

## Prescription Drug Coverage for Medicare Beneficiaries: A Summary of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Prepared by Health Policy Alternatives, Inc. for The Henry J. Kaiser Family Foundation

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Title of Bill	Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
General Approach	Voluntary drug benefit under Medicare Part D delivered through private riskbearing entities under contract with the Department of Health and Human Services (DHHS). Drug benefits provided through stand-alone prescription drug plans (PDPs) or comprehensive plans, integrated with enhanced Part A and B benefits, under Part C (renamed Medicare Advantage (MA)). Government fallback plan authorized for areas without sufficient plan choices. Also provides subsidies for drug coverage to enrollees in qualified retiree plans. Establishes a demonstration for a Medicare competitive government contribution system (Comparative Cost Adjustment Program) beginning in 2010 that includes traditional Medicare.  Interim prescription drug discount card program (2004-2005) with subsidies for the low-income who do not have other drug coverage.
Effective Date	1/1/2006 for Part D benefit.
Eligibility	Individuals entitled to Part A or enrolled in Part B may enroll in Part D.
Benefit Package	All Part D Medicare PDPs and Medicare Advantage prescription drug (MA-PD) plans must offer at least the standard drug coverage or its actuarial equivalent (called "basic" coverage). Actuarially equivalent plans may not have a deductible larger than the standard deductible, and the out-of-pocket threshold must be the same. PDP and MA plan sponsors may also offer separate plans with richer coverage.
Monthly Premium	Part D standard coverage – CBO estimate of \$35 per month on average in first year (2006) and increasing to \$58 per month in 2013 – based on enrollee's choice of plan. For late enrollment, the premium amount is increased by the greater of an amount the Secretary determines is actuarially sound or one percent for each month the individual did not have creditable coverage after the end of the individual's initial enrollment period. For MA plans, the drug premium is calculated in the same way, but may be offset by savings from Part A and B benefits.  At enrollee option, Part D premiums may be paid directly to the PDP or MA plan, deducted from beneficiary's Social Security check, or paid through an electronic funds transfer.

Deductible	\$250 in 2006 (indexed to grow annually by the growth in per capita Part D drug spending by Medicare beneficiaries). Estimated to be \$445 in 2013.
Cost-Sharing	25% above the deductible and up to initial coverage limit (\$2,250 in 2006 increasing to an estimated \$4,000 in 2013), or actuarially equivalent copayments. Enrollee pays 100% of negotiated price between initial limit and stop-loss threshold; greater of \$2 generics/\$5 brand copays or 5% coinsurance above stop-loss threshold. (Thresholds are indexed to grow annually by the growth in per capita Part D drug spending by Medicare beneficiaries.)
Stop-Loss Threshold Applied to Out-of-Pocket Spending	\$3,600 in 2006 (\$5,100 in total Rx spending), increasing to \$6,400 (\$9,066 in total Rx spending) in 2013. After reaching threshold, enrollee pays greater of \$2 generics/\$5 brand drugs (indexed as above), or 5% coinsurance. Excludes cost of drugs not on (or treated as being on) plan's formulary. Also excludes payments from other private insurance, such as employer retiree health coverage.
Government Subsidies for General Medicare Population	Overall federal subsidy is 74.5% of the basic Part D coverage, provided through direct premium subsidies and reinsurance. Plans receive reinsurance for 80% of benefit costs for standard drug coverage (including dispensing costs but excluding administrative costs) above stop-loss threshold.
Government Subsidies for Low-Income Population— Premiums	All Medicaid full benefit dual eligibles (regardless of income and assets) are eligible for a full premium subsidy. Other enrollees with incomes below 135% of poverty and who meet asset test receive a full premium subsidy. The subsidy is equal to the weighted average premium for basic benefits available in the region (but in no case less than the lowest-cost plan available). The asset test is \$6,000 single/\$9,000 couple in 2006 (indexed to increase annually with inflation). (The government will also subsidize most of any late enrollment penalties.) All other beneficiaries with incomes below 150% of poverty and who meet an asset test of \$10,000 single/\$20,000 couple (indexed to inflation) will receive premium subsidies based on a sliding scale.
Government Subsidies for Low-Income Population— Cost-Sharing	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 out-of-pocket 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 out-of-pocket threshold. However, 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 out-of-pocket 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.
Treatment of Dual Eligibles	As of January 1, 2006, states will no longer be able to receive federal Medicaid matching funds to cover prescription drugs (including Part D costsharing and drugs excluded from Part D coverage due to a Part D plan's formulary) for dual eligibles, except to provide coverage for classes of drugs not covered by Medicare Part D (e.g., over-the-counter drugs). Medicaid full benefit dual eligibles will be eligible for Medicare Part D and will be considered eligible for the low-income premium and cost-sharing subsidies described above, regardless of their income or assets. QMBs, SLMBs, and QIs will be eligible for Part D and may be deemed eligible for low-income premium and cost-sharing subsidies if the Secretary determines the state applies substantially the same eligibility requirements as provided for Part D. i
Administration of the Low-Income Subsidy	Eligibility for low-income subsidies will be determined by state Medicaid programs, with states receiving their regular matching rate for associated administrative costs. Eligibility determinations will also be made by the Social Security Administration (SSA), with \$500 million appropriated through FY 2005 to cover new administrative costs. Determinations effective for up to one year. A model, simplified application form will be developed to allow for beneficiary attestation of assets (accompanied by recent statements, if any, from financial institutions), subject to penalty for perjury. The Secretary will inform PDPs and MA-PD plans of subsidy eligibility and level. Plans provide the subsidy, and the Secretary reimburses them for their costs, which may be on a capitated basis.
Role of Private Plans/Traditional Medicare  Role of Fallback plan	Benefits provided through private, risk-bearing plans (shared risk with government through risk corridors in first years and reinsurance). Provides for limited risk plans if necessary to guarantee at least two plan options offered by different entities (at least one PDP) in each area. Secretary contracts with private entities for fallback plans for areas within regions failing to meet minimum plan access standard. Fallback plans must offer standard benefit, and accept management fees tied to performance risk. Fallback plan enrollee premiums equal to 25.5% of estimated average per capita costs (including administrative expenses) of providing drug benefits in region. Prohibits a national fallback plan.
Payments to Drug Plan Sponsors	Part D plans will receive an amount equal to the monthly-approved bid, adjusted for risk and geographic price variations. Payment will be a combination of government contribution and enrollee premium (paid directly

