Prescription Drug Coverage for Medicare Beneficiaries: An Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(Public Law 108-173)

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Title of Bill	Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173). Enacted December 8, 2003.
Overview	Outpatient prescription drug coverage is added to the Medicare program through a new Part D. The voluntary drug benefit under Medicare Part D would be delivered through private risk-bearing entities under contract with the Department of Health and Human Services (DHHS). Drug benefits would be provided through stand-alone prescription drug plans (PDPs) or comprehensive plans, integrated with Part A and B benefits, under Part C (renamed Medicare Advantage (MA)). Government fallback plans are authorized to serve areas without sufficient plan choices. Provides subsidies to sponsors of retiree plans that provide qualified drug coverage for their Part D eligible enrollees. Establishes a demonstration for a Medicare competitive government contribution system (Comparative Cost Adjustment Program) beginning in 2010 that includes traditional Medicare. CBO estimates direct federal spending would increase $410 billion over the budget period 2004-2013 for the prescription drug program. A Medicare Prescription Drug Discount Card program and Transitional Assistance Program are established for 2004 and 2005 with subsidies for low-income beneficiaries who do not have prescription drug coverage.
Effective date of Medicare drug benefits	Part D drug benefit effective January 1, 2006. The Medicare Prescription Drug Discount Card and Transitional Assistance Programs will be implemented within 6 months of enactment and continue into 2006 during a transition period.
Eligibility	Beneficiaries entitled to Part A or enrolled in Part B are eligible to enroll in Part D.
Mandatory or voluntary participation and Part D enrollment	Voluntary Part D. Enrollees in traditional fee-for-service may enroll in a Medicare Prescription Drug Plan (PDP). Enrollees in Medicare Advantage Prescription Drug (MA-PD) plans would obtain drug benefits through their MA-PD plan. MA private fee-for-service enrollees may receive Part D benefits through a PDP if their plan does not offer Part D coverage. MSA plan enrollees may enroll in a PDP. The Secretary shall establish a process for enrollment, disenrollment, termination, and change of enrollment similar to, and coordinated with, MA in terms of residency requirements, exercise of choice, coverage election periods, coverage periods, guaranteed issue and renewal, and marketing. Beneficiaries eligible for Part D by November 15, 2005, will have an initial enrollment period that corresponds to the annual MA open-election period. Those becoming Part D eligible after November 15, 2005 will have an initial enrollment period as for MA plans. Special enrollment periods will be established for involuntary loss of creditable drug coverage; errors in enrollment; exceptional circumstances; Medicaid coverage; and discontinuance of MA-PD coverage during the first year of eligibility. Beneficiaries with greater than 63 days without creditable drug coverage will be subject to a late enrollment penalty. The late enrollment penalty is the greater of an amount the Secretary determines is actuarially sound or 1 percent of the monthly premium for every month the individual did not have creditable coverage after the end of the individual's initial enrollment period. (See also "premium subsidies for low-income enrollees.") Creditable coverage includes coverage that meets or exceeds the actuarial value of Part D standard coverage provided under: Medicaid, a group health plan (including FEHBP), a qualified retiree plan, a state pharmaceutical assistance program (SPAP), veterans' or military coverage, Medigap, or other coverage the Secretary determines appropriate. All the above plan sponsors, except Medicaid, must disclose to the Secretary and to enrollees whether their plan's drug coverage meets or exceeds the value of standard drug coverage, and if it does not meet requirements of the rules regarding Part D late enrollment. The Secretary may waive the late enrollment penalty for beneficiaries not adequately informed of the value of their alternative coverage. CBO estimates 93% of Medicare beneficiaries will participate in Part D.
Termination of Part D coverage	The Secretary shall establish a process and rules regarding termination of enrollment in Part D plans, similar to rules regarding termination in MA plans. Misrepresentation of information regarding third-party reimbursement shall constitute grounds for termination.

Plan election process	Beneficiaries enrolled in Part D and not enrolled in an MA plan (other than an MSA or private fee-for-service plan without drug coverage), will make an annual election to enroll in a PDP serving their geographic area of residence during an election period. Beneficiaries must enroll in a qualified plan during specified open-election periods in order to avoid penalties. MA plan enrollees will choose their MA plan during the same election periods and receive drug coverage from the MA plan. Election periods will be the same for MA plan annual and special election periods. There will be an initial 6-month election period beginning November 15, 2005. Special election periods will be established for circumstances such as involuntarily losing drug coverage. Beneficiaries will be allowed to change plans annually, so long as they maintain continuous drug coverage. Plans may not refuse enrollment to any beneficiary except for capacity limitations. Full-benefit dual eligibles who do not select a plan during the open-election period will be default enrolled in a plan with a premium at or below the low-income benchmark by the Secretary. If more than one plan is available in the area, enrollment will be on a random basis. Such individuals may decline or change default enrollments.
Information	The Secretary is to broadly disseminate information on Part D. Information activities must be coordinated with general Medicare and MA information requirements and include comparative plan information. Comparative information must cover benefits; enrollee premiums; quality and performance; cost-sharing; consumer satisfaction and the method for determining the late enrollment penalty. The Secretary is to provide PDP and MA-PD plan sponsors with identifying information about Part D eligible individuals only as necessary to facilitate efficient marketing and enrollment. Plan sponsors may use the information only for plan marketing and enrollment. Plans must disclose information in a clear, accurate and standardized form, on access (including pharmacy networks); operation of any formulary, enrollee cost-sharing; and the medication therapy management program. Other specified information would have to be provided upon request. Entities must have a mechanism for providing specific information upon request, including making information on specific changes in their formularies available through a website. Entities must furnish enrollees an easily understood explanation of benefits form and notice of benefits in relation to the initial coverage limit and annual out-of-pocket limits for the current year whenever drugs are provided (but not more often than as specified by the Secretary).
Benefit package	A standard benefit package is defined in law. Plan sponsors may offer the standard package or basic coverage (i.e., an actuarially equivalent package, with a deductible not greater than the standard deductible, the same out-of-pocket (OOP) limit, the same actuarial value up to the initial coverage limit (see below), and the same value of unsubsidized coverage), if approved by the Secretary. Plans must provide enrollees access to negotiated prices regardless of whether benefits are payable due to the deductible or coverage limit. Plan sponsors may offer plans with supplemental benefits (reduced cost-sharing, increased initial limit, or coverage of drugs excluded from Part D) but only if they also offer a plan with basic coverage in the same area. The same rule applies to MA-PD plans, however, in lieu of basic coverage they may offer a plan with supplemental benefits so long as the cost of those benefits is fully offset by a rebate on Part A and B benefits.
Annual deductible	The standard drug package has an annual deductible of $250 in 2006. For subsequent years, the deductible amount will be indexed to the annual growth in average per capita spending by Medicare beneficiaries for Part D drugs and rounded to the nearest $5. Plans providing basic coverage may apply a lower, but not greater, deductible within the overall actuarial equivalence requirements.

