such non-drug policies (without an exclusion based on preexisting conditions). Medigap issuers would be required to notify individuals of these changes 60 days prior to the Part D open enrollment period. Medigap insurers could not be required to participate as an eligible entity under the new Part D. **Section 103.**	Effective January 1, 2006, 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 Medigap policy would have the following 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 2006 (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 non-drug Plans A through G to individuals who enrolled in Part D within 63 days and who were covered until then by Medigap policy H, I, or J. **Section 104**.

Temporary Drug Discount Card Endorsement Program

Provision	S. 1	H.R. 1
Establishment	The Secretary would establish a program under which the Secretary would endorse card programs offered by prescription drug card sponsors meeting certain requirements and would make available information on such programs to beneficiaries. The Secretary would implement the New Sections 1807 (drug card program) and 1807A (relating to the low-income) to assure that discounts and benefits were available no later than January 1, 2004. The Secretary would provide for an appropriate transition and discontinuation of the programs; such transition would ensure that benefits continued to operate until the first Part D enrollment period ended. **Section 111.**	The Secretary would be required to establish a program to: (1) endorse prescription drug discount card programs meeting certain requirements; (2) provide for prescription drug accounts; and (3) make available information on such programs to beneficiaries. The Secretary would begin operation of the endorsement program within 90 days of enactment. The account part of the program would begin no later than September 2004. The Secretary would provide for an appropriate transition and termination of the program on January 1, 2006. **Section 105**

Provision	S. 1	H.R. 1
Enrollment	The program would be voluntary. Any individual entitled to, or enrolled in, Part A and enrolled in Part B would be eligible to enroll in an endorsed prescription drug card program. The Secretary would be required to establish procedures for identifying eligible beneficiaries. The Secretary would also be required to establish procedures under which beneficiaries could make an election to enroll and disenroll in an endorsed card program. **Section 111.**	The program would be voluntary. Eligible beneficiaries would be defined as persons eligible under Part A or enrolled in Part B, but not enrolled in an MA plan offering qualified prescription drug coverage. The Secretary would establish a process through which an eligible beneficiary could make an election to enroll under the new Section 1807 with an endorsed program. The beneficiary would have to enroll for a year in order to receive the benefits for the year. An individual would, in general have only one opportunity for enrollment. This would occur during an initial, general enrollment period as soon as possible after enactment, and annually thereafter. The annual open enrollment periods would be coordinated with those for MA. **Section 105**
Selection of entity	Eligible sponsors would be entities with demonstrated experience and expertise in operating a prescription drug discount card program or similar program that the Secretary determined to be appropriate to provide benefits to Medicare beneficiaries. Such entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers, other entities, or any combination of these. The Secretary would provide information which compared the costs and benefits of various programs. This information dissemination, intended to promote informed choice, would be coordinated with the dissemination of other educational information on other Medicare options. A beneficiary could only be enrolled in one endorsed program at a time. Each card sponsor would make available to each beneficiary (through the Internet or otherwise) information that the Secretary identified as being necessary to provide for informed choice by beneficiaries among endorsed programs; this would include information on enrollment fees, negotiated prices, and services related to drugs offered under the program. The sponsor would have to provide information on how the formulary functioned. The Medicare toll-free number, 1-800-MEDICARE, would be used to receive and respond to inquiries and complaints. Sponsors seeking endorsement of a card program would submit required information to the Secretary. The Secretary would review the information and determine whether to endorse the program. A program could not be approved unless it and the sponsor complied with the requirements of the new Section 1807. **Section 111.**	The Secretary would establish a process through which an eligible beneficiary would select an eligible entity to provide access to negotiated prices. The entity would be one which had been awarded a contract and served the state in which the beneficiary resided. Eligible entities would be pharmaceutical benefit management companies, wholesale and retail pharmacy delivery systems, insurers, MA organizations, other entities, or any combination of these. The enrollment process, established by the Secretary, would use rules similar to those established for MA. Individuals could not select more than one entity at a time and, except for unusual circumstances, change the selection once a year. The process would provide for selecting eligible entities for individuals who enrolled in the new Section 1807, but failed to select an entity. Entities would compete for beneficiaries on the basis of discounts, formularies, pharmacy networks, and other services. If an eligible entity served a state, it would be required to serve the entire state. **Section 105**