	to plan or through the government). Government shares risk with drug plans through reinsurance (80% of allowable drug costs exceeding the stop-loss threshold) and risk corridors. Drug plans would be required to assume more, but not total, risk over time.  Medicare Advantage plans receive payments for drug coverage in a similar manner and also receive reinsurance payments.
Covered Drugs	Drugs, biological products and insulin (and medical supplies associated with the injection of insulin as defined by the Secretary) that may be dispensed only by prescription and 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 would be drugs for which benefits are payable 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 Part D or plan requirements, could be excluded from coverage, but determinations would be subject to reconsideration and appeal.
Formularies	Plans may have a formulary, so long as the formulary meets standards. A formulary must be developed and reviewed by a pharmacy and therapeutic (P&T) committee that includes at least one practicing physician and one practicing pharmacist, each independent and free of conflict with the plan; and with expertise in the care of elderly or disabled. A majority of P&T committee must be practicing physicians or pharmacists. Formulary must include drugs within each therapeutic category and class as defined by the plan; plans may change categories and classes only at the beginning of the plan year except as allowed to account for new drugs or therapeutic uses. The United States Pharmacopeia will develop model categories and classes that may be used by plans. Plans that use the model may not be found by the Secretary to be in violation of antidiscrimination requirements regarding plan design. The P&T committee must have procedures to educate enrollees and providers concerning the formulary. Appropriate notice must be made to enrollees, pharmacists, pharmacies, and physicians before a drug is removed from the formulary or the tier status is changed.
Access to Drugs Not on Formulary or Preferred Drug List	Enrollees may appeal for coverage of non-formulary drugs only if the prescribing physician determines that all drugs on any tier of the formulary for treatment of the same condition would not be as effective for the patient, or

would have significant adverse effects for the patient, or both. In plans with tiered cost-sharing, plans must have an exceptions process to allow an enrollee to request a non-preferred drug to be covered as a preferred drug if the prescribing physician determines that the preferred drug either would not be as effective for the patient, or would significant adverse effects for the patient, or both. Denials are subject to appeal by the enrollee. The appeals process requirements are the same as apply under Medicare Part C, including external independent review and appeals to the Secretary and judicial review (subject to the same minimums for amounts in controversy). **Drug Pricing** Plans would negotiate prices with manufacturers and suppliers of covered drugs and with pharmacies. Enrollees must have access to their plan's negotiated prices even if no benefits are paid. Negotiated prices must take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and include any dispensing fees. Each plan must disclose to the Secretary the aggregate negotiated price concessions made available by a manufacturer. The Secretary would have to keep this information confidential. Plan sponsors must provide that each pharmacy that dispenses a covered drug inform the enrollee at the time of purchase (or at the time of delivery for mail order) of any differential between the price of the drug and the price of the lowest-cost generic that is therapeutically equivalent and bioequivalent and available at the pharmacy. Drug prices negotiated for Medicare beneficiaries by a PDP, MA-PD plan, qualified retiree plan, or endorsed discount card program will not be applicable to Medicaid "best price" provisions. **Medicaid Financing** All individuals eligible for Part A or enrolled in Part B are eligible for Part D drug benefits, including those who are also enrolled in Medicaid. States may continue to provide coverage for classes of drugs not covered under Part D and receive federal matching payments. 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 Medicaid 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.