Beneficiary coinsurance/ copayments	The standard drug package has beneficiary coinsurance of 25% for spending above the deductible and up to the initial coverage limit ($250 to $2,250 in 2006). Plans providing basic coverage may require different coinsurance or copayments that are actuarially consistent with an average cost-sharing of 25%. Once the annual out-of-pocket (OOP) threshold is reached ($3600 in 2006), enrollees will pay the greater of $2 for generics/$5 for brand drugs, or 5% coinsurance. The copayments will be indexed (as above) and rounded to the nearest 5 cents.
Drug benefit: Annual benefit limits or cap	The initial coverage limit in 2006 is $2,250, after which the enrollee will pay 100% of the plan's negotiated price until reaching the OOP threshold. For subsequent years, the initial coverage limit will be indexed (as above), and rounded to the nearest $10. Plans providing basic coverage must provide the same actuarial benefit amount up to the initial coverage limit.
Annual out-of-pocket (OOP) limit	The annual OOP threshold is $3,600 in 2006. For subsequent years, the OOP threshold will be indexed (as above), and rounded to the nearest $50. Deductible, cost-sharing, and costs above the annual coverage limit count towards the OOP threshold unless they are paid by a third party (except a state pharmaceutical assistance program, another individual such as a family member, or as a low-income subsidy for drug benefits provided under this bill). Costs for nonformulary drugs (or drugs not treated as formulary drugs) do not count. Plans providing basic coverage must provide the same OOP threshold as in the standard package. The Secretary, in coordination with the Secretaries of Treasury and Labor, is authorized to establish a process to obtain information on third-party payment of Medicare enrollee drug expenditures, and alert plan sponsors about such reimbursements.
Income-related benefits	No provision.
Beneficiary premiums	PDP enrollees pay a premium for drug coverage equal to the difference between the government's premium subsidy for basic coverage and their plan's total premium. The portion of the enrollee obligation attributed to Part D coverage in MA-PD plans is calculated in the same way. The base premium is adjusted to reflect amounts associated with any supplemental drug benefits, any applicable late enrollment penalty, or any applicable low-income premium subsidies. The premiums for a plan, (except for late enrollment penalties and low-income subsidies) must be uniform for all enrollees. The government subsidy is based on the national weighted average monthly bid for basic coverage, adjusted for geography, after taking into account estimated reinsurance payments. Bids for MSA plans, MA private fee-for-service plans, specialized MA plans, PACE and cost contract plans are not included. The average enrollee premium for Part D drug coverage in 2006 is estimated by CBO to be $35.
Government premium subsidies -- Medicare population in general	The total government subsidy (through direct premium subsidies and reinsurance) for the Medicare population in general is equal to 74.5% of program costs for basic drug coverage. The percentage rate of subsidy applied to the national average premium will vary from year to year in relation to estimated government costs for reinsurance and will be geographically adjusted. Premium subsidies to plans will be adjusted for enrollee risk.
Government reinsurance subsidies	Part D PDP and MA-PD plans receive government reinsurance payments of 80% of allowable drug costs over the annual OOP threshold for an enrollee. "Allowable costs" means drug benefit costs, including dispensing fees but excluding administrative costs, under a plan related to basic coverage that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the plan or the enrollee.

Collection of premiums and distribution of subsidies	Plans are paid their total approved bid amounts, risk-adjusted, from a combination of government subsidy and enrollee premium. Drug plan sponsors must permit enrollees, at the enrollees' option, to have premiums withheld from Social Security checks, by electronic funds transfer arrangements from debit or credit card accounts, or otherwise as specified by the Secretary (including payment by an employer on behalf of a beneficiary). Monies for Part D premiums withheld from Social Security checks will be deposited in the Medicare Prescription Drug Trust Fund. MA plans may not charge for the SSA withholding option. The Secretary shall transmit necessary information to SSA for withholding purposes. The Secretary shall provide for consolidation of premiums for Part C, Part D and supplemental benefits for MA enrollees. Enrollees in fallback plans must agree to have premiums withheld from their SS checks (or as otherwise provided for Part B premiums). The Secretary shall notify plans of the individuals eligible for low-income subsidies. Plans are to reduce premium and cost-sharing for these individuals and will be paid the subsidy amounts by the Secretary. The amounts may be computed and reimbursed on a capitated basis, with appropriate risk adjustment.
Premium subsidies for low-income enrollees	All Part D eligible individuals who are also Medicaid full benefit dual eligibles (regardless of income and assets) or Supplemental Security Income (SSI) recipients are eligible for a full premium subsidy. Other Part D enrollees with incomes below 135% of poverty and assets that do not exceed $6,000 single, $9,000 couple in 2006 (indexed to the CPI) are entitled to a full premium subsidy equal to the weighted average premium for basic coverage offered by plans in the region (i.e. the low-income benchmark premium), or, if greater, the premium for the lowest cost basic coverage plan available in the region. The government shall also subsidize 80% of any late enrollment fee applicable for up to 60 months and 100% for any additional months. All other beneficiaries with incomes below 150% of poverty and who meet an asset limit of $10,000 single/$20,000 couple (indexed to the CPI) receive additional premium subsidies based on a sliding scale. CBO estimates that 36% of Medicare beneficiaries will be eligible for low-income Part D subsidies.
Cost-sharing assistance for low-income enrollees	Medicaid full benefit dual eligibles are deemed to be eligible for low-income subsidies, regardless of income or assets. Those with incomes up to 100% of poverty will have no deductible and have copays of $1 generics/$3 brand (indexed to CPI), up to the OOP threshold, then no copay requirements. Medicaid full benefit dual eligible enrollees with incomes above 100% of poverty, and Part D enrollees who are not full benefit duals but have incomes below 135% of poverty and meet the asset test as above (i.e., $6,000/$9,000), will have no deductible, pay no more than $2 generics/$5 brand drugs, and have no cost-sharing above the OOP threshold. Institutionalized full benefit dual eligibles will have no cost-sharing requirements. Other Part D enrollees with incomes below 150% of poverty who meet the asset test as above (i.e., $10,000/$20,000) will pay a $50 annual deductible, 15% coinsurance up to the stop-loss threshold and $2 generic/$5 brand copays above the OOP threshold. The deductible and the $2 and $5 copayment amounts will be indexed to grow annually by the growth in per capita Part D drug spending by Medicare beneficiaries.
Determination of eligibility for low-income subsidies (and financing)	Eligibility for the low-income subsidies will be determined by state Medicaid programs (or by the Social Security Administration (SSA)). All full benefit dual eligibles (regardless of income or assets) will be considered eligible for the low-income subsidies; QMBs, SLMBs, and QIs could be deemed eligible if the Secretary finds that a state's eligibility requirements are substantially the same as under Part D. The federal government will pay states for the administrative costs at the regular matching rate for administrative expenses. Appropriations are authorized to cover the Social Security Administration's costs. Determinations are effective for up to one year, as specified by the Secretary. Redeterminations shall be made as provided by the state Medicaid plan or as provided by the Commissioner of Social Security. A model, simplified application form will be developed to allow for beneficiary attestation of assets (to be accompanied by recent statements, if any, from financial institutions), subject to penalty for perjury. The Secretary will inform PDPs of enrollees' subsidy eligibility and level. Plans provide the subsidy, and the Secretary reimburses them for their costs.