Provision	S. 1	H.R. 1
Fees	Card sponsors could charge annual enrollment fees, not to exceed $25. The fee would be the same for all eligible Medicare beneficiaries enrolled in the program and would be collected by the card sponsor. Each card sponsor would issue a discount card to program enrollees. **Section 111.**	The enrollment fee would be $30 with the 2004 fee including any portion of 2003 covered by the program. The fee would be collected in the same manner as Part B premiums are collected from social security payments, except the collection would be made only once a year. States could pay the fee for some or all low-income enrollees in the state. No federal matching payments would be available. The Secretary would make 2/3 of the fee collected available to the eligible entity. Each eligible entity would be required to issue a card and an enrollment number to each enrolled beneficiary and to provide for electronic methods to coordinate with prescription drug accounts established under the new Section 1807A. **Section 105**
Beneficiary protections	Each endorsed drug card program would have to meet beneficiary protection requirements, including those relating to beneficiary appeals and marketing practices. They would also have to ensure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price. Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access (including adequate emergency access) for beneficiaries enrolled in the program. Convenient access would be determined by the Secretary and would take into account reasonable distances to pharmacy services in both urban and rural areas. Each card sponsor would be required to have in place procedures for assuring that quality service was provided to eligible beneficiaries enrolled in a prescription drug discount card program. They would also have to safeguard individually identifiable information in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Sponsors would be prohibited from charging any fees, except for the annual enrollment fee. Each card program would be required to provide pharmaceutical support services such as education, counseling, and services to prevent adverse drug interactions. **Section 111.**	Beneficiary protections would be established including guaranteed issue and nondiscrimination provisions. Entities would be required to disseminate, to each beneficiary who selected the entity, summary information on negotiated prices, access to such prices through pharmacy networks, and how the formulary functioned. Upon request, entities would be required to provide general coverage, utilization, and grievance information. In addition, entities would be required to have a mechanism for providing specific information upon request. The new Part D provisions relating to pharmacy access would apply to eligible entities. To the extent the Secretary determined they could be implemented on a timely basis, entities would be required to meet the new Part D provisions with respect to development and application of formularies and the requirements to have in place an effective cost and drug utilization management program, quality assurance measures and systems, and a program to control fraud, abuse and waste. Each entity would be required to have in place meaningful procedures for hearing and resolving grievances and for expedited determinations and reconsiderations of coverage determinations. Entities would be required to provide pharmaceutical support services. They would also be required to provide for confidentiality and accuracy of enrollee records and periodic reports to the Secretary. They would have to meet additional requirements identified by the Secretary, including those that ensured that enrollees were not charged more than the lower of the negotiated retail price or the usual and customary price. **Section 105**