■ Best Price Requirements	The Medicaid Qualified Individual (QI) program is extended through September 2004.  Prices negotiated for the Medicare Prescription Drug Discount Card program or for Medicare Part D benefits by a PDP under Part D, by a MA-PD plan under Part C, by a qualified employer plan, or by a Medicare endorsed discount card program, would not apply to Medicaid "best price" requirements.
Treatment of Retiree Health Drug Coverage	Qualified retiree plans with drug coverage at least actuarially equivalent to standard Part D coverage will receive subsidies of 28% of costs for coverage above \$250 and up to \$5,000 in 2006 in spending per Medicare enrollee (indexed thereafter in same manner as Rx deductible and stop-loss threshold). Enrollees receiving Medicare drug subsidies through their qualified retiree plan may not enroll in Part D. Payments would not be taxable as income to employers and would be fully deductible.
Medicare Supplemental Insurance	No Medigap policies providing drug coverage may be sold, issued, or renewed after January 1, 2006, except renewals for non-Part D enrollees would 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 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. NAIC would revise benefit packages to reflect changes in law, and define two new Medigap packages. The first package would cover 50% of cost-sharing, except 100% for preventive benefits; no coverage of the Part B deductible; coverage of 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 would be similar except it would cover 75% of cost-sharing and have 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.
State Pharmacy Assistance Programs	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 a Part D enrollee will count towards the individual's

	Part D stop-loss 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. Must submit recommendations to Congress and the President by January 1, 2005.
Interim Drug Program	Establishes a Medicare Prescription Drug Discount Card and Transitional Assistance Program to be implemented within six months of enactment. Card programs would have to meet specific requirements and could charge up to a \$30 annual enrollment fee. Beneficiaries would have a choice of at least 2 card programs (offered by two different sponsors) but can enroll in only one program at a time. Permits Secretary to limit (but not below two) number of sponsors awarded contracts in a state. For discount card program enrollees with incomes <135% of poverty who do not have Medicaid (except the medically needy as provided by the Secretary) or drug coverage, the government would pay the enrollment fee and deposit \$600 to enrollee card accounts to be used for drug expenses. Subsidized enrollees with incomes <135% of poverty would still be required to pay 10% coinsurance on each prescription; or 5% in cases of those <100% of poverty. Card sponsors would have to pass on to card enrollees negotiated prices on covered drugs and disclose to Secretary extent to which negotiated price concessions are passed through to enrollees. Discount card drug prices would not apply to Medicaid "best price" requirements.
Financing of Drug Benefit	Medicare Part D subsidies will be financed by general federal revenues, and maintenance of effort payments by states (see Medicaid Financing above).
Medicare Private Plan Reforms Not Related to Drug Coverage	Renames Part C, Medicare+Choice, as Medicare Advantage (MA) and reforms plan payment method. Increases payments to MA plans beginning in 2004, establishes new payment method beginning in 2006. Establishes a 6-year demonstration of comparative cost adjustment (CCA) program beginning in 2010 that includes traditional Medicare.
Regional Plans	Establishes regional PPO option beginning in 2006 ("MA Regional Plans"). These plans must serve one or more MA regions (the Secretary will establish between 10 and 50). An organization could offer a plan(s) in all regions. They would have to be licensed in at least one state in which they operate and have applications pending for licensure in other applicable states. No limit on number of plans per region. MA regional plans must offer a single deductible for Part A and B benefits, catastrophic out-of-pocket limits for in-network Part A and B benefits and catastrophic limits for all Part A and B out-of-pocket

expenditures. Establishes a Stabilization Fund of \$10 billion for 2007 through 2013 (plus 50% of any savings generated by plans costing less than the benchmark) to provide enhanced payments to MA regional plans to encourage plan entry and retention. Provides for risk—sharing with government in 2006 and 2007 through risk corridors. Plans paid on basis of plan bids in relation to a benchmark (a blend of MA area benchmarks and MA regional plan bids within a region) in same manner as all MA plans (see below).
In 2004 and 2005, the capitation rate for each area would be the greater of current law rates or the adjusted average per capita cost (AAPCC) with direct medical education amounts removed and VA/DOD costs included. Budget neutrality would not apply to blend rates in 2004. Beginning in 2004, the minimum percentage increase would be the greater of a two percent increase or the national per capita MA growth rate (excluding any adjustments made before 2004 for projection errors).
VA/DOD costs for care provided to Medicare beneficiaries would be incorporated into the calculation of the capitation rates and the AAPCC in each area beginning in 2004.
No change is made in implementation of risk adjustment (current law provides for a phase-in with 100% of rates to be subject to risk adjustment in 2007).
Beginning in 2006, a benchmark for providing Part A and B benefits will be computed for each region (see above) and for each local MA plan service area. Each MA plan's bid would be compared to the applicable benchmark. Plans with bids above the benchmark would be paid the benchmark and collect any additional amounts 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 reduction in premium for Part D or for extra benefits; cash; or other means approved by the Secretary. The Secretary must provide a mechanism to consolidate enrollee premiums for Parts C and D.  Plans must allow, at enrollee option, for premiums to be paid through deduction from Social Security checks, through an electronic funds transfer method, or otherwise.
The benchmarks for MA plans for Part A and Part B benefits would be the weighted average of the annual MA capitation rates for counties within each plan's service area (for MA regional plans, the service area is the region). Bids and benchmarks would be adjusted for demographics and health status risk.

"Premium Support" System	Beginning in 2010, establishes a "Comparative Cost Adjustment Program," a demonstration to test competition between local private MA plans and traditional Medicare that would be implemented for six years. No more than six metropolitan area demonstration sites would be selected, each having at least two private local plan options that together enroll at least 25% of beneficiaries. Areas with different levels of private plan competition would be selected. In the demonstration areas, the government contribution towards enrollment in traditional FFS Medicare or a private MA plan would be derived from a weighted average of FFS and local MA plan bids.  Enrollees in plans below the average would receive premium reductions equal to 75% of the difference between the plan bid and the benchmark; those in plans costing more than the benchmark would pay the difference through an increase in their Part B premium. The impact on Part B premiums would be phased-in and in no case could be greater than 5% per year; premiums for low-income beneficiaries would not be affected. The demonstration could not be extended or expanded without Congressional action.
New Part B preventive benefits	Authorizes Medicare coverage of an initial preventive physical examination, subject to deductible and beneficiary cost-sharing. A covered initial preventive physical examination is one performed no later than six months after the individual's initial coverage date under Part B. Applies to services furnished on or after January 1, 2005, but only for those individuals whose coverage begins on or after such date.  Cardiovascular disease screening: Provides for Medicare coverage of cardiovascular disease screening blood tests, effective beginning January 1, 2005.  Diabetes screening: Provides for Medicare coverage of diabetes screening for at-risk individuals, effective beginning January 1, 2005.
Part B deductible	Increases the annual Part B deductible from \$100 to \$110 for 2005 and then increases it by the same percentage as the Part B premium increase. Estimated to be \$115 in 2006 and increase to \$166 by 2013.
Part B premium	Provides for income-relating the Part B premium beginning in 2007 for higher-income beneficiaries. These beneficiaries will see a reduction in the government subsidy of their Part B premium from the 75% currently provided. The reduction is phased-in (in equal increments) over five years. The schedule for the changes in the premium subsidy is: \$80,000 -\$100,000: 65% \$100,000-\$150,000: 50%

	\$150,000-\$200,000: 35% Above \$200,000: 20%. Income thresholds reflect income for 2007 and then are indexed to increase annually by the Consumer Price Index (CPI). Thresholds for married couples are twice the amounts shown. An estimated 3% of Part B enrollees will be affected in 2007 increasing to 6% in 2013.
Administration	No new agency is established. Authorizes a center within CMS to coordinate administration of Parts C and D. Requires an actuary dedicated to Parts C and D.
CBO 10-Year Estimate of Changes in Direct Spending	\$395 billion net change in direct spending: * \$410 billion for Medicare Rx benefit; \$14 billion for Medicare Advantage health plan provisions; -\$22 billion for fee-for-service provisions; -\$13 billion from income-related Part B premium; -\$1 billion for regulatory reform; \$6 billion for Medicaid and other provisions; -\$1 billion drug patent changes *All estimates rounded to nearest billion.

QMB, SLMB, and QI refer to categories of Medicare beneficiaries who are not sufficiently poor to meet Medicaid's income and resource eligibility (i.e. "asset test") standards for full Medicaid benefits but do qualify for some degree of Medicaid assistance with Medicare cost-sharing. The asset test varies from state to state but is generally \$4,000 per individual/\$6,000 per couple, excluding certain items such as a home. Specifically:

**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 Part A and Part B 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 federal poverty level and with limited assets. Medicaid pays the Medicare Part B monthly premium for these individuals. States receive capped allotments for these individuals, so participation may be limited by available funds.



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