PRESCRIPTION DRUG COVERAGE FOR MEDICARE BENEFICIARIES

Summary of the Proposed Rule to Implement the Medicare Prescription Drug Benefit (Title I of the Medicare Modernization Act of 2003)

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

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OVERVIEW

In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173), referred to as the Medicare Modernization Act or MMA. Title I of the MMA establishes a new Part D of Medicare, which will provide an outpatient prescription drug benefit beginning in January 2006.

On August 3, 2004, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the *Federal Register* (69 FR 46631) that contains the regulations to implement the Medicare Prescription Drug Benefit (Title I of the MMA). Public comments were due to CMS on October 4, 2004, and the final regulations for Title I are expected to be published early in 2005. Given the high level of interest in the regulations for implementing the Medicare drug benefit, Health Policy Alternatives, Inc. prepared a summary of the proposed rule for The Henry J. Kaiser Family Foundation, so that interested readers can quickly obtain information about how CMS proposes to implement the drug benefit.

The proposed rule for the drug benefit was divided into several subparts, corresponding to the various sections of the MMA that address the Part D prescription drug benefit program. This summary document outlines the main topics in each subpart, along with issues raised in the preamble to the proposed regulation corresponding to each subpart. In the preamble, CMS identifies various options being considered to implement certain features of the law and also seeks public comment on how best to address certain issues. Many of the areas that fall within the discretionary regulatory authority of CMS have yet to be addressed, pending the receipt and consideration of the public comments. Also certain issues in Title I, such as designation of the geographic regions for delivery of the drug benefit and the procedures for risk adjustment of payments to plans, are being addressed through separate regulations or guidance. Information from CMS's announcement on December 6, 2004 of the prescription drug plan service areas is included in this summary.

This summary document will be updated shortly after the final rule is published to reflect decisions made by CMS after consideration of the public comments on the proposed rule. Other decisions issued by CMS through separate guidance may also be included.

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Subpart A: General Provisions

PROPOSED RULE	PREAMBLE
§423.4 Definitions. • *Actuarial equivalence:* a state of equivalent value demonstrated through the use of generally accepted actuarial principles using processes and methods established through CMS guidelines. • *Brand name drug:* a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act. (A brand name drug is a drug marketed under a proprietary, trademark-protected name.) • *Fallback prescription drug plan: Brand name drug:* a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act. (A brand name drug is a drug marketed under a proprietary, trademark-protected name. • *Fallback prescription drug plan*: a prescription drug plan (PDP) offered by a fallback entity that: o Offers only standard prescription drug coverage; o Provides access to negotiated prices; and o Meets other requirements as specified by CMS in subpart Q. • *Formulary*: the entire list of Part D drugs covered by a PDP sponsor's or MA organization's drug plan. • *Full benefit dual eligible individual:* an individual who, for any month: o Has coverage for the month under a PDP or MA-PD plan; and o Is eligible for full Medicaid benefits for the month under any eligibility category in the State plan or a Section 1115 demonstration (not including Pharmacy Plus demonstrations). Also includes any individual determined by the State to be eligible for medical assistance as medically needy for any month if the individual was eligible for medical assistance in any part of the month. • *Generic drug*: a drug approved by the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). (A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.) • *Insurance risk:* for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State, does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (e.g., labor costs or productivity). • *MA*: Medicare Advantage, which refers to the program authorized under Medicare Part C. • *MA plan*: health benefits coverage offered under a policy or contract with Medicare by an MA organization. • *MA-PD plan*: an MA plan that provides qualified prescription drug coverage. • *Medicare prescription drug account:* the account created within the Federal Supplementary Medical Insurance (SMI) Trust Fund for purposes of Medicare Part D. • *Part D eligible individual*: an individual who is entitled to or enrolled in Medicare Part A and/or Part B. • *PDP region:* a prescription drug plan region as determined by CMS. • *PDP sponsor*: a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. • *Prescription drug plan or PDP:* prescription drug coverage that is offered under a policy, contract, or plan that has been approved by CMS and is offered by a PDP sponsor that has a contract with CMS that meets contract requirements.	The actuarial equivalence concept is applied in 3 different contexts in the law: 1. Definition of creditable coverage; 2. The value of Part D coverage and bid components; and 3. Qualified retiree coverage. In each context the term will be defined from the perspective of the beneficiary or the plan. CMS defines it very generally in the proposed regulation and expects to provide future guidance.

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• *Service area:* for purposes of eligibility to enroll to receive Part D benefits: o For a PDP, an area of one or more PDP regions; and o For an MA-PD plan, an area that meets the definition of an MA service area. • *State Pharmaceutical Assistance Program (SPA*P): a program (other than Medicaid) operated by a State (or under contract with a State) that: o Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals; o Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls; o Meets the benefit coordination requirements specified in subpart J of this part; and o Does not change or affect the primary payor status of a Part D plan. • *Subsidy-eligible individual:* a Part D eligible individual who enrolled in a PDP or MA-PD plan and who has an income below 150% of the poverty level and meets the resource requirements specified in subpart P. • *Tiered cost-sharing:* a process of grouping Part D drugs into different cost sharing levels within a PDP sponsor's formulary.	
§423.6 Cost-sharing in beneficiary education and enrollment-related costs. • The requirements pertaining to the payment of fees established by CMS for cost-sharing of enrollment related costs that apply to MA plans (§422.6) also apply to PDP sponsors under Part D.	Fees are used to defray part of the costs of the national beneficiary education campaign, including dissemination of print materials, the 1-800-MEDICARE telephone line, Medicare.gov web site, support for State health insurance assistance programs (SHIPS), and other activities. Annually, up to $200 million in fees will be allocated between PDPs and MA plans in the same proportion as their share of aggregate Part C and Part D expenditures to total Medicare expenditures. Assessments on plans are based on a formula that calculates each plan sponsor's proportion of total expenditures to expenditures for all plans in the category (i.e., PDPs or MA plans).

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart B: Eligibility and Enrollment

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§423.30 Eligibility to enroll. • A beneficiary must reside in the PDP or MA-PD plan's service area MA enrollees may not enroll in a PDP except for those in a PFFS or MSA plan.	Individuals residing abroad or incarcerated would not have late enrollment penalty.
§423.34 Enrollment process. • To enroll, an individual must complete the PDP's enrollment form or other process permitted by CMS. • PDP sponsors must: o Enroll all eligible individuals who elect the plan during enrollment periods, o Process the enrollment request according to CMS guidelines. o Provide prompt notice of acceptance or denial in a format and manner specified by CMS.	Full benefit dual eligibles who do not elect a PDP or MA-PD will be auto-enrolled on a random basis.
§ 423.36 Enrollment periods. • Establishes initial enrollment periods: o November 15, 2005 through May 15, 2006, (for those first eligible prior to January 31, 2006),. o For those first eligible for Part D in February 2006, November 15, 2005 through May 31, 2006. o Upon becoming eligible for Medicare in March 2006, the same as the individual's initial enrollment period for Part B, (or 3 months before and after the month of Part D eligibility). • Establishes special enrollment periods (SEPs) for: o Involuntary loss of creditable coverage; o Persons not adequately informed about the status of creditable coverage; o Unintentional, inadvertent, or erroneous enrollment or nonenrollment due to a federal employee's action; o Full benefit dual eligible individuals; o Individuals who disenroll from an MA-PD plan during the first year of MA plan eligibility; o Individuals enrolled in PDPs when PDP sponsor's contract is terminated; o Individuals who no longer reside in PDP service area; and o Individuals who experience a substantial breach of contract by their plan.	SEP allowing continuous open enrollment period for institutionalized individuals will be established through manual instructions. Clarifies that a full benefit dual eligible individual enrolled in an MA-PD plan will generally be auto-enrolled into that plan.
§ 423.38 Effective dates. • Plan elections made: o Prior to Medicare entitlement or enrollment will be effective the first day of the month of entitlement or enrollment. o During or after the month of entitlement/enrollment will be effective the first day of the month following Part D enrollment, or following Part D eligibility. • Elections made during the annual coordinated election period will be effective the first day of the following calendar year, except for January 1, 2006 through May 15, 2006, when elections will be effective the first day of the calendar month following enrollment. • SEP enrollments will be effective as determined by CMS.	