Resource requirements (asset test)	The asset test for full-benefit dual eligibles will be based on the state Medicaid plan. For benefits applicable to others (i.e., not full benefit duals) with incomes less than 135% of poverty, the asset test will be $6,000 individuals/$9,000 couples (indexed annually to the Consumer Price Index (CPI)). For benefits applicable to those under 150% of poverty, the asset test is $10,000 individuals/$20,000 couples (indexed annually to the CPI).
Financing of low-income subsidies	All premium and cost-sharing subsidies for Part D drug benefits, including those for the low-income, will be paid through Medicare. States will be required to make a payment to the federal government each month equal to the product of: 1) a "take back" factor, which is set at 90% for 2006 and phased down to 75% for 2015 and later years; 2) the number of dual eligibles enrolled in full Medicaid coverage in that month; and 3) a per capita amount designed to approximate the amount a state would have spent each month on Medicaid prescription drugs per full dual eligible in the absence of the Medicare bill. This "per capita amount" is based on a state's per capita Medicaid spending on Part D covered prescription drugs for full dual eligibles in 2003, trended forwarded through 2006 by the growth in national per capita prescription drug expenditures and in 2007 and later years by per capita growth in Part D spending.
Covered drugs	Drugs, biological products and insulin (including medical supplies associated with injection as defined by the Secretary) that are covered under Medicaid and vaccines licensed under Section 351 of the Public Health Service Act. Includes coverage for any use of a covered outpatient drug for a medically accepted indication, as defined under Medicaid.
Drugs excluded from coverage	Excluded are drugs for which payment is available under Medicare Parts A or B, and those in categories that may be excluded under Medicaid (i.e., weight loss or gain, fertility, cosmetic or hair growth, cough or cold relief, vitamins and minerals, non-prescription drugs, barbituates, and benzodiazepines) except for smoking cessation agents. Drugs not meeting the Medicare definition of reasonable and necessary, or not prescribed according to plan or Part D requirements, can be excluded from coverage by plans, but determinations are subject to appeal.
Formulary rules	Plans may have a formulary (including tiered cost-sharing) so long as the formulary meets standards. Formularies must be developed by a pharmacy and therapeutic (P&T) committee; a majority of P&T committee must be practicing physicians or pharmacists; and the committee must have at least one practicing physician and one practicing pharmacist independent and free of conflict with respect to the sponsor and plan, both with expertise in the care of elderly or disabled. The formulary must include drugs within each therapeutic category and class; decisions must be based on the strength of scientific evidence and standards of practice; and must take into account whether the formulary drug has therapeutic advantage in terms of safety and efficacy. A PDP sponsor may not change categories and classes other than at the beginning of each plan year, except as the Secretary permits to account for new therapeutic use and newly covered Part D drugs. The P&T committee must have procedures to educate providers and enrollees concerning the formulary; and appropriate notice must be made to enrollees and physicians before a drug is removed from the formulary or the tier status of a drug is changed. The United States Pharmacopeia, in consultation with PBMs and others, will be asked to develop a model list of categories and classes to be used by plans and to revise the list from time to time. Plans using the model list cannot be found by the Secretary to have a design of categories and classes intended to discourage enrollment by certain beneficiaries. Formulary requirements may be met by a PDP sponsor directly or through arrangements with another entity.