Provision	S. 1	H.R. 1
Negotiated prices	Card sponsors would provide enrolled beneficiaries with access to negotiated prices used by the sponsor for payment for prescription drugs, provided such drugs were not excluded under the program's formulary. The term negotiated price would include all discounts, direct or indirect subsidies, rebates, price concessions, and direct or indirect remunerations. Medicaid negotiation rules, including rebate requirements, would not apply. Card sponsors could not recommend switching an eligible beneficiary to a drug with a higher negotiated price, unless a licensed health professional recommended a switch based on a clinical indication. Negotiated prices could not change more than once every 60 days. **Section 111.**	Entities would be required to provide beneficiaries with access to negotiated prices (including applicable discounts). Negotiated prices could not be limited to mail order drugs. Entities and contracting pharmacies could not charge beneficiaries for any required services. Entities would be required to disclose to the Secretary the extent to which discounts, or rebates or other remuneration or price concessions made available by a manufacturer were passed through to enrollees; such information would be confidential. Entities would be required to notify enrollees at the time of purchase of the differential between any prescribed drug and the cost of the lowest cost available generic drug that was therapeutically equivalent and bioequivalent. **Section 105**
Formularies	Sponsors could use a formulary. Sponsors electing to use a formulary would be required to establish a pharmaceutical and therapeutic committee to develop and review the formulary. The formulary would have to include drugs within each therapeutic category and class of covered drugs (as defined by the Secretary) although not necessarily for all drugs within such categories and classes. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been made available. **Section 111.**	If the entity used a formulary, negotiated prices would only be available for formulary drugs. **Section 105**
Oversight	The Secretary would provide appropriate oversight to ensure compliance of programs; including verification of the negotiated prices and services provided. Each program sponsor would be required to report to the Secretary on program performance, use of drugs by beneficiaries, financial information of the sponsor, and other information required by the Secretary. The Secretary could not disclose any proprietary data that were reported. The Secretary could use Parts A and B claims data for purposes of conducting a drug utilization review program. **Section 111.**	Eligible entities would submit periodic reports to the Secretary on performance, utilization, finances, and other matters specified by the Secretary. The Secretary would provide appropriate oversight to ensure compliance of eligible entities with requirements, including verification of discounts and services provided. **Section 105**
Accounts; low-income	Under a new Section 1807A, the Secretary would award contracts to prescription drug card sponsors, offering a program that was endorsed by the Secretary to offer a prescription drug card assistance program to eligible low-income beneficiaries. The program would begin no later than January 1, 2004. The Secretary would provide for a transition and discontinuation of the drug card program and the low-income assistance card program when the new Part	The Secretary would be required to establish a prescription drug account for each enrolled individual and deposit into the account the federal contribution amount. This amount would be $800 for an accountholder with income under 135% of poverty, $500 for an accountholder with income between 135% and 150% of poverty, and $100 for other persons. Income would be determined under the state Medicaid program or by the

Provision	S. 1	H.R. 1
	D program became effective. The transitional programs would continue to operate at least 6 months after the date benefits first became available under Part D. All individuals meeting the definition of QMB, SLMB, or QI-1, who were not eligible to receive drug benefits under Medicaid, could receive assistance with their prescription drug costs. These persons would have access, through a drug discount card, to up to $600 per year. The entire $600 benefit would be available for the entire year; any balance left on the card in one year could be carried forward. Beneficiaries would be subject to cost-sharing requirements which could not be less than 10% of the negotiated price for a drug. Cost-sharing charges would not count against the $600. At a minimum, card sponsors would provide low-income enrollees with a minimum of a 20% discount from the average wholesale price for each covered drug. In general, the enrollment procedures established for the drug discount card program would apply for this program. Each sponsor offering an assistance card program would be required to enroll any low-income person wishing to enroll if the program served the geographic area where the beneficiary resided. An individual enrolling in an assistance card program would be simultaneously enrolled in a discount card program offered by the sponsor. Enrollment fees would be waived for these individuals and would instead be paid by the Secretary. Eligible beneficiaries would have to be provided the information required for the discount card program. In addition, sponsors would be required to notify low-income enrollees, on a periodic basis, of the amount of coverage remaining and on the grievance and appeals process under the program. Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access for beneficiaries enrolled in the program. The Secretary would determine whether convenient access was provided; mail order pharmacies would not be included in the determination. Further, the Secretary could not make a determination that convenient access had been provided, unless an appropriate arrangement was in place for low-income persons in long-term care facilities. Drug discount card managers could establish formularies. A low-income 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. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable for a preferred drug if the prescribing	Social Security Administration (SSA). Such sums as may be necessary would be authorized to be appropriated to the SSA. If the program was not in effect for all of 2004, the amounts would be prorated. Persons would not be eligible for a federal contribution if they were eligible for drug coverage under Medicaid, group health plan, Medigap, medical care for members of the uniformed services, Veterans' medical care, Federal Employees Health Benefits program, or the Indian Health Care Improvement Act. Contributions to the accounts would include federal contributions, any state contributions, private contributions (including employer and individual contributions) and spousal rollover contributions. If the accountholder was married at the time of death, the amount in the account attributable to public contributions would be credited to the account, if any, of the surviving spouse, or if the spouse was not an eligible beneficiary, into a reserve account to be held for when the spouse became an eligible beneficiary. Costs of the Voluntary Medicare Outpatient Prescription Drug Discount and Security Program would not be considered in calculating the Part B premium. **Section 105**