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§ 423.42 Coordination of enrollment and disenrollment through PDPs. • To disenroll, an individual may: o Enroll in another PDP; o File a disenrollment request as prescribed by CMS; or o Disenroll through other CMS approved mechanisms. • PDP sponsors are responsible for: o Submitting disenrollment notices to CMS within specified timeframes; o Providing notice to the enrollee; and o Filing and retaining disenrollment requests for a CMS specified period. • Retroactive disenrollment may be granted by CMS if: o There was never a valid enrollment; or o A valid disenrollment request was not acted upon. • Maintenance of enrollment: individuals remain enrolled until the individual: o Successfully enrolls in another PDP; o Voluntarily disenrolls from the PDP; o Is involuntarily disenrolled from the PDP; or o The PDP is discontinued.	
§ 423.44 Disenrollment by the PDP. • PDP sponsors may not involuntarily disenroll individuals or request or encourage disenrollment. • Exceptions when PDP may disenroll: o Nonpayment of premium in timely manner;* o Disruptive behavior by enrollee.* • Exceptions when PDP must disenroll: o Enrollee no longer resides in service area;* o Enrollee loses Medicare entitlement (CMS will notify the PDP); o Enrollee dies; o PDP sponsor terminates contract with CMS (enrollee notice required as specified by CMS);* o Enrollee materially misrepresents information on third party coverage (CMS makes determination; PDP may decline future enrollment; enrollee may reenroll in a PDP at next annual election period.) • Timely notice including reason for disenrollment and notice of right to a grievance hearing must be given for circumstances marked with *. • Disenrollment process for nonpayment of premiums requires sponsor to demonstrate reasonable collection efforts and compliance with notice requirements. Sponsor may not allow individual to reenroll until all past premiums are paid. • Disruptive behavior is behavior that: o Jeopardizes the health or safety of the person or others; o Impairs sponsor's ability to furnish services to the person or others; o Does not comply with the material terms of the enrollment agreement. • PDP sponsor must document the behavior to CMS and efforts to resolve problems. CMS decides. • Disenrollment is effective the first day of the following month. PDP may decline future enrollment by the	*Seeks comments on whether plans disenrolling a beneficiary for disruptive behavior, nonpayment of premiums, or misrepresentation of 3rd party reimbursement should be permitted to refuse to reenroll the beneficiary, as is the case in the MA program.*

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person. CMS may consider an expedited process in certain circumstances.	
§ 423.46 Late enrollment penalty. • A late enrollment penalty applies when there is a period of 63 days or longer when the individual was not enrolled in a PDP and did not have creditable coverage.	
§ 423.48 Information about Part D. • Each plan must annually provide CMS specified information necessary for beneficiaries to make informed decisions among plans.	Information would be provided to beneficiaries at least 30 days before their initial enrollment period and annually thereafter in connection with the annual coordinated election period. Public information campaign would include: outreach, information, mailings, and enrollment assistance with and through appropriate Federal and state agencies, including state health insurance assistance programs (SHIPS) with special efforts to ensure that low-income individuals know of additional benefits for them, and to reach disadvantaged and historically underserved populations. Information would be available in Spanish and, when appropriate, other languages. Proposes extending Medicare.gov price comparison website to PDP and MA-PD plans, as well as the 1-800-MEDICARE toll free phone line.
§423.50 Approval of marketing materials and enrollment forms. • Plan marketing materials or enrollment forms may not be distributed unless they have been submitted to CMS 45 days prior to use (10 days if using CMS model language) and they are not disapproved. o Plan sponsors meeting CMS performance requirements may use materials 5 days after submission if not disapproved. • Marketing materials include materials that; o Promote the PDP; o Provide information on enrollment; o Explain benefits or rules; o Explain covered services. o Examples of marketing materials are provided. • CMS review guidelines include provision of adequate written: o Description of rules, benefits, fees; o Explanation of grievance and appeals process; o Other necessary information; o Appropriate notification of the public of the enrollment period;	*Seeks comments on whether it is appropriate to preclude acceptance of enrollment forms at pharmacies the way providers are precluded from accepting MA enrollment forms. Seeks comments on advisability of allowing PDP sponsors to provide additional products (such as financial services) to further assist beneficiaries to manage their drug expenses and on appropriate limitations on such activities.* *Seeks comments on questions about how to implement provision allowing CMS to share identifying information on beneficiaries with drug plans in order to facilitate marketing of drug coverage: What type of information would facilitate? Should beneficiaries be given*

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o Notice of potential plan termination; and o Materials that are not materially inaccurate or misleading; o Materials using language(s) appropriate for the population of the market area. • Materials not disapproved in one region are deemed approved in other regions except for region-specific information. • PDPs may not: o Provide cash or other enrollment inducements; o Engage in discriminatory activity such as targeted marketing based on income; o Solicit door-to-door; o Confuse or mislead beneficiaries, including claiming they are recommended or endorsed by CMS; o Use providers to distribute PDP comparison information unless all plans involved concur and CMS approves; o Accept enrollment forms where health care is delivered; o Use names that imply a plan is not open to all beneficiaries; and o Engage in other CMS prohibited marketing activities. • PDPs must: o Allocate marketing resources to the disabled population; and o Maintain an enrollment system.	*opportunity to block? Should use of information be limited to written contacts or include telephone contacts? Should information be shared only upon request? Only at scheduled times of year? CMS indicates that since the statute permits such sharing, it would not violate HIPAA.*
§423.56 Procedures to determine and document creditable status of prescription drug coverage. • Definition of creditable coverage: any of the following with an actuarial value at least equal to standard coverage; o PDP or MA-PD plans; o Medicaid; o Group health plans including FEHBP, and qualified retiree plans; o Supplemental drug coverage programs; o Veterans benefits; o Medigap; o TRICARE and military coverage; o Individual health insurance; and o Indian health service benefits. • All of the above except PDP or MA-PD plans must disclose to Medicare enrollees in form prescribed by CMS the actuarial value of drug benefits. • If coverage is not creditable, these plans must disclose: o Fact that the actuarial value does not meet requirements; o Limited periods for PDP enrollment; and o Possibility of late enrollment penalty. • These plans must also disclose creditable coverage status to CMS. • If an individual is not adequately informed, he/she may apply to CMS to have coverage treated as creditable.	Proposes to determine whether alternative coverage meets the test of actuarial equivalence to the standard Part D benefit by comparing the average expected payout under such coverage (or, in the case of employment-based group health plans, under all benefit packages offered by the employer) to the average expected payout under the standard Part D benefit. Proposes to accept attestation of actuarial equivalence if an entity documents it, submits documentation to CMS, and makes documentation available to enrollees. *Seeks comments on whether there are other forms of coverage that should be treated as creditable coverage.*

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart C: Benefits and Beneficiary Protections

PROPOSED RULE	PREAMBLE
§423.100 Definitions. • *Alternative prescription drug coverage:* coverage other than standard prescription drug coverage that is either (1) basic alternative coverage (alternative coverage that is actuarially equivalent to defined standard coverage), or (2) enhanced alternative coverage. • *Basic prescription drug coverage:* standard prescription drug coverage or basic alternative coverage. • *Bioequivalent*: has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act. • *Covered Part D drug:* **includes** any of the following if used for a medically accepted indication (as defined under Medicaid in section 1927(k)(6) of the Act): o A drug that may be dispensed only upon a prescription (described in Medicaid sections 1927(k)(2)(A)(i) through (iii)); o A biological product (described in Medicaid sections 1927(k)(2)(B)(i) through (iii)); o Insulin (described in Medicaid section 1927(k)(2)(C)); o Syringes, needles, alcohol swabs, and gauze associated with insulin injection; or o A vaccine licensed under section 351 of the Public Health Service Act. • **Does not include:** o Drugs for which payment as so prescribed and dispensed or administered to an individual is available with respect to that individual under Parts A or B (even though a deductible may apply, or even though the individual is eligible for coverage under Parts A or B but has declined to enroll in Parts A or B); and o Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid pursuant to sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents. • *Group health plan:* has the meaning given such term in Sec. 411.101 (any arrangement made by one or more employers or employee organizations to provide health care to current or former employees, the employer, others associated with the employer in a business relationship, or their families. Includes self-insured plans, governmental plans, and union or employee organization plans. Also includes employee-pay-all plans but does not include a plan that is unavailable to employees; e.g., only for self-employed. • *Incurred costs:* costs incurred by a Part D enrollee for covered Part D drugs covered under (or treated as covered under) a PDP or MA-PD plan: o That are not paid for under the plan as a result of application of cost-sharing rules, and o That are paid for by the enrollee or on behalf of the enrollee by another person (and are not reimbursed through insurance or other third party payment arrangement), under a State Pharmaceutical Assistance Program, or through Part D low-income subsidies. • *Insurance or otherwise:* means a plan (other than a group health plan) or program that provides, or pays the cost of, medical care including any of the following: o Health insurance coverage as defined in HIPAA (42 U.S.C. 300gg-91(b)(1); o An MA plan; o A program of all-inclusive care for the elderly (PACE); o An approved State child health plan (SCHIP); o Medicaid (including under a section 1115 waiver);	CMS considering the exclusion of outpatient drugs for which a manufacturer requires tests or monitoring services be purchased from the manufacturer. The regulation excludes coverage under Part D if the individual "is eligible for coverage under Parts A or B but has declined to enroll." *Seeks comments re: any drugs that may require specific guidance with regard to their coverage under Part D and gaps that may exist in the combined "Part D & B" coverage package.* *Seeks comments on definition of dispensing fee for home infusion therapy.* Offers options: (1) Include only activities related to the transfer of possession of the drug from the pharmacy to the beneficiary, including charges for mixing drugs, delivery, and overhead. (2) Include Option 1 plus amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be administered. (3) Include Options 1 and 2 plus activities for assuring proper administration of the drugs, such as skilled nursing visits and ongoing monitoring by a clinical pharmacist.