Access to drugs not on formulary or preferred drug list	In plans with tiered cost-sharing, enrollees may request that non-preferred drugs be covered as preferred drugs if the prescribing provider determines that the preferred drug would not be as effective or would have adverse effects for the patient. Denials are subject to appeal, including external review and appeal to HHS. Only the individual can bring an appeal. Enrollees may appeal determinations regarding nonformulary drugs only if the prescribing physician determines that all drugs on the plan's formulary for treatment of the same condition would not be as effective or would have adverse effects for the patient.
Appeals process for drug coverage	Plan sponsors must have meaningful grievance procedures and appeals processes that conform to MA requirements, including requirements for determinations, reconsiderations, external review and expedited decisions. Full appeal rights, including external review, also apply to decisions related to the application of tiered cost-sharing and coverage of non-formulary drugs.
Treatment of drugs already covered by Medicare	Drugs, as prescribed and dispensed or administered, for the individual, for which payment is available (or would be available but for the application of a deductible) under Part A or B are excluded from Part D coverage.
Drug pricing	Plan sponsors are to negotiate prices with manufacturers and suppliers of covered drugs. Prices negotiated by plan sponsors (PDP, MA-PD, or qualified retiree plans) on behalf of Part D enrollees shall not be applicable to Medicaid "best price" provisions. PDP sponsors must provide that each pharmacy inform the enrollee at the time of purchase (or, for mail order, at the time of delivery) of any differential between the price of the drug to the enrollee and the price of the lowest-cost generic equivalent available at the pharmacy. Plan sponsors must disclose to the Secretary, on a confidential basis, the aggregate negotiated price concessions received from drug manufacturers which are passed through as lower subsidies, lower premiums, or lower prices. The Secretary may periodically audit plan sponsors' financial statements and records to ensure proper disclosures and accounting. The Secretary is prohibited from interfering with negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for reimbursement of covered drugs.
Access to price discounts	Plans must provide enrollees with access to negotiated prices regardless of whether benefits are payable. Negotiated prices shall take into account price concessions, such as discounts, direct or indirect subsidies, rebates, direct or indirect remunerations, and dispensing fees.
Eligible entities	Plan sponsors must be licensed as risk-bearing entities in each state in which they offer coverage. Entities must assume risk for Part D benefits on a prospective basis; private reinsurance is permitted. Entities not so licensed can receive a waiver from the Secretary under procedures similar to those for provider-sponsored organizations under MA. Certain grounds for approval will be deemed to be met in the case of states that do not have a licensing process for PDP sponsors. The Secretary, in consultation with NAIC, is to establish solvency and capital adequacy standards by January 1, 2005. PDP sponsors not licensed will have to be certified for compliance with such standards. The Secretary may periodically review and revise regulatory requirements but may not implement significant changes other than at the beginning of a calendar year.
Service areas	The Secretary shall establish PDP regions consistent, to the extent practicable, with MA regions (see below). (No less than 10 and no more 50 regions will be established. A PDP may be offered in more than one region or nationwide. PDPs must serve an entire region.

Contracts with private entities	The Secretary shall enter into contracts with all eligible entities that meet standards for one-year terms. The Secretary may not contract with a PDP sponsor if the entity: submitted a bid to offer a fallback plan in any region for the year; offers a fallback plan in any region during the year; or offered a fallback plan in the previous year (includes entities acting as subcontractors of PDP sponsors, but not of MA plan sponsors). A contract with a sponsor can cover more than one plan. The Secretary has similar authority to negotiate the terms and conditions of PDPs as the Director of the Office of Personnel Management has with respect to FEHBP plans and shall approve plans only if they comply with requirements for actuarial value and plan design. The Secretary may only approve limited risk plans if necessary to meet minimum plan access requirements. In approving limited risk plans, priority shall be given to plans with the highest level of risk (taking into account plan bids). A limited risk plan must assume more than a de minimis level of risk. MA minimum enrollment requirements will apply, except the Secretary may increase the minimum as appropriate, and the requirements will be waived in the first year. Provisions on anti-fraud and abuse, intermediate sanctions, and termination apply to drug plans in the same manner as they apply to MA plans.
Information required of eligible entities	Sponsors have to submit information on the coverage to be provided; actuarial value of the coverage based on an individual with a national average risk profile; the bid, including actuarial certification of the actuarial basis for the premium, the portion of the premium attributable to supplemental benefits, assumptions regarding the reduction in the bid resulting from the reinsurance subsidy, and assumed administrative expenses; the service area; level of risk assumed (i.e., modifications for limited risk plans); and additional information required by the Secretary. The Secretary shall provide for filing consolidated information as incentives for PDPs offered in more than one region. The Secretary shall establish methods for determining actuarial valuation, which shall take into account the effect of alternative benefit structures on utilization.
Risk-sharing arrangements	Drug plan sponsors (other than fallback plans) share risk with the government through reinsurance (see above) and risk corridors for basic coverage. In 2006 and 2007, plans will be at full risk for spending within 2.5% of a target amount (defined as total premiums minus administrative costs). Plans will be at risk for 25% of spending in the corridor between 2.5% and 5% of the target, and at risk for 20% of costs more than 5% from the target (the government shares savings below the target and shares losses above the target within the corridors). A special transition corridor will be established where, if 60% of plans with at least 60% of total Part D enrollees have allowable costs more than 2.5% above the target, plans will be at risk for only 10% of those costs. For 2008-2011, risk corridors will be modified so that plans will be at full risk for costs within 5% of the target, at 50% risk for costs falling in the corridor between 5% and 10%, and at 20% risk for costs more than 10% from the target. After 2011, the Secretary is to establish corridors that could not be less than those in effect in 2011. For the purpose of the risk corridors, allowable costs are based on the costs incurred by the entity for standard drug benefits, net of discounts, administrative costs, and reinsurance payments. Plans will be at full risk for any supplemental drug benefits. Enrollee premiums will not be affected by any change in payments resulting from the risk corridors. Plans are required to disclose necessary information to the Secretary on a confidential basis to be used to the extent necessary to determine payments.