Provision	S. 1	H.R. 1
	physician determined that the preferred drug was not as effective for the individual or had adverse effects for the individual. Sponsors offering assistance card programs would be required to process claims, negotiate with brand name and generic manufacturers and others for low prices, track individual beneficiary expenditures, and perform other functions specified by the Secretary. Entities would be required to assure that low-income beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that was therapeutically equivalent and bioequivalent and that was available at the pharmacy or other dispenser. Entities would also be required to have meaningful procedures for hearing and resolving grievances, comparable to those established for Medicare+Choice plans. In addition, eligible entities would be required to meet Medicare+Choice requirements relating to coverage determinations. Sponsors seeking to offer an assistance program would be required to submit information to the Secretary, in the manner specified by the Secretary. The Secretary would have to determine that the entity was appropriate to provide benefits to low-income beneficiaries, was able to manage the monetary assistance provided under the program, agreed to submit to audits by the Secretary, and provided other assurances require by the Secretary. There would be no limit on the number of sponsors who could be awarded contracts. The contract would be for the lifetime of the program and cover the same service area served by the sponsor under the card program under Section 1807. The sponsor could submit an application for endorsement under both programs simultaneously. **Section 111.**	

Other

Provision	S. 1	H.R. 1
Recommendations for technical corrections	The Secretary would be required to submit a legislative proposal within 6 months of enactment containing necessary technical and conforming amendments. **New Section 1860D-26(d)**	Similar provision. **New Section 1860D-10**
Part B only individuals	The Administrator would be required to conduct a study, and report to Congress by January 1, 2005, on allowing persons not entitled to Part A, but enrolled in Part B, to enroll in Part D. **Section 102.**	No provision.

Provision	S. 1	H.R. 1
Medicare Payment Advisory Commission (MEDPAC)	MEDPAC membership would be expanded to 19 and include experts in the area of pharmacology and prescription drug benefit programs. MedPAC duties would be expanded to include review of competition among eligible entities offering drug plans and beneficiary access to such plans and covered drugs, particularly in rural areas. Three field hearings would be required in 2007. **Section 105**.	No provision.
Study on variations in drug spending and utilization	The Secretary, on an ongoing basis, would study variations in spending and drug utilization under Part D to determine the impact on premiums. The Secretary would examine the impact of geographic adjustments to the monthly national average premium on the maximization of competition and the ability of eligible entities to contain costs. The Secretary would submit an annual report to Congress beginning in 2007. **Section 106.**	No provision.
Limitation on prescription drug benefits of Members of Congress	During calendar year 2004, the actuarial value of the drug benefit of any Member of Congress enrolled in a FEHBP plan could not exceed the actuarial value of any prescription drug benefit under Title XVIII of the Social Security Act passed by the first session of the 108th Congress and enacted into law. **Section 107**.	No provision. (However, House passed H.R. 2631which would provide that the actuarial value of the prescription drug benefits offered to Medicare eligible enrollees by a plan under the federal employees health benefits program would be at least equal to the actuarial value of the prescription drug benefits offered by such plan to its enrollees generally).
Standards of practice in nursing facilities	The Secretary would be required to conduct a thorough review of the standards of practice for pharmacy services provided to patients in nursing facilities. The Secretary would assess the current standards, clinical services and other service requirements generally used in long-term settings and evaluate the impact of these standards with respect to patient safety, reduction of medication errors, and quality of care. Within 18 months of enactment, the Secretary would be required to submit a report to Congress on the study containing: (1) a detailed description of the Secretary's plans to implement the Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients; and (2) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of care in such manner. **Section 110.**	Within 6 months of enactment, the Secretary would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care; and (3) recommend necessary actions. The Secretary would submit a report to the Congress on the findings and recommendations. **New Section 1860D-10**.
Medication therapy management	The Secretary would be required to establish a 1-year assessment program to contract with qualified pharmacists to provide medication therapy management services to fee-for-service beneficiaries. The Secretary would designate six geographic areas (at least two rural), each containing not less than three sites.	No provision.