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o Veterans health care program; and o Any other government-funded program that directly provides health care to individuals. • *I/T/U pharmacy*: a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization. • *Long-term care facility:* a skilled nursing facility, as defined in Medicare section 1819(a), or nursing facility, as defined in Medicaid section 1919(a). • *Long-term care pharmacy:* a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents. • *Long-term care network pharmacy:* a long-term care pharmacy that is a network pharmacy. • *Negotiated prices:* prices for covered Part D drugs that (1) are available to beneficiaries at the point of sale at network pharmacies; and (2) take into account discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations and include any dispensing fees. • *Network pharmacy:* a licensed pharmacy (not a mail order pharmacy) under contract with a PDP sponsor or MA organization to provide negotiated prices to its prescription drug plan or MA-PD plan enrollees. • *Non-preferred pharmacy:* a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy. • *Out-of-network pharmacy:* a licensed pharmacy that is not under contract with a PDP sponsor or MA organization to provide negotiated prices to its prescription drug plan or MA-PD plan enrollees. • *Person:* a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency. • *Plan allowance:* the amount PDPs and MA-PD plans use to determine their payment and enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies. • *Preferred drug:* a covered Part D drug on a PDP or MA-PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary. • *Preferred pharmacy*: a network pharmacy that offers Part D enrollees lower cost-sharing for covered Part D drugs than a non-preferred pharmacy. • *Qualified prescription drug coverage:* any standard or alternative prescription drug coverage. • *Required prescription drug coverage:* coverage under an MA-PD plan that consists of either (1) basic drug coverage; or (2) enhanced alternative coverage, for which there is no MA supplemental beneficiary premium due to the application of a credit against the premium of an MA plan rebate. • *Rural:* a five-digit ZIP code in which the population density is less than 1,000 persons per square mile. • *Standard prescription drug coverage*: must be either (1) standard prescription drug coverage that provides for cost-sharing up to the initial limit and after out-of-pocket threshold as described in the law, or (2) standard coverage that provides for actuarially equivalent cost-sharing. • *Suburban:* a five-digit ZIP code with population density between 1,000 and 3,000 persons per square mile. • *Supplemental benefits:* benefits that meet the requirements for enhanced alternative coverage. • *Therapeutically equivalent*: drugs that are rated as therapeutic equivalents under FDA's most recent publication of ``Approved Drug Products with Therapeutic Equivalence Evaluations.'' • *Third party payment arrangement:* any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.	

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• *Urban:* a five-digit ZIP code in which the population density is greater than 3,000 persons per square mile. • *Usual and customary (U&C) price*: the price that a pharmacy charges a customer who does not have any form of prescription drug coverage.	
§423.104 Requirements related to qualified prescription drug coverage. • A PDP sponsor offering a PDP or an MA organization offering an MA-PD plan must: o Provide enrollees with benefits directly by the plan sponsor or through arrangements with other entities. CMS reviews and approves these benefits using written guidelines and other instructions. o Offer that plan to all eligible beneficiaries in the plan's service area (except if the plan has capacity limits; o Include qualified prescription drug coverage (i.e., standard or alternative prescription drug coverage). • *Standard prescription drug coverage* includes access to negotiated prices, provides coverage of covered Part D drugs, and must meet the following requirements: o An annual deductible of, for 2006, $250; or, for subsequent years, the amount for the previous year, increased by the annual percentage increase, and rounded to the nearest multiple of $5. o Cost-sharing under the initial coverage limit of: ▪ 25% coinsurance for costs above the deductible and up to the initial coverage limit; or ▪ Actuarially equivalent to an average coinsurance of no more than 25 percent; or ▪ Tiered co-payments without limit, consistent with an average 25% coinsurance. o The initial coverage limit is, for 2006, $2,250; for subsequent years, the amount for the previous year, increased by the annual percentage increase, and rounded to the nearest $10. o Coinsurance for costs that fall between the initial coverage limit and the annual out-of-pocket threshold that is equal to 100%. o After costs exceed the annual out-of-pocket threshold, cost-sharing equal to the greater of: ▪ In 2006, $2 for a generic drug or preferred drug multiple source drug and $5 for any other drug; and for subsequent years, the co-payment amounts for the previous year increased by the annual percentage increase and rounded to the nearest 5 cents; or ▪ Five percent coinsurance; or ▪ A plan may substitute actuarially equivalent cost-sharing. o An annual out-of-pocket threshold of, for 2006, $3,600; for subsequent years the amount for the previous year increased by the annual percentage increase rounded to the nearest $50. o The annual percentage increase is the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the U.S. for Part D eligible individuals based on data for the 12-month period ending in July of the previous year. • *Alternative prescription drug coverage* includes access to negotiated prices, provides coverage of covered Part D drugs, and meets the following requirements: o Has an annual deductible that does not exceed the annual deductible specified in law; o Imposes cost-sharing no greater than that specified in law once the annual out-of-pocket threshold specified in law is met; and o Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. The unsubsidized value of coverage is the amount by which the actuarial value of	Proposes that the following circumstances count as incurred costs (with plans explicitly accounting for such differentials in valuation of coinsurance in bids): • any differential between a network retail pharmacy's price and a network mail order price for an extended supply of a drug purchased at a retail pharmacy: and • any differential between an out-of-network pharmacy's usual and customary price for a drug purchased in accordance with the out-of-network access rules (see below). Indicates that definitions have been proposed to encourage appropriate charitable assistance to count toward enrollees' incurred costs. CMS is considering whether assistance in paying enrollee's OOP cost-sharing obligations through manufacturers' patient assistance programs would be allowed under federal anti-kickback laws. *Seeks comment on treatment of health savings accounts (HSAs) with respect to TROOP.* Indicates preference for allowing HSA contributions to count toward incurred costs (since these funds are analogous to a beneficiary's bank account). *Seeks comment on how to treat FSAs, HRAs, and MSAs.* Payments made to the beneficiary by these programs do not count toward TROOP. *Seeks comments on how to maximize savings for people in need of HIV/AIDS mediations under the 340B program.* *Seeks comment on possible alternative data sources that can be used to determine the*

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the coverage exceeds the actuarial value of the subsidy payments; and o Provides coverage that, based upon an actuarially representative pattern of utilization, provides for the payment, with respect to costs incurred that are equal to the initial coverage limit of an amount equal to at least the product of (1) the amount by which the initial coverage limit for the year exceeds the deductible; and (2) 100% minus the coinsurance percentage. • *Enhanced alternative coverage* includes basic prescription drug coverage and supplemental benefits, which include: o Coverage of drugs other than covered Part D drugs; and/or o Any of the following changes that increase the actuarial value of benefits above the actuarial value of defined standard prescription drug coverage: ▪ A reduction in the annual deductible; ▪ A reduction in cost-sharing, or ▪ An increase in the initial coverage limit. o A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a PDP in that service area that provides basic prescription drug coverage. • Effective January 1, 2006, an MA organization may not offer: o an MA coordinated care plan in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and o Prescription drug coverage (other than that required under Parts A and B) to an enrollee under an MSA plan, or under another MA plan (including a private fee-for-service plan), unless the drug coverage under such other plan provides qualified prescription drug coverage. • A plan must provide its enrollees with access to negotiated prices for drugs included in its formulary. o Negotiated prices must be provided even if no benefits are payable to the enrollee because of deductible, or coinsurance requirements following satisfaction of any initial coverage limit. • Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, by PDP, MA-PD, or qualified retiree plans, will not be taken into account in establishing Medicaid's best price under section 1927(c)(1)(C). o A plan sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals or in the form of lower monthly beneficiary premiums and/or lower covered Part D drug prices at the point of sale. o Information on negotiated prices disclosed to CMS is protected under the confidentiality provisions applicable under Medicaid section 1927(b)(3)(D). o CMS may conduct periodic audits of the financial statements and all records of PDP sponsors and MA organizations pertaining to any qualified prescription drug coverage they may offer.	*annual percentage increase.* Observes that basic alternative coverage could theoretically vary from standard coverage by combining features such as a reduction in the deductible, and changes in cost-sharing (e.g. tiered coinsurance equal to the 25% coinsurance), but indicates that utilization effects might make that problematic. *Seeks comments on whether there are basic alternative benefit designs that go beyond actuarially equivalent standard coverage.* *Seeks comments on interpretation of "value" as equal to the "total value" of the standard coverage.)*
§423.112 Establishment of prescription drug plan service areas. • The service area for a PDP consists of one or more PDP regions. • CMS establishes PDP regions in a manner consistent with the establishment of MA regions. o To the extent practicable, PDP regions are the same as MA regions. o CMS may establish PDP regions that are not the same as MA regions if CMS determines that the	Final PDP regions announced by CMS on December 6, 2004 (http://www.cms.hhs.gov/medicarereform/mmaregions/): 34 PDP regions including 25 one-state regions; six two-state regions (OR/WA; NH/ME; ID/UT; PA/WV; AL/TN; IN/KY); one