Provisions to assure access in all areas	The Secretary is to assure that every beneficiary has a choice of at least 2 plans (sponsored by different organizations), offering basic coverage only, or, if an MD-PD plan, offsetting any supplemental benefits with savings from Part A and B benefits so that there is no supplemental premium. At least one plan must be a PDP. The Secretary may approve limited risk plans in order to assure access. If there are still not 2 plans with approved bids, the Secretary shall contract with one "fallback" non-risk-bearing entity (through the federal procurement process) to administer standard coverage in all fallback areas within each region for the following year. The contract will be for 3 years but will be effective only for years in which the area was a fallback area. There can be no national fallback plan. The fallback entity will be required to meet PDP sponsor requirements and may not have submitted a bid to provide a PDP (or acted as a subcontractor for a PDP sponsor). The fallback plan will offer standard Part D coverage. The fallback plan sponsor will be paid the actual costs of drug benefits (taking into account negotiated price concessions) for enrollees and management fees subject to performance related to cost-containment, quality clinical care, customer service, and benefit administration. The enrollee premium for the fallback plan will be uniform and equal 25.5% of the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, for the region. Fallback entities may not market or brand the fallback plan. CBO estimates that, in 2006, about 18% of Part D enrollees will be in reduced-risk or "fallback" plans; 5% in 2013.
Conditions of participation for contracting entities	Plan sponsors must have in place, directly or through arrangements, a cost-effective drug utilization management program (with incentives to reduce costs, such as through use of generics); quality assurance systems to reduce medical errors and adverse drug interactions; and program to control fraud, abuse, and waste. Plans must have a medication therapy management program, that may be furnished by a pharmacist, and must be designed to assure covered drugs are appropriately used by enrollees with chronic diseases taking multiple drugs, and are likely to incur annual drug costs that exceed a level specified by the Secretary. The program shall be developed in cooperation with pharmacists and physicians and may distinguish between services in ambulatory and institutional settings. The resources and time required to implement the program shall be taken into account by plan sponsors in establishing pharmacist fees and must disclose to the Secretary such fees upon request. The Secretary shall conduct consumer satisfaction surveys to obtain comparative information on plans. Deeming of accreditation relating to access to covered drugs, quality assurance and medication management, and confidentiality and accuracy of enrollee records will apply to PDP sponsors in the same manner as it applies to MA organizations. Plan sponsors must permit coordination of benefits with SPAPs and other drug plans and not impose fees unrelated to the costs of coordination.
Relationship to state laws	Federal standards supersede state laws to the extent they are inconsistent in the same manner as for MA plans. Specifically superseded are laws related to benefit requirements including cost-sharing, premiums, inclusion or treatment of providers, coverage determinations (including appeals and grievance processes), and marketing materials. State premium taxes on PDPs or MA plans are prohibited.
Pharmacy benefit cards	Plans must issue, and reissue as appropriate, a card or other technology that may be used to assure access to negotiated prices. Standards are to be developed in consultation with the National Council for Prescription Drug Programs and other standard-setting organizations. Standards shall be recognized by a date the Secretary determines to be sufficient to allow plan sponsors to use standards by January 1, 2006.

Electronic prescribing	Within one year following the promulgation of final standards, prescriptions that are transmitted electronically must comply with standards for real-time electronic transmittal of information on eligibility and benefits (including formulary and prior authorization requirements); medication history; and information on lower cost, appropriate alternatives, and individual medical history information upon request of the professional or pharmacist (in compliance with HIPAA privacy rules); to the prescriber, dispensing pharmacy, and pharmacist. Standards are to be designed to improve patient safety, quality, and efficiencies in the delivery of care. To the extent practicable, the standards should be designed to not impose undue administrative burden, to be compatible with HIPAA standards, to permit exchange of drug labeling and drug listing information maintained by FDA and the National Library of Medicine, and to permit individuals to designate a particular pharmacy. By September 1, 2005, the Secretary shall adopt initial standards from recommendations of the National Committee of Vital and Health Statistics in consultation with standards setting organizations, practicing physicians and pharmacists, hospitals, pharmacies, PBMs, state boards of pharmacy and medicine, experts on electronic prescribing and appropriate federal agencies. A one-year pilot project to test the initial standards will begin January 1, 2006 (but will not apply where there is adequate industry experience). Participation in the pilot is voluntary. The Secretary must report to Congress by April 1, 2007, with an evaluation of the pilot and promulgate uniform final standards by April 1, 2008. Standards shall supersede state laws or regulations that are contrary to the standards and pertain to the transmission of medication history and information on eligibility, benefits and prescriptions. Provides for regulations to protect hospitals, group practices, and PDP or MA plan sponsors under the anti-kickback and self-referral laws.
Drug utilization review (DUR) requirements	Plan sponsors must have in place, directly or through arrangements, a cost-effective drug utilization management program (including incentives to reduce costs when medically appropriate, such as through the use of generics); quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use; a medication therapy program; and a program to control fraud, abuse and waste. The medication therapy management program is to be designed to assure that drugs for enrollees with chronic diseases, multiple prescriptions, and likely to incur high costs are used appropriately to optimize therapeutic outcomes and reduce adverse events. The program shall be developed in conjunction with practicing physicians and pharmacists, and the costs associated with program implementation must be taken into account by plans in setting pharmacist fees (and amounts disclosed to the Secretary upon request). MA private fee-for-service plans do not have to comply with the requirements to have a cost and drug utilization management program.
Confidentiality	Plan sponsors must comply with requirements concerning privacy, confidentiality and accuracy of enrollee records in the same manner as MA plans.
Pharmacy access rules	Plan sponsors must permit the participation of any pharmacy that meets terms and conditions that the plan has established. A plan may reduce coinsurance or copayments for drugs dispensed by in-network pharmacies, but in no case can the reduced copayments result in an increase in payments made to the plan by the government. Plan sponsors must secure access to a sufficient number of pharmacies (other than mail order) to ensure convenient access (including adequate emergency access). Requires the Secretary to establish access rules that are no less favorable to plan enrollees than the access rules for purposes of the TRICARE Retail Pharmacy program as of March 13, 2003. Plans are required to permit enrollees to receive benefits (which may 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 enrollees. Plans cannot require pharmacies to accept insurance risk as a condition of participation.