Provision	S. 1	H.R. 1
	The program would be implemented between October 1, 2004 and January 1, 2005. Beneficiaries in an area could participate if they identified a qualified pharmacist to furnish medication therapy management services. The Secretary would enter into contracts with qualified pharmacists to provide such services. The fee established under the contract would be designed to test various payment methodologies including one that applied a relative value scale and fee schedule. Payments would be made from the Part B trust fund and be budget neutral. The Secretary would be required to make data on the program available and report to Congress within 6 months of completion of the program. **Section 110**.	
Reporting requirements for trustees reports	The trustees of the Medicare Part A and B trust funds would be required to submit a combined report on the status of the two trust funds including the Prescription Drug Account. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury and the percentage such amount bore to all other obligations of the Treasury in that year. This calculation would be made separately for Medicare benefits and for administrative and other expenses. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 50-year projections would also be required. The report would also provide a comparison of the rates of growth for both benefits and administrative costs to the rates of growth in the gross domestic product, health insurance costs in the private sector, employment-based health insurance costs in the public and private sectors, and other areas as determined appropriate by the Board of Trustees. The provision would express the sense of the Congress that the committees of jurisdiction would hold hearings on these reports. **Section 131.**	The trustees of the Medicare Part A and B trust funds would be required to submit a combined report on the status of the two trust funds and the Prescription Drug Trust Fund. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury for payment of benefits and the percentage such amount bore to all other general revenue obligations of the Treasury in that year. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 75-year projections would also be required. The report would also provide a comparison to the rate of growth in the gross domestic product. **Section 131**.
Trustees' report on Medicare's unfunded obligations	The 2004 trustees reports would be required to include an analysis of the total amount of unfunded obligation of Medicare. The analysis would compare long-term obligations of Medicare to the dedicated funding sources for the program (not including general revenues). **Section 132**.	No provision.

Provision	S. 1	H.R. 1
Pharmacy benefit managers transparency requirements	An eligible entity offering a Medicare prescription drug plan under Part D or an MA organization offering an MA plan under Part C could not enter a contract with a pharmacy benefit manager (PBM) owned by a pharmaceutical manufacturing company. PBMs would be required to provide the following information, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General for the Department of Health and Human Services: (1) aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer; (2) the amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs (as measured by volume); and (3) the percentage differential between the price PBMs paid pharmacies and the price the PBM charged the PDP or MA organization. **Section 133.**	No provision.
Office of the Medicare beneficiary advocate	Within 1 year of enactment, the Secretary would be required to establish an Office of the Medicare Beneficiary Advocate within the Department of Health and Human Services. The Office would establish a toll-free number for beneficiaries to obtain information on the Medicare program, particularly with respect to Part D. It would establish a WEB site with easily accessible information on PDPs and MA plans. **Section 134.**	No provision.
Transitioning Part B coverage	No provision.	Not later than January 1, 2005, the Administrator would be required to submit a report containing recommendations for providing benefits under Part D for drugs currently paid for under Part B. **New Section 1860D-10**
Information disclosure to carry out Medicare Catastrophic Prescription Drug Program	No provision.	The provision would permit the Secretary of the Treasury, upon written request from the Secretary of Health and Human Services (HHS) to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. The information that could be disclosed is taxpayer identity information and the adjusted gross income for the taxpayer or, if less, the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000); or (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would each be treated separately with each person considered to have an

Provision	S. 1	H.R. 1
		adjusted gross income equal to one-half of the total. Return information disclosed could be used by officers and employees of HHS only for administering the prescription drug benefit. They could disclose the annual out-of-pocket threshold applicable to an individual to the entity offering the individual prescription drug coverage. The sponsor could use such information only for the purposes of administering the benefit. **Section 106**

State Pharmaceutical Assistance Programs

Provision	S. 1	H.R. 1
Transition commission	No provision.	A State Pharmaceutical Assistance Transition Commission would be established to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission would include: (1) a representative of each governor from each state with a program that the Secretary identified as having a benefit package comparable to or more generous than the new Part D; (2) representatives from other states that had pharmaceutical assistance programs, as appointed by the Secretary; (3) representatives (not exceeding the total under number 1 and number 2) of organizations that represented interests of participants, appointed by the Secretary; (4) representatives of MA organizations; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner; (2) protection of the financial and flexibility interests of states so they were not financially worse off; and (3) principles of Medicare modernization outlined in Title II of the Act. The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later. **Section 107.**