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establishment of these regions improves access to benefits for Part D eligible individuals. o CMS establishes a PDP region(s) for the territories. o CMS may revise the PDP regions. • Nothing in this section prevents a PDP from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.	four-state region (CT/MA/RI/VT); one three-state region (DE/DC/MD); and one seven-state region (IA/MN/MT/NE/ND/SD/WY). In addition, each territory is its own region. Principles for defining regions include having an adequate number of beneficiaries to assure PDP viability but not too many because of plan capacity and degree of risk concerns; minimizing the variation in average state prescription drug spending within a region; and making PDP regions conform as closely as possible to MA regions. There are 26 MA regions (which include consolidations of several of the PDP regions).
§423.120 Access to covered Part D drugs. ***Pharmacy access requirements.*** • A PDP or MA-PD plan must have a contracted pharmacy network, with other than mail-order pharmacies, sufficient to ensure that for enrollees residing in the plan's service, the following requirements are met: o Urban areas: at least 90% of enrollees, on average, live within 2 miles of a network pharmacy; o Suburban areas: at least 90% of enrollees, on average live within 5 miles of a network pharmacy; and o Rural areas: at least 70% of enrollees, on average, live within 15 miles of a network pharmacy. • A plan's contracted pharmacy network may be supplemented by mail order pharmacies. • CMS waives the pharmacy access requirements in the case of: o An MA-PD plan that provides its enrollees with access to covered drugs through pharmacies owned and operated by the MA organization, provided the network is sufficient to provide comparable access. o An MA private fee-for-service plan that offers qualified prescription drug coverage; and provides access to covered drugs dispensed at all pharmacies, without charging excess cost-sharing. • In establishing its contracted pharmacy network, a plan sponsor: o Must contract with any pharmacy that meets the plan's terms and conditions; and o May not require a pharmacy to accept insurance risk as a condition of participation. • A plan sponsor that provides coverage other than defined standard coverage may reduce co-payments or coinsurance (relative to those applicable when drugs are obtained through a non-preferred pharmacy) when an enrollee obtains the covered Part D drug through a preferred pharmacy. o If the plan provides actuarially equivalent standard coverage, the plan must still meet the requirements. o Any cost-sharing reduction must not increase CMS subsidy payments. • A plan sponsor must permit its enrollees to receive benefits, which may include a 90-day supply of covered drugs, at a network retail pharmacy instead of a network mail-order pharmacy, provided the enrollee pays for any differential in the negotiated price for the drug at the retail pharmacy.	*Seeks comment on whether to require that sponsors make a standard contract available to all pharmacies.* Only retail pharmacies could be counted for the purpose of meeting the access standard. A plan can contract with pharmacies outside of their service area so long as they meet the access requirements within their service areas. Suggests that such contracts may be of benefit to "snowbirds," and would obviate the need for out-of-network access to covered Part D drugs in many cases. Such out-of-network access also would assure access to drugs provided by long-term care pharmacies for enrollees residing in institutions that do not contract with the enrollee's PDP or MA-PA. A regional MA-PD plan would have to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access standards in its local service area. *Seeks comments on this interpretation of the access requirement.* *Seeks comment on permissible ways to assure enrollees' access to Federally Qualified Health Center (FQHC) and rural*

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Formulary requirements. • A plan sponsor that uses a formulary must meet the following requirements: o Formulary must be reviewed by a pharmacy and therapeutic (P&T) committee that includes: ▪ A majority of members who are practicing physicians and/or practicing pharmacists. ▪ At least one practicing physician and one practicing pharmacist who are independent and free of conflict with the sponsor and plan, and who are experts in care of the elderly or disabled. ▪ The P&T committee must: ▪ Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed literature, pharmacoeconomic studies, outcomes data, and other appropriate information. ▪ Consider whether the inclusion of a particular drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy. ▪ Document in writing its decisions regarding formulary development and revision. o A plan's formulary must include: ▪ At least two drugs in each therapeutic category and class, with different strengths and doses. ▪ Only one drug if the category or class includes only one covered Part D drug. • A plan sponsor must: o Not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as CMS permits due to new therapeutic uses and newly approved drugs, o Periodically evaluate and analyze treatment protocols and procedures related to its plan's formulary. o Provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a drug from its formulary, or changing the tiered cost-sharing status. o Not remove a drug from its formulary, or make any change in the tiered status of a drug, between the beginning of the annual coordinated election period and 30 days after the beginning of the contract year. o Establish policies and procedures to educate and inform providers and enrollees concerning its formulary. o Issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs. The card or technology must comply with CMS standards.	*pharmacies because they may face barriers to inclusion in commercial plan networks.* Interpreting this provision to allow plans to vary cost-sharing not only based on type of drug or formulary tier but also on a plan's pharmacy network. Because such tiered cost-sharing cannot result in increased government payments, proposing that such pharmacy network distinctions be included in plans' benefits subject to the same actuarial tests that apply for tiered cost-sharing structures based on formulary. CMS would review the way plans draw their preferred pharmacy networks to ensure that they are not likely to discourage enrollment by certain Part D eligible individuals. An enrollee who chooses to obtain an extended supply of a drug through a network retail pharmacy would be responsible for any differential between the network's retail and mail order's negotiated price. *Seeking comments on proposal that this differential be counted as an incurred cost against the OOP threshold.* CMS expects that emergency out-of-network access be guaranteed under at least the following scenarios: (1) enrollee is traveling outside plan's service area, runs out or loses the covered drugs or becomes ill and needs a covered drug and cannot access a network pharmacy; (2) enrollee cannot obtain a covered drug in a timely manner within his or her service area because, e.g., no network pharmacy is within a reasonable driving distance that provides 24 hour/7 days a week service; (3) when an enrollee resides in a long-term care facility and the contracted LTC pharmacy does not participate in his/her network; (4) when an enrollee must fill a prescription for a covered drug, and that particular drug (e.g., orphan or specialty drug) is not regularly stocked at accessible network

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	retail or mail-order pharmacies. *Seeks comments on these requirements.* Notes that even with these requirements, plans would have some flexibility to design out-of-network coverage policies, e.g., plans could limit the amount of covered drugs dispensed out-of-network, require the use of mail order pharmacies as appropriate for extended out of network travel, and/or require a plan notification process for individuals who fill at out-of-network pharmacies. **Financial responsibility for out-of-network access.** An enrollee is financially responsible for the sum of the following costs of a covered drug: (1) any deductible or cost-sharing (relative to the plan allowance); and (2) any differential between the out-of-network pharmacy's usual and customary prices and the plan's allowance (including any applicable beneficiary cost-sharing) Both the enrollee and the plan would be financially responsible for the drugs obtained out-of-network, though paper claims may have to be filed and payment reconciled after the drug purchase instead of at the point of sale. The deductible is what would have otherwise applied if the drug had been purchased at a network pharmacy. Cost-sharing would be applied relative to the plan allowance for the drug, defined as the amount plans use to determine their payment and enrollees' cost-sharing purchased at out-of-network pharmacies. *Seeks comments on this definition.* Notes that current industry practice is to define the plan allowance as the lowest of the contractual discount offered to pharmacies in a plan's standard contract), maximum allowable cost, or the pharmacy's usual and customary price. Provides an

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	example. If plan requires 25% coinsurance at a network pharmacy, beneficiary would pay 25% of the plan allowance for that drug. If plan requires $10 co-payment at a network pharmacy, enrollee would still pay $10 at out-of-network pharmacy. In addition to this cost-sharing, the enrollee would be responsible for any difference in the price between the out-of-network pharmacy's U&C price and the plan allowance for the drug. *Seeks comments on the definition of U&C price.* Notes concern that pharmacies may increase their U&C prices to increase total reimbursement. "This would be prejudicial to beneficiaries in need of out-of-network access, but also to uninsured individuals purchasing drugs at retail pharmacies, and we seek feedback on permissible ways to prevent such an outcome." Notes that plans would in effect be financially held harmless for out-of-network use by enrollees. This is necessary to curb unnecessary use of out-of-network pharmacies and to ensure that plans can ensure cost-savings for beneficiaries and Medicare. *Seeks comments on this proposal.* Beneficiary cost-sharing would be counted as an incurred cost against the OOP threshold because such out-of-network access is a covered benefit. Includes the price differential described above. *Seeks comments on counting this differential toward the OOP threshold consistent with the definition of "incurred cost."* Under this definition, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. Also, any such differential would also count toward the deductible. Considering allowing PDPs and MA-PD plans to count I/T/U pharmacies toward network access requirements if: (1) such pharmacies are under contract with the plan, and (2) it would

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	be impossible or impracticable for the plan to meet the access standard in rural parts of its service area without the inclusion of an I/T/U pharmacy/ies in that count because there is not a sufficient number of non-I/T/U pharmacies in those areas willing and able to contract with the plan in accordance with its terms and conditions. *Seeks comments on this exception, including any impact it might have on pharmacy access for non-AI/AN Part D enrollees residing in those areas*. *Seeks comment regarding how to balance convenient access to LTC pharmacies with appropriate payment to such pharmacies and regarding the advantages and disadvantages of these two approaches*. Notes that PDPs do not have an incentive to include home infusion therapies in pharmacy networks and indicates that it is considering requiring that MA-PDs and PDPs contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees. The access rules would be at least as favorable as those under TRICARE. *Seeks comment on advantages and disadvantages of such an approach, how the requirements could be structured, and any other issues they should consider.* *Seeks comment on interpretation of statute that "developed and reviewed" by a P&T committee means that the committee's decisions regarding the formulary are binding on the plan.* *Seeks comment on appropriateness of strengthening requirement by requiring more than just one pharmacist and one physician as independent and free of conflict. Seeks comment regarding standards and criteria CMS could use to determine that a plan's*

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	formulary classification that is not based on the model classification system does not discriminate against certain classes of eligible beneficiaries. Seeks comments as to minimum timeframes for periodic evaluation and analysis of protocols and procedures related to formulary (example, quarterly, annually). "Affected enrollee" would be a plan enrollee currently taking a covered Part D drug that is either being removed from the formulary or whose preferred or tiered cost sharing status is changing. Proposes to rely on the National Council for Prescription Drug's "Pharmacy ID Card Standard." It will provide further operational guidance to entities wishing to become sponsors in time for them to use the standards and have their cards approved by CMS beginning January 1, 2006. CMS intends, however, that these standards require that plans use something other than an enrollee's social security number as an identifier on their cards
§423.124 Special rules for access to covered Part D drugs at out-of-network pharmacies. • A plan sponsor must assure that enrollees have adequate access to covered drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy. • An enrollee is financially responsible for the sum of the following costs for drugs obtained out-of-network: o Any deductible or cost-sharing (relative to the plan allowance) and o Any differential between the out-of-network pharmacy's usual and customary price and the plan allowance including any applicable beneficiary cost-sharing) for that covered Part D drug.	
§423.128 Dissemination of plan information. • A plan sponsor must disclose the following information to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter: o The plan's service area. o Benefits offered under the plan, including: ▪ Applicable conditions and limitations. ▪ Premiums. ▪ Cost-sharing and cost-sharing for subsidy eligible individuals. ▪ Any other conditions associated with receipt or use of benefits.	