Federal Trust Funds and Trustees	A Medicare Prescription Drug Account (MPDA) will be established in the SMI (Part B) Trust Fund. Amounts payable from the MPDA will be excluded from calculation of the Part B premium. Amounts necessary to cover payments from the MPDA and maintain an appropriate contingency margin are authorized to be appropriated from general federal revenues. An initial contingency reserve of up to 10% of estimated 2006 benefit costs is authorized to be appropriated to the MPDA. A Transitional Assistance Account (TAA) is established within the SMI (Part B) Trust Fund. Funds are appropriated to the TAA to cover the costs of the transitional discount card subsidies. Funds to cover administrative expenses for the discount card program are authorized to be appropriated from the TAA. Amounts payable from the TAA will be excluded from calculation of the Part B premium. Any balance left in the TAA will be transferred to the MPDA when the program ends.
Federal financing	Financing for the Part D coverage subsidies and the transitional prescription drug subsidies will come from general federal revenues.
Administration	$1 billion is appropriated from the Medicare HI and SMI Trust Funds for the Centers for Medicare and Medicaid Services, and $500 million is appropriated for the Social Security Administration to be used for implementation of the legislation. Funds will remain available through September 2005. The Secretary is prohibited from interfering with negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for reimbursement of covered drugs. The law does not call for the establishment of a new administrative agency.
Reports to Congress and/or the President related to Medicare prescription drug benefits	The Secretary shall report to Congress by January 1, 2009 on regional variations in prescription drug spending, including the amount attributable to price variation and per capita utilization that is not accounted for by risk adjustment. Within 18 months of enactment, the Secretary is to report to Congress on pharmacy services provided to patients in nursing homes. The Secretary is to contract with the Institute of Medicine (IOM) to study drug safety and quality issues. The study is to be completed within an 18-month period and a report submitted to Congress. By January 1, 2007, the Secretary is to report to Congress on the feasibility and advisability of contracting for Part C and Part D on a multiyear basis. Within 18 months of enactment, the Secretary is to report to Congress on making prescription drug information accessible for blind and visually-impaired individuals. The Secretary shall report annually to Congress on limited risk and fallback Part D plans, including recommendations on reducing the need for such plans. The Secretary shall contract with the IOM to conduct an evaluation of the Quality Improvement Organizations (QIOs) and report to Congress by June 1, 2006. The Federal Trade Commission is to report to Congress within 18 months of enactment on the differences in costs incurred by enrollees and plans for drugs dispensed by PBM owned mail-order pharmacies versus other pharmacies. The Comptroller General shall report to Congress on trends in employment- based retiree health coverage. An initial report is due within one year of enactment and a final report by January 1, 2007.
Boards or Advisory Committees	A State Pharmaceutical Assistance Transition Commission is established (see SPAPs below).
Original FFS Medicare	Beneficiaries in the original FFS Medicare program will have the choice of at least 2 prescription drug plans with basic only coverage (or supplemental benefits offset by Part A and B rebates in the case of an MA-PD plan), offered by different sponsors, and at least one of which is a PDP. Additional plans, and plans with supplemental drug benefits, may also be available. The Secretary is to contract with an entity to provide a government fallback plan if not enough risk or limited risk plans are available. The Centers for Medicare and Medicaid Services will continue to administer the entire Medicare program.

Employer-sponsored retiree health coverage	Retiree plan sponsors may pay Part D premiums to enroll retirees in Medicare Part D, or can supplement Medicare Part D coverage. However, any third party payments for Part D enrollee cost-sharing will not count toward the Part D OOP limit for the individual. Qualified retiree health plans providing drug coverage at least actuarially equivalent to standard coverage to Part D eligible individuals (not enrolled in Part D) will receive subsidies of 28% of allowable covered prescription drug costs per enrollee, not including the deductible, up to $5,000 in drug spending in 2006 (indexed thereafter to the annual growth in average per capita spending by Medicare beneficiaries for Part D drugs). Subsidies will not be treated as income to plan sponsors for tax purposes.
Medicare supplemental coverage	No Medigap policies providing drug coverage may be sold, issued, or renewed after January 1, 2006, except renewals for non-Part D enrollees will be allowed. Part D enrollees who had Medigap policies covering drugs may continue in the policy, modified to remove the drug benefits with an appropriate adjustment in premium; or may enroll in a Medigap policy A, B, C, or F on a guaranteed issue basis (without preexisting condition exclusions), offered by the same issuer, if they apply during the Part D open enrollment period. Medigap issuers must provide written notice during 60 days before initial Part D open-enrollment period to each policyholder with drug coverage of their ability to continue in their current plan, as modified to remove drug coverage, or switch to a substitute guaranteed issue policy without drug coverage. The notice must also say whether the policy provides creditable coverage, and if it does not, notify them of the late enrollment penalty for enrolling in Part D outside the enrollment period. The Secretary will request NAIC to revise benefit packages to reflect changes in law, and define two new Medigap packages. The first package will provide coverage for 50% of Part A and B cost-sharing, except 100% for preventive benefits; no coverage of the Part B deductible; coverage of all hospital inpatient coinsurance and long-term hospital stays; and provide an annual out-of-pocket limit on cost-sharing of $4,000 in 2006 (indexed annually for inflation). The second package is similar except it covers 75% of cost-sharing and has a $2,000 annual out-of-pocket limit. States may not require insurers to participate as sponsors of Part D plans as a condition for issuing Medigap policies.
Medicaid	The federal government will assume the costs of providing Part D drugs to dual eligibles, but will require a financial maintenance of effort by states. States will be required to make a payment to the federal government each month equal to the product of: 1) a “take back” factor, which is set at 90% for 2006 and phased down to 75% for 2015 and later years; 2) the number of dual eligibles enrolled in Part D and full Medicaid coverage in that month; and 3) a per capita amount designed to approximate the amount a state would have spent each month on prescription drugs per full benefit dual eligible in the absence of the Medicare bill. This “per capita amount” is based on a state’s per capita Medicaid spending on Part D covered prescription drugs for full dual eligibles in 2003, trended forward through 2006 by the growth in national per capita prescription drug expenditures and in 2007 and later years by per capita growth in Part D spending. The Medicaid Qualified Individual (QI) program is extended through September 2004.

State Pharmaceutical Assistance Programs (SPAPs)	State Pharmacy Assistance Programs (SPAPs) may, at state option, provide supplemental drug coverage to Part D enrollees by purchasing extra benefits from a Part D drug plan or providing a supplemental benefit program. SPAP payments on behalf of enrollees count toward the Part D OOP threshold. Appropriates $62.5 million for each of FY2005 and 2006 to provide federal payments to SPAPs for enrollee education and counseling to facilitate awareness, selection and enrollment in Part D plans. Establishes a State Pharmaceutical Assistance Transition Commission three months after enactment to develop a proposal for addressing the unique transitional issues facing SPAPs and their participants due to implementation of Medicare Part D. The Commission is to have a representative of each state that the Secretary identifies as operating a statewide program providing eligibility and benefits at least comparable to the low-income assistance offered under Part D. It will also include representatives from other states with SPAPs; representatives of other interested organizations; representatives of MA organizations, PBMs, and other private insurers; and other members as the Secretary specifies. The Commission shall submit recommendations to Congress and the President by January 1, 2005. The Commission will terminate 30 days after the report is submitted.
Medicare Advantage (MA) and Enhanced Fee-for-Service (EFFS) plans	Part C (M+C) is renamed "Medicare Advantage" (MA) as the program for private plans participating in Medicare. The MSA plan option is made permanent and enrollment limits are eliminated. Effective January 1, 2006, MA plan sponsors (except MA private fee-for-service and MSA plans) must offer at least one plan in each of their service areas that includes basic Part D coverage or Part D coverage that includes supplemental benefits the costs of which are offset by a rebate for Part A and B benefits. MA organizations may offer additional plans with richer drug benefits. MA enrollees in Part D must receive Part D benefits from their MA plan (except MSA plan enrollees will get drug benefits from a PDP; and private FFS enrollees will receive benefits from a PDP if the plan does not offer Part D). Adds a new regional PPO plan option. Subsidies for Part D drug benefits provided through MA–PD plans are the same as for PDPs (including direct premium subsidies, and risk corridors and reinsurance). CBO estimates that the MA provisions will increase direct federal spending by $14 billion over 2004-2013.
Regional plans	Establishes new MA regional plans (PPO model) (and imposes a moratorium on new local MA PPO plans for 2006 and 2007) covering large, defined regions; with no limit on the number of plans per region. MA regional plans must serve an entire region (one of the 10 to 50 to be defined by the Secretary by January 1, 2005, based on a market survey); they may serve more than one region, or all regions. MA regional plans must include a single combined deductible for Part A and Part B benefits, a catastrophic limit on in-network Part A and B benefits, and a catastrophic limit for total Medicare Part A and B benefits in their benefit package. MA regional plan payments will be calculated in a similar manner as for local MA plans (see below) except for computation of the benchmark. They will share risk with the government through risk corridors in the first 2 years. A $10 billion stabilization fund is created to provide extra payments as incentives for regional MA plan entry and retention. The fund will also receive 50% of any savings to the government from regional plans with bids lower than the benchmark. Generally, regional MA plans must comply with standards applicable to local MA PPO plans.
Interim M+C plan payments (2004-2005)	In 2004, the M+C capitation rate for each area is the greater of rates under current law, or the adjusted average per capita cost (AAPCC) with direct medical education amounts removed and VA/DOD costs included. Budget neutrality does not apply to blend rates in 2004. Beginning in 2004, the minimum percentage increase is equal to the national per capita growth rate (excluding any adjustments made before 2004 for projection errors). Includes implementation provisions for payments in 2004. CBO estimates direct spending will increase by $1.3 billion during 2004-2005 for M+C provisions.
VA/DOD utilization by Medicare beneficiaries	VA/DOD costs are incorporated into the calculation of the capitation rates and the AAPCC in each area, beginning in 2004.
Risk adjustment	No change is made in implementation of health status risk adjustment (current law provides for a phase-in with 100% of rates to be subject to risk adjustment in 2007).

Plan payments (2006 forward)	MA plans (including new MA regional plans) submit bids for provision of Part A and Part B benefits (Part D drug benefits are bid and paid separately). Plan bids are compared to a benchmark calculated for the service area. Plans are paid the benchmark amount by the government. Plans with bids above the benchmark collect the difference directly from enrollees through premiums. Plans with bids below the benchmark must provide enrollees with 75% of the value of the difference between the bid and the benchmark through supplemental benefits; and/or a reduction in the Part B or Part D premiums. The Secretary is to provide a mechanism to consolidate enrollee premiums for Parts C (basic and supplemental benefits) and Part D.
Benchmark – MA and/or EFFS plans	The benchmarks for MA local plans are the average of the annual MA capitation rates for counties within each plan's service area, weighted by enrollment. Bids and benchmarks are risk-adjusted. The benchmark for MA regional plans are calculated in a similar manner, except that they blend MA area capitation rates with MA regional plan bids. The capitation rates are weighted by the FFS national market share rather than the region-specific FFS market share.
Premium support	Beginning in 2010, a "Comparative Cost Adjustment Program" is established as a demonstration to test competition between private plans and traditional Medicare. The demonstration is authorized for up to six years. No more than 6 metropolitan area demonstration sites can be selected, each having at least 2 private local plan options that together enroll at least 25% of the area's Medicare beneficiaries. Areas with different levels of private plan competition are to be selected. In the demonstration areas, the government contribution towards enrollment in traditional FFS Medicare or a private MA plan will be derived from a weighted average of FFS and local MA plan bids. Enrollees in plans below the average will receive premium reductions equal to 75% of the difference between the plan bid and the benchmark; those in plans costing more than the benchmark will pay the difference through an increase in their Part B premium. The impact on Part B premiums will be phased-in and in no case will be greater than 5% per year; Part B premiums for low-income beneficiaries will not be affected. The demonstration cannot be extended or expanded without Congressional action. CBO estimates the comparative cost adjustment provisions will reduce direct spending by $0.3 billion over the 2004-2013 budget period.

Transitional discount card program	Establishes a Medicare Prescription Drug Discount Card and Transitional Assistance Program to be implemented within 6 months of enactment. Card programs have to meet specific requirements and can charge up to a $30 annual enrollment fee. Card programs cannot serve only a portion of a state. Beneficiaries have a choice of at least 2 card programs (offered by 2 different sponsors) but can enroll in only one program at a time. Changing of card programs will only be permitted between 2004 and 2005, or in special circumstances. Permits the Secretary to limit (but not below two) the number of sponsors awarded contracts in a state. Card sponsors must pass on to card enrollees negotiated prices on covered drugs and disclose to the Secretary the extent to which negotiated price concessions are passed through to enrollees. Discount card drug prices do not apply to Medicaid "best price" requirements. Endorsed discount card sponsors must have meaningful grievance procedures. Endorsed discount card programs shall be considered covered entities for the purposes of HIPAA confidentiality rules (the Secretary may waive such privacy rules as appropriate for a limited time). Card sponsors may market products or services directly to enrollees only if the product or service is related to a covered drug; or to the discount price for a nonprescription drug. Special provisions are included for card sponsors that are MA plan sponsors or have cost contracts so that they may limit their card programs to their enrollees and their network pharmacies.
Transitional low-income assistance	Establishes a transitional assistance program. For discount card program enrollees with incomes <135% of poverty who do not have Medicaid or other drug coverage (except Medicare Part C), the government will pay the enrollment fee and provide $600 per year to enrollee card accounts to be used for drug expenses. Unused balances will carry forward to the next year. Subsidized enrollees with incomes <135% of poverty will still be required to pay 10% coinsurance on each prescription; or 5% in cases of those with incomes <100% of poverty. Benefits must be coordinated with SPAPs and MA plans. Provides for self-certification of eligibility for transitional assistance, under penalty of perjury, and subject to verification of eligibility through a method established by the Secretary. The Secretary shall establish procedures and waive requirements as necessary to provide transitional assistance to eligible beneficiaries residing in long-term care facilities. Allotments are provided for transitional assistance in the territories.
Other provisions related to drug coverage	Bill also includes pharmaceutical patent and importation provisions; changes the payment method for outpatient drugs covered under Medicare Part B; and provides for a demonstration of coverage of self-injected biologicals under Part B.
CBO 10-year estimate of changes in direct spending	$394.8 billion net change in direct spending: $409.8 billion for Medicare Rx benefit; $14.2 billion for health plan reforms; -$21.5 billion for fee-for-service provisions; -$13.3 billion for income-related Part B premium; $0.5 billion for administrative improvements; $5.7 billion for Medicaid and other provisions; -$0.6 billion for access to generic drugs. $0.5 billion net change in revenues: $7.2 billion increase in tax revenues due to drug benefit; -$6.7 billion decrease in tax revenues due to Health Savings Accounts.

DEFINITIONS

AAPCC: Adjusted Average Per Capita Cost. The AAPCC is a measure of the per-beneficiary costs of the required Medicare benefit services for a given county.

Contracting Entity: This term refers to the pharmacy benefit manager, health insurer, retail drug chain, or other qualified entity that would contract with Medicare to administer the new Medicare drug benefit.

CMS: The Centers for Medicare & Medicaid Services, formerly called the Health Care Financing Administration (HCFA), is part of HHS and is responsible for administering the Medicare and Medicaid programs.

Dual Eligibles: General term for low-income Medicare beneficiaries who qualify for some degree of Medicaid assistance. Dual eligibles who qualify for full Medicaid benefits are sufficiently poor to meet Medicaid's income and resource eligibility standards (i.e., they are receiving cash assistance through Supplemental Security Income (SSI) program or because their medical and long-term care expenses cause them to spend down to Medicaid eligibility levels). For these beneficiaries, states provide the full range of Medicaid benefits and generally pay Medicare's Part B premium. Other categories of dual eligibles who qualify for some but not full Medicaid assistance are:

> **QMBs:** Qualified Medicare Beneficiaries. A Medicare beneficiary with an income below 100% of the federal poverty level and with limited assets. Medicaid pays the Medicare Part B premium and all required cost-sharing under Medicare.
>
> **SLMBs:** Specified Low-Income Medicare Beneficiaries. A Medicare beneficiary with an income between 100% and 120% of the federal poverty level and with limited assets. Medicaid pays the Medicare Part B monthly premium for these individuals.
>
> **QIs:** Qualified Individuals. A Medicare beneficiary with an income between 120% and 135% of the poverty level and with limited assets. Medicaid pays the Medicare Part B monthly premium for these individuals. States receive annual allotments to cover these individuals and may cease to enroll otherwise eligible individuals if the allotments are insufficient.

FEHBP: The Federal Employees Health Benefits Program is the program of private health insurance options available to federal employees, annuitants, and dependents.

FFS Medicare: The original fee-for-service Medicare program, also sometimes referred to as "traditional Medicare."

HCFA: Health Care Financing Administration. This federal agency, recently renamed the Centers for Medicare & Medicaid Services (CMS), is part of HHS and is responsible for administering the Medicare and Medicaid programs.

HHS: U.S. Department of Health and Human Services.

M+C: Medicare+Choice. Medicare beneficiaries may currently elect to enroll in an M+C plan as an alternative to original, fee-for-service Medicare (also known as traditional Medicare), if such a plan is available in their area. An M+C plan is a private plan that has contracted with CMS to provide the Medicare benefit package for a capitated payment amount. A majority of M+C plans also offer benefits that are not covered by original Medicare, including coverage for outpatient prescription drugs.

Medigap: This is the common name given to a private health insurance policy designed to supplement the coverage provided by the original fee-for-service Medicare program and that meets certain federal standards. Medigap plans pay for some or all Medicare cost-sharing requirements. They may also reimburse for some services not covered by Medicare.

MSAs: Medical Savings Account plans. An MSA plan is a type of private plan that may be offered to Medicare beneficiaries as an alternative to traditional Medicare. An MSA plan would offer high deductible coverage in conjunction with an MSA account.

NAIC: The National Association of Insurance Commissioners is the trade association for the nation's state insurance commissioners. The NAIC develops model standards for insurance policies that are adopted on a voluntary basis by the states.

Reinsurance: As used in this legislation, the federal government would pay all or a percentage of claims once an individual enrollee's claims exceeded a pre-determined threshold. This is usually referred to as "individual" or "specific" reinsurance." This type of reinsurance differs from "aggregate reinsurance," where the federal government would pay all or a percentage of claims once a private plan's aggregate claims for all enrollees exceeded a pre-determined threshold.

Risk corridors: These are contractual safeguards that limit an insuring entity's risk of losing money but also limit its gains (profits). In a typical risk-corridor arrangement, a target would be established based on an estimate of the claims and administrative cost of a benefit. Gains or losses inside a risk corridor around that target would be the full responsibility of the insuring organization. Additional gains or losses beyond the risk corridor would be shared with or borne by, in the case of Medicare, the federal government.

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