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o A description of how to obtain more information on cost-sharing requirements, including tiered or other co-payment levels applicable to each drug (or class of drugs). o The manner in which any formulary (including any tiered formulary structure) functions, including: ▪ The process for obtaining an exception to a plan's tiered cost-sharing structure; ▪ A description of how an individual may obtain additional information on the formulary. o The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs, and that the plan meets all access requirements. o Provisions for access to covered drugs at out-of-network pharmacies. o All grievance, coverage determination, reconsideration, exceptions, and appeal rights and procedures. o A description of the quality assurance program, including the medication therapy management program. o The enrollees' disenrollment rights and responsibilities. • Upon request of a Part D eligible individual, a plan sponsor must provide the following information: o Information and instructions on how to exercise election options under this part; o Procedural rights (including grievance, coverage determinations and appeals procedures); and o The fact that a plan sponsor may terminate or refuse to renew its contract, or, in the case of an MA plan, reduce the service area, and the effect of those actions on enrollees; o Covered services, cost sharing, and out-of-pocket spending limits; o The extent to which an enrollee may obtain benefits from out-of-network providers; o The types of pharmacies that participate in the plan's network and the extent to which an enrollee may select among those pharmacies; and out-of-network pharmacy access; o Premiums; o The plan's formulary; o The plan's service area; o Quality and performance indicators for benefits under a plan as determined by CMS; o The procedures the plan sponsor uses to control utilization of services and expenditures; o The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as: ▪ Grievances. ▪ Rights to a reconsideration. o Financial condition of the plan sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the plan sponsor.	Strongly recommends that plans provide some sort of 24/7 access to their toll-free call centers in order to provide timely responses to time-sensitive questions. Seeks *comments on whether CMS should require the more stringent 24/7standard.*
• Each plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include: o A toll-free customer call center that is open during usual business hours, provides customer telephone service, including to pharmacists, in accordance with standard business practices; o An Internet Web site that includes a current plan formulary, updated at least weekly, and provides enrollees with at least 30 days notice regarding the removal or change in tiered status of a drug. o The provision of information in writing, upon request. • A plan sponsor must provide, in a form easily understandable to enrollees, during any month when	A plan could provide the EOB electronically if the enrollee elected to receive notice in such form. Provides rationale for waiving

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prescription drug benefits are provided, an explanation of benefits (EOB) that includes: o The item or service for which payment was made and the amount of the payment for each item or service; o A notice of the individual's right to request an itemized statement; o The cumulative, year-to-date total amount of benefits provided, in relation to: ▪ The deductible for the current year. ▪ The initial coverage limit for the current year. ▪ The annual out-of-pocket threshold for the current year. o The cumulative, year-to-date total of incurred costs to the extent practicable. o Any applicable formulary changes.	requirements for I/T/U and territory pharmacies.
§423.132 Public disclosure of pharmaceutical prices for equivalent drugs. • A plan sponsor must require a pharmacy to inform an enrollee of any differential between the price of a drug and the price of its lowest priced generic version available at that pharmacy, unless the particular drug being purchased is the lowest-priced generic version available at that pharmacy. • The information must be provided at the point of sale or, in the case of mail order, at the time of delivery. • CMS waives this requirement in the case of: o An MA private fee-for-service plan that provides enrollees with access at all pharmacies, and does not charge additional cost-sharing for out-of-network pharmacies. o An out-of-network pharmacy; o An I/T/U network pharmacy; o A network pharmacy that is located in any of the U.S. territories; and o Other circumstances where CMS deems the requirements impossible or impracticable. • CMS modifies the timing requirement for long-term care network pharmacies, which must meet the requirement within a time period specified by CMS.	*Seeks comments on the appropriateness of proposed waivers, as well as additional circumstances it should consider.* Notes that a similar public disclosure requirement was waived for endorsed discount card sponsors under several of the same circumstances. *Seeks comments on appropriate standards for timing of such disclosure by LTC pharmacies to institutionalized Part D enrollees.*
§423.136 Privacy, confidentiality, and accuracy of enrollee records. • PDP sponsors are required to comply with the following provisions in the same manner as MA organizations: o Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including HIPAA and the privacy rule promulgated under HIPAA; o Ensure that medical information is released only in accordance with applicable Federal or State law; o Maintain records and information in an accurate and timely manner; and o Ensure timely access by enrollees to records and information pertaining to them.	PDP sponsors would be considered covered entities under the HIPAA privacy rule with enforcement by Office of Civil Rights.

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

PROPOSED RULE	PREAMBLE
§423.150 -§423.153(c) Cost and utilization management, quality assurance, medication therapy management programs (MTMP), and programs to control fraud, abuse, and waste. • Each plan sponsor must have established a cost-effective drug utilization management program, a quality assurance program, an MTMP, and a program to control fraud, abuse, and waste. • A cost-effective drug utilization management program must include incentives to reduce costs when medically appropriate; and maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications. • A **quality assurance** program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The program must establish processes for: o Drug utilization review; o Patient counseling; and o Patient information record-keeping.	Within parameters described in preamble and regulation, plans would have flexibility to design these programs. Distinguishes drug utilization management and qualify assurance (QA) systems as population based whereas an MTMP involves targeted, direct patient care. Plans can use different dispensing fees to encourage use of multiple source drugs over single source drugs. (However, therapeutic substitution would require explicit prescriber notification and approval.) The program could also employ prior authorization, step therapy, tiered cost-sharing, and other tools. *Seeks comments on whether there are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards.* *Seeks comments on whether these tools should be under the direction and oversight of a P&T committee to ensure an appropriate balance between clinical efficacy and cost effectiveness.* Regarding policies and systems to prevent over- or under-utilization, plans must inform enrollees of program requirements and procedures to prevent unintended interruption in drug therapy. This would include, for example, how to proceed if special circumstances require prescriptions to be refilled before the targeted refill date. **Quality Assurance.** Proposes that the QA requirements generally need to comply with section 4401 of OBRA of 1990 (relating to Medicaid pharmacy standards). *Seeks comments on whether the Medicaid standards*

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	are in fact industry standards, and whether they are appropriate for Part D, and if so, how they should be adapted. Seeks comments on whether there are other industry standards that CMS might adopt. Plan sponsors must have systems and measures established to ensure that network pharmacies are complying with their QA requirements. *Seeks comment on the cost and challenges associated with these systems and measures. Suggests what these elements might be (e.g., e-prescribing), clinical decision support systems, educational interventions, bar codes, adverse event reporting, and provider and patient education). Seeks comments on which, if any, elements of a QA system should be required. Interested in best practices, cost and benefits, challenges in implementation, types of data useful for reducing medication errors, etc.* In the future, CMS may require reporting of error rates to be used to evaluate plans, and may be published for enrollees to use in plan selection. *Seeks comments on how to evaluate plans based on the QA measures and systems they have, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in plan choices.* Includes an FDA definition of medication error as one it would use initially in interpretative guidance (from Bar Code regulation). Defines medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such events may be related to professional practice; healthcare products, procedures,

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	and systems including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." *Seeks comment on this definition.*
§423.153 (d). Medicare therapy management program (MTMP). • **A medication therapy management program (MTMP):** o Must assure that drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; o Must, for the targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions; o May be furnished by a pharmacist; and o May distinguish between services in ambulatory and institutional settings. • Targeted beneficiaries for the MTMP are enrolled Part D eligible individuals who: o Have multiple chronic diseases; o Are taking multiple covered Part D drugs; and o Are likely to incur annual costs for drugs that exceed a predetermined level that CMS determines. • The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians. • The MTMP must be coordinated with any care management plan established for a targeted individual under a Medicare chronic care improvement program. • An applicant to become a plan sponsor must: o Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs. o Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others. Reports of these amounts are protected under Medicaid section 1927(b)(3)(D).	*Seeks comments before establishing MTMP requirements. What requirements and/or guidelines should be formulated in the regulation? Interested in best practices, essential components of MTMPs, and which quality assurance requirements, if any, should be included in MTMPs. Interested in measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services, and how these services can improve quality and reduce costs.* CMS identifies a range of MTMP services, such as performing patient health status assessments, formulating drug treatment plans, maintaining high cost specialty medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in state-approved collaborative drug therapy management. Enrollees would not be required to pay a separate fee for MTMP services although the cost could be reflected in the premium rate. MTMPs have the potential to lower overall Part D costs. *Seeks comment on how to integrate MTMP services and financial incentives into the Medicare Chronic Care Improvement (MCCI) program*. *Seeks comments on defining "multiple chronic diseases" and "multiple covered Part*

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	D drugs" for purpose of determining which enrollees qualify for MTMP services, or whether this is best left to the plan as part of its benefit design. CMS prefers to delegate to the plans the decision of the level of annual costs that an enrollee would have to likely incur to qualify for MTMP services. *Seeks comment on this as a policy and legal matte and on what guidance to give plans to ensure services are well targeted.* CMS says qualified professionals other than pharmacists could be providers of MTMP services. Expects this decision to be based on beneficiary preference and existing beneficiary-provider relationships. **MTMPs and pharmacy fees.** Expects plan sponsors to describe in their applications how the resources used and time required for MTMPs are used in establishing fees for pharmacists and other MTMP providers. CMS would investigate if CMS receives complaints that fees are not being paid as described in application. Such fees would be distinct from dispensing fees and should be included in the general administrative costs in the plan bid. Fee information would be confidential. CMS might apply intermediate sections or terminate plans for not paying fees or correcting errors upon notice. CMS does not have authority to mandate that plans pay a certain amount for MTMP services, and would not adjudicate disputes. **Chronic Care Improvement Program (CCIP)**. *Seeks comments on how MTMP services through the new CCIPs (established by the MMA) can be coordinated with PDP MTMPs.*

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§423.153(e) Fraud, abuse, and waste. • Plan sponsors must develop performance standards to evaluate, prevent, and investigate **fraud, abuse, and waste**. These standards will apply to the sponsor's evaluation of PDPs, MA-PDs, pharmacy benefit managers, or other subcontractors managing or coordinating the benefit for the organization or sponsor, pharmacies, physicians, and any other providers with whom the sponsor does business. • In the case of an MA plan the requirements related to quality assurance and waste, fraud and abuse control program do not apply.	*Seeks comments as to possible requirements over and above the incentives operating in at risk plans. Seeks comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiently research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste.* Notes that requirements apply not only to plans and their staffs, but also to the PBMs, pharmacies, physicians, and other providers they deal with. *Seeks comments on the value and need for requiring plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to Medicare. Seeks comments on the value of certain specified requirements and on the implementation, scope, and operation of an effective and robust fraud, abuse, and waste control program for plan sponsors.*
§423.156 Consumer satisfaction surveys. • CMS conducts consumer satisfaction surveys of PDP and MA-PD enrollees similar to the surveys it conducts of MA enrollees.	The Consumer Assessment of Health Plans (CAHPS) (or perhaps a modification of CAHPS) will likely be the vehicle used to collect this information. CMS will work with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring enrollee experience with their drug coverage, a sampling strategy, and an implementation strategy.
§423.159 Electronic prescription program. • Plan sponsors must have the capacity to support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D enrollees, once final standards are effective. • An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including voluntary standards promulgated by CMS as well as final standards established by CMS once final standards are effective.	Describes activities of National Committee on Vital and Health Statistics (NCVHS) to date. Notes that comments received in response to this NPRM will be considered along with the NCVHS' recommendations in the development of an NPRM on e-prescribing. *Seeks comments that help CMS identify consensus or reach consensus on e-prescribing standards ahead of the statutory time frame, and to help identify and evaluate industry experience based on pilot programs*

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	engaged in e-prescribing in 2004 and 2005. Aside from plans having the capacity to support final e-prescribing standards, CMS notes that there is no requirement that prescriptions be written or transmitted electronically (by physicians or pharmacies). Only entities that participate in a pilot testing of certain e-prescribing standards must implement e-prescribing using the initial standards adopted by the Secretary. Others will be encouraged to use the standards. If there is adequate industry experience with the standards, the Secretary may propose them as final standards in an NPRM (even if pilot testing is not completed). *Seeks comments on this strategy, including any concerns about potential unintended consequences.* *Seeks comments regarding:* • *Steps to spur adoption of e-prescribing, overcome implementation challenges and improve Medicare operations (notes differential payments by MA plans to physicians for using e-prescriptions must comply with the self-referral prohibition*.) *Quality measures related to the use of e-prescribing, and other MA-PD quality measures that reflect effective e-prescribing systems.* • *Possible federal activities that would promote e-prescribing by providers, including publishing best practices and making technical information products available, educational efforts or data analyses that might help practitioners understand benefits of e-prescribing, and ways it can further reduce costs to Medicare and promote quality.* • *How beneficiary population may view e-prescribing and what steps may be taken to get them to use this modality.*

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§**423.162 Quality Improvement Organization (QIO) activities.** • Quality Improvement Organizations (QIOs) are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. • QIOs offer assistance according to contracts established with the Secretary. • Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of 42 CFR Part 480. • Plan sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs. • For purposes of 42 CFR Parts 476 and 480, MA organizations and PDP sponsors are included in the definition of ``health care facility.''	Plans to issue guidance on how QIOs can provide this assistance and would coordinate the activities of the QIOs with the quality related activities of there stakeholders. Expects that the data needed by the QIOs would include payment related information and additional items such as prescriber supply. *Seeks comments about collection and use of information for providing quality improvement assistance.*
§ **423.165 Compliance deemed on the basis of accreditation.** • A plan sponsor is deemed to meet all of the requirements of any of the areas described below if: o The sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area by a private, national accreditation organization approved by CMS; and o The accreditation organization uses the standards approved by CMS for the purposes of assessing the sponsor's compliance with Medicare requirements. • Deemable requirements: o Access to covered drugs under §423.120 and §423.124. o Cost and utilization management, quality assurance, MTMP, and programs to control fraud, abuse, and waste, as provided under §423.153. o Privacy, confidentiality, and accuracy of enrollee records, as provided under Sec. 423.136. • The date the plan sponsor is deemed to meet the applicable requirements is the later of the following: o The date the accreditation organization is approved by CMS. o The date the plan sponsor is accredited by the accreditation organization. • A plan sponsor deemed to meet Medicare requirements must: o Submit to surveys by CMS to validate its accreditation organization's accreditation process; and o Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements). • CMS removes part or all of a plan sponsor's deemed status for any of the following reasons: o CMS determines, on the basis of its own investigation, that the plan sponsor does not meet the Medicare requirements for which deemed status was granted; o CMS withdraws its approval of the accreditation organization that accredited the plan sponsor; o The plan sponsor fails to meet the requirements to submit survey information. • CMS retains the authority to initiate enforcement action against any plan sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.	This process mirrors one used for deeming compliance with Medicare fee-for-service requirements and the MA program. CMS expects the accreditation organization to have a system in place for enforcing compliance with CMS' standards (such as sanctions for motivating correction of deficiencies), but CMS cannot delegate to the accreditation organization the authority to impose the intermediate sanctions established by section 1860D-12 of the Act or termination of the PDP contract. Deeming applies only to CMS' enforcement of this regulation, and neither its enforcement of this regulation nor accreditation by an accrediting body undercuts the Office for Civil Rights enforcement of the HIPAA privacy rule.

PROPOSED RULE	PREAMBLE
§423.168 Accreditation organizations. • CMS may approve an accreditation organization for a given standard under this part if it meets the following: o It applies and enforces standards that are at least as stringent as Medicare's requirements; o It complies with the application and reapplication procedures; o It ensures that: ▪ Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity; ▪ The majority of the membership of its governing body is not comprised of managed care organizations, PDP sponsors or their representatives; and ▪ Its governing body has a broad and balanced representation of interests and acts without bias. • CMS publishes a notice in the Federal Register whenever it is considering granting an accreditation organization's application for approval which: o Announces CMS's receipt of the accreditation organization's application for approval; o Describes the criteria CMS uses in evaluating the application; and o Provides at least a 30-day comment period. • After reviewing public comments, CMS publishes a final notice in the Federal Register indicating whether it has granted the accreditation organization's request for approval, and If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years. • An accreditation organization approved by CMS must, on an ongoing basis: o Provide to CMS in written form and on a monthly basis all of the following: ▪ Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements). ▪ Notice of all accreditation decisions. ▪ Notice of all complaints related to deemed PDP sponsors or MA organizations. ▪ Information about any plan sponsor against which the accrediting organization has taken remedial or adverse action within 30 days of taking the remedial or adverse action. ▪ Notice of any proposed changes in its accreditation standards or requirements or survey process. o Within 30 days of a change in CMS requirements, submit the following to CMS: ▪ An acknowledgment of CMS's notification of the change. ▪ A revised crosswalk reflecting the new requirements. ▪ An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS. o Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. o Within 3 days of identifying in a sponsor a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.	

PROPOSED RULE	PREAMBLE
o Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited PDP sponsors and MA organizations. o On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends. • Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following: o CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when: ▪ CMS imposes new requirements or changes its survey process; ▪ An accreditation organization proposes to adopt new standards or changes in its survey process; or ▪ The term of an accreditation organization's approval expires. o CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate: ▪ A 20% rate of disparity between certification by the accreditation organization and certification by CMS on standards that do not constitute immediate jeopardy to patient health and safety if unmet; ▪ Any disparity between certification by the accreditation organization and certification by CMS on standards that constitute immediate jeopardy to patient health and safety if unmet; or ▪ That, regardless of the disparity rate, there are widespread or systematic problems in an organization's accreditation process and that accreditation no longer assures that the Medicare requirements are met. o CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following: ▪ Reviewing documents. ▪ Auditing meetings concerning the accreditation process. ▪ Evaluating survey results or the accreditation status decision-making process. ▪ Interviewing the organization's staff. o If an equivalency review, validation review, on-site observation, or CMS's daily experience with the accreditation organization suggests that it is not meeting the requirements of this subpart, CMS will give the organization written notice of its intent to withdraw approval. o CMS may withdraw its approval of an accreditation organization at any time if CMS determines that: ▪ Deeming no longer guarantees that the plan sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or ▪ The accreditation organization has failed to meet its obligations.	

PROPOSED RULE	PREAMBLE
o An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination.	
§423.171 Procedures for approval of accreditation as a basis for deeming compliance. • A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS): o The types of PDPs and MA-PD plans that it reviews as part of its accreditation process. o A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk). o Detailed information about the organization's survey process, including the following: ▪ Frequency of surveys and whether surveys are announced or unannounced. ▪ Copies of survey forms, and guidelines and instructions to surveyors. ▪ Descriptions of the survey review and accreditation status decision making process; procedures used to notify accredited plan sponsors of deficiencies and to monitor the correction of those deficiencies; and ▪ The procedures used to enforce compliance with accreditation requirements. o information about the individuals who perform surveys for the accreditation organization, including: ▪ Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process; ▪ Education and experience requirements surveyors must meet; ▪ Content and frequency of the in-service training provided to survey personnel; ▪ Evaluation systems used to monitor the performance of individual surveyors and survey teams; and ▪ Organization's policies and practice for the participation, in surveys or in the accreditation decision process, by an individual who is professionally or financially affiliated with the entity being surveyed. o A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. o A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs. o A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements. o A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization. o A list of all currently accredited PDP sponsors and MA organizations and the type, category, and	

PROPOSED RULE	PREAMBLE
expiration date of the accreditation held by each of them. o A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS. o The name and address of each person with an ownership or control interest in the organization. • A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation: o Written presentation demonstrating its ability to furnish CMS with electronic data in CMS compatible format. o A resource analysis that demonstrates adequate staffing, funding, and other resources. o A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of Sec. 423.168(c). • If CMS needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for it to provide the additional information. • CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff. • CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that: o States whether the request for approval has been granted or denied; o Gives the rationale for any denial; and o Describes the reconsideration and reapplication procedures. • An accreditation organization may withdraw its application at any time before it receives the formal notice. • An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration. • An accreditation organization that has received notice of denial of its request for approval may submit a new request if it: o Has revised its accreditation program to correct the deficiencies on which the denial was based; o Can demonstrate that the plan sponsors that it has accredited meet or exceed applicable Medicare requirements; and o Resubmits the application in its entirety. • An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart F: Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

PROPOSED RULE	PREAMBLE
§423.258 Definitions. • *Full risk plan* means a PDP that is not a limited risk plan or a fallback prescription drug plan. • *Limited risk plan* means a PDP that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level in its bid. Does not include a fallback prescription drug plan. • *PDP Standardized bid amount* means, for a PDP that provides basic prescription drug overage, the PDP approved bid; for a PDP or MA-PD with supplemental coverage, the portion of the approved bid attributable to basic prescription drug coverage.	
§423.265 Submission of bids and related information. • An applicant may submit a bid to become a PDP sponsor or to become an MA organization offering an MA-PD plan, except CMS will not accept a bid from a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant: o Submitted a bid in the first year of a contract period to offer a fallback PDP in any PDP region; o Offers a fallback PDP in any PDP region during the year; or o Offered a fallback PDP in that PDP region during the previous year. o Applies to be a subcontractor of a PDP sponsor that is offering a plan. Does not apply to subcontractors of an MA organization except insofar as the MA organization is applying to act as a PDP sponsor of a PDP plan. • Each potential PDP or MA-PD sponsor must submit bids and supplemental information described in this section for each PDP or MA-PD plan it intends to offer in the subsequent calendar year, in a format specified by CMS not later than the first Monday in June, • Each bid must: o Reflect a uniform benefit package, including premium (except as provided for any late enrollment penalty) and all applicable cost sharing, for all enrollees in the plan. o Reflect the applicant's estimate of its average monthly revenue requirements to provide qualified drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in §423.329 below. o Include costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits. o Not include costs for enrollee deductible, co-payments, coinsurance, or payments projected to be made by CMS for reinsurance, or other costs for which the sponsor is not responsible. o Be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his/her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids. o Include a description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing. o Provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines, including adjustment for the effect that	CMS will publish risk adjustment factors and identify characteristics of average individual in the 45 day notice in advance of bids (February 18, 2005 for 2006 bids). Costs reflected in the bid would include only those to be incurred by the plan (for benefits and administration) and exclude costs paid by enrollees and expected reinsurance payments. Expected reinsurance payments must be identified separately. Costs for supplemental benefits must be identified separately. CMS will provide guidance on format for bid submission but is expecting to develop a fully automated process including electronic signatures. *Seeks comment on additional information needed to prepare bids and suggestions for other methods that the process could be structured to allow for later pricing data and still meet the need to inform beneficiaries.* *Seeks comments on how to obtain clear information on drugs included in the formulary.* Describes actuarial valuation processes and methods being considered by CMS. CMS will specify data sources, methods, assumptions and other techniques, and formats in further guidance. Any utilization effect of supplemental benefits would have to be loaded into the supplemental portion of the bid. A qualified actuary must certify the plans

PROPOSED RULE	PREAMBLE
providing alternative coverage (rather than defined standard coverage) has on drug utilization, if applicable: ▪ The actuarial value of the qualified coverage for a Part D individual with a national average risk profile for the factors described in §423.329 below and the basis for the estimate. ▪ The portion of the bid attributable to basic coverage and that attributable to supplemental benefits. ▪ The assumptions regarding reinsurance amounts used in calculating the bid. ▪ The assumptions regarding low-income cost-sharing used in calculating the bid. ▪ The amount of administrative costs and return on investment or profit included in the bid. o Include a description of the service area of the plan. o Specify, for a PDP but not an MA-PD, the level of risk assumed in the bid. Any modification in risk will apply to all plans offered by the PDP sponsor in a PDP region and may include: ▪ Increase in Federal percentage assumed in initial risk corridor. An equal percentage point increase in the percents applied for costs between the first and second threshold limits. This provision does not affect the application of a higher percentage for plans in 2006 or 2007. ▪ Increase in Federal percentage assumed in second risk corridor. An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit. ▪ A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages. o Include an estimate of the plan's average risk score for all projected enrollees for purposes of risk adjusting any supplemental premium. o Include any additional information CMS requests to support bid amounts and facilitate negotiation.	actuarial valuation (which may be prepared under his/her direction or review). Must be a member of the American Academy of Actuaries. May be an outside actuary. *Seeks comments on multiple issues related to actuarial valuation and tests for alternative coverage.* Since the supplemental premium bid will be based on an average risk profile, CMS will negotiate with plans to allow supplemental premium to adequately account for risk of plan enrollees.
§423.272 Review and negotiation of bid and approval of plans submitted by potential plan sponsors. • CMS reviews bid information in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan using authority similar to that of the Director of the Office of Personnel Management for federal employee health benefits. • CMS will approve the PDP or MA-PD plan only if the plan and the sponsor comply with all applicable CMS requirements, including those related to the provision of qualified coverage and actuarial determinations. • CMS only approves a bid if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements for benefits provided under that plan, less the sum of the actuarial value of the reinsurance payments. • CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. o If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopoeia, that formulary may not be found to discourage enrollment on the basis of its categories and classes alone. • There is no limit on the number of full risk plans that CMS approves; CMS approves a limited risk plan if	**Authority to review bids.** Consistent with OPM law and practice, CMS is interpreting its review authority to extend to determining if bids are in keeping with premiums charged in other insurance contexts (adjusted for comparable populations), including rates of increase. In addition, CMS observes that OPM has broad authority to negotiate the level of benefits, including the ability to prescribe "reasonable minimum standards for health benefit plans." CMS is considering similar regulations to those used by OPM in this regard and (48 CFR Chapter 16). *Seeks comments on this subject.* CMS observes though that it prefers to rely on competition rather than negotiation. **Bid and benefit package review.** CMS

PROPOSED RULE	PREAMBLE
the access requirements are not otherwise met for a PDP region. o CMS gives priority in approval to those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the plan with the highest assumption of risk. In no case does CMS approve a limited risk plan with no (or a minimal) level of financial risk. o CMS only approves the minimum number of limited risk plans needed to meet access requirements. • PFFS plans choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements with the following exceptions: o These plans are exempt from the review and negotiation process, and are not held to the revenue requirements standard; o These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements. o If the plan covers drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are participating providers, certain network access standards and the disclosure of the availability of lower cost generic drugs do not apply to the plan.	believes it has authority to negotiate: administrative costs; aggregate costs; benefit structure; and plan management. Factors to be considered regarding discrimination include benefit design; use of discriminatory limits or preauthorization; and supplemental benefits that may attract healthier enrollees. **Rebate reallocation for MA-PD plans.** CMS will require MA-PD plans to modify benefit structures after the average premium is determined to account for assumptions related to applying Part D rebate savings to premiums. **Private sector price negotiation and formulary design**. CMS observes that by not allowing the government to require any particular formulary, the statute ensures that plan P&T committees will have the flexibility to make changes in their classifications and lists of preferred drugs based on the most current evidence-based information (subject to specific limitations). CMS will evaluate plan formulary categories and classes in comparison to the model guidelines developed by U.S.P. In addition to evaluating any discriminatory features, CMS will evaluate the number of categories in formularies that do not meet the model guidelines and the choice of drugs available in those categories with respect to meeting the needs of the Medicare population. After the initial year of the program, CMS will also review the history of plan formulary appeals to identify issues with the plan's formulary, and will conduct additional research on evaluating formularies and drug benefit designs. *Seeks comments on evaluation.* CMS may also review plan cost sharing (i.e., tiers).

PROPOSED RULE	PREAMBLE
	Bid level negotiation. *Seeks comments on least burdensome way to obtain pricing and utilization data for actuarial review.* Observes that CMS could deny a bid if it did not believe that the bid and its underlying drug prices reflected market rates but would use this authority only on the rare occasion that the plan's data differs significantly from its peers without any indication of the factors accounting for the difference.
§423.279 National average monthly bid amount. • For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids in order to calculate the base beneficiary premium. o The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each PDP and MA-PD plan. o The calculation does not include bids submitted for MSA plans, MA PFFS plans, specialized MA plans, PACE programs, and reasonable cost reimbursement contracts. • The national average monthly bid amount is a weighted average, with the weight for each plan weighted by the number of Part D enrollees in the plan in the reference month as a percent of the total number of Part D eligible individuals enrolled in all plans included in the calculation of the national average bid amount in the reference month. o CMS determines the weighted average for 2005 to be used for the 2006 calculation. • CMS establishes an appropriate methodology for adjusting the national average monthly bid amount to take into account differences in prices for covered Part D drugs among PDP regions. o CMS does not apply any geographic adjustments if it determines that price variations among PDP regions are negligible. o CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.	CMS anticipates that it would identify a date by which the national average monthly bid amount would be published, and it would use the bids that had passed a certain level of approval as of that date as the basis for the calculation. CMS proposes how to calculate weights for the first year: MA plans with drug coverage would be weighted by their enrollment as of March 31, 2005. New MA-PDs would get zero weight. The remaining enrollees in a region would be assigned evenly to the number of PDP sponsors in the region, and then allocated evenly to each plan of the sponsor in the region. *Seeks comments on how to weight plan premium bids in the first year.* **Geographic adjustment.** No geographic adjustment will be made in the first years while CMS gathers data on prices. *Seeks comments on regional price variation in drug prices and factors that contribute to variation.*
§423.286 Rules regarding premiums. • The monthly beneficiary premium for a PDP or MA-PD in a PDP region is the same for all part D eligible individuals enrolled in the plan. • The monthly beneficiary premium for a PDP or MA-PD plan is the base beneficiary premium, adjusted for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties. • The beneficiary premium percentage for any year is a fraction, the: numerator of which is 25.5%; and denominator of which is as follows:	CMS estimates the base beneficiary premium, after taking into account reinsurance subsidies, will be 32% of the national average bid amount in 2006. Observes that during the first several years of the program, CMS would specify that the late enrollment penalty amount would be 1% of the base beneficiary premium per month. Once it has sufficient data on experience

PROPOSED RULE	PREAMBLE
(i) 100 % minus the percentage established in paragraph (b)(2)(ii) of this section. (ii) The percentage established in this paragraph equals the total reinsurance payments that CMS estimates will be paid under §423.329(c) for the coverage year; divided by: the amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to prescription drug plans and MA-PD plans that are attributable to the standardized bid amount during the year, taking into amounts paid by both CMS and enrollees. • The base beneficiary premium for a PDP for a month is equal to the product of the beneficiary premium percentage as specified above and the national average monthly bid amount for the month. • The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable: o If the amount of the standardized bid amount exceeds the amount of the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. o If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. o The portion of the bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk score of the plan by multiplying by the plan average risk score. o The base beneficiary premium is increased on a monthly basis by the amount of any late enrollment penalty, which is the greater of an amount that CMS determines is actuarially sound or, 1% of the base beneficiary premium for each uncovered month in the period. ▪ In 2006 and 2007 the penalty amount will be 1% per month unless another amount is specified in a separate issuance by the Secretary. • The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual. • The monthly beneficiary premium charged under a fallback plan is calculated under special rules described in §423.867 below.	under the program with respect to individuals who enroll after their Initial Enrollment Periods, CMS will be able to determine the appropriate penalty amount, that is, either 1% or a greater amount to be adopted. *Seeks comments from insurers, actuaries, and others on appropriate levels for late enrollment penalties to encourage enrollment and protect against selection bias.*
§423.293 Collection of monthly beneficiary premium. • In general, premium collection rules apply to PDP sponsors (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under Part C. • CMS estimates and specifies the portion of the late enrollment penalty attributable to increased actuarial costs assumed by the plan sponsor (and not taken into account through risk adjustment or through reinsurance payments) as a result of the late enrollment. • Collection of late enrollment penalty: o In the case of a late enrollment penalty collected through withholding from social security, CMS pays the plan only the portion of the penalty attributable to increased actuarial costs. o In the case of a late enrollment penalty collected from a Part D eligible individual in another manner, CMS reduces payments to the plan sponsor by this amount. • The collection requirements of this section do not apply to fallback PDPs; fallback plans follow their own requirements set forth in §423.867 below.	CMS does not anticipate paying plans any additional funds for late enrollees in the initial years.

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart G: Payments to PDP Sponsors and MA Organizations Offering
MA-PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage

PROPOSED RULE	PREAMBLE
§423.308 Definitions and terminology. • *Actually paid:* the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that could serve to decrease the costs incurred by the sponsor for the drug. • *Allowable reinsurance costs:* the subset of gross covered prescription drug costs that are attributable to basic or standard benefits only and that are actually paid by the sponsor or by (or on behalf of) an enrollee under the plan. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation. • *Allowable risk corridor costs:* the subset of prescription drug costs (not including administrative costs, but including dispensing costs) that are attributable to basic or standard benefits only and that are incurred and actually paid by the sponsor under the plan. Costs may be based upon imposition of the maximum amount of permitted co-payments. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization as a result of the insurance effect of enhanced alternative overage in accordance with CMS guidelines on actuarial valuation. • *Coverage year:* a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year. • *Gross covered prescription drug costs:* those costs incurred under a Part D plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. They equal: o All reimbursement paid by a plan sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when associated with an enrollee obtaining drugs under the plan; plus o All cost-sharing amounts paid under the plan by or on behalf of an enrollee in order to obtain drugs covered under the plan, regardless of whether the coverage exceeds basic coverage. • *Target amount:* for any PDP or MA-PD plan, equals the total amount of payments (from CMS and enrollees) to that plan for the year for all standardized bid amounts as risk adjusted, less the administrative expenses (including return on investment) assumed in the standardized bids.	*Seeks comments on methods and data that can be used to determine actual net costs, especially with respect to reinsurance payments.* Proposes that any administrative fees paid to plans above or below fair market value be considered price concessions.
§423.315 General payment provisions. • CMS payments under this section are made from the Medicare Prescription Drug Account. • CMS provides a direct subsidy in the form of advance monthly payments equal to the plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium. • CMS provides reinsurance subsidy payments on an as-incurred basis and final reconciliation to actual allowable reinsurance costs.	

PROPOSED RULE	PREAMBLE
• CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible enrollees. CMS provides low-income cost-sharing subsidy payments through interim payments and reconciliation to actual allowable reinsurance costs. • CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year. • CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs. • For private fee-for-service plans, CMS determines the amount of reinsurance payments. The provisions regarding risk sharing do not apply. • The amount payable to a PDP sponsor offering a fallback PDP is the amount determined under the contract for the plan.	
§423.322 322 Requirement for disclosure of information. • Payments to plan sponsors are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law. • Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. o This restriction does not limit OIG authority to conduct necessary audits and evaluations.	*Seeks comments on content, format and optimal frequency of data feeds (considering more frequently than annually).* Proposes requiring for 100% of claims: enrollee name, HIC#; birth date; NDC code; quantity; cost before copay (ingredient, dispensing fee and sales tax); copay; and date filled. *Seeks comments on nature and format of data for risk adjustment; reinsurance; risk sharing; and program audit.*
§423.329 Determination of payment. • CMS makes a direct subsidy payment for each eligible beneficiary enrolled in a PDP or MA-PD plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status, and reduced by the base beneficiary premium for the plan. • CMS makes reinsurance subsidy payments as provided below. • CMS makes low-income cost-sharing subsidy payments as provided below. • CMS establishes an appropriate methodology for adjusting the standardized bid amount, to take into account variation in costs for basic prescription drug coverage among PDPs and MA-PD plans based on the differences in actuarial risk of different enrollees. Any risk adjustment is designed to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans. o In establishing the risk adjustment methodology CMS takes into account the similar methodologies used to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program. o PDP sponsors must submit data on drug claims that can be linked at the enrollee level to Part A and Part B data; MA-PD sponsors must submit data on drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS. o CMS publishes the risk adjusters for the upcoming calendar year at the time of publication of risk adjustment factors for MA plans,	*Seeks comments on how to address risk adjustment so that there is no incentive or disincentive to enroll low-income subsidy beneficiaries. Also seeks comments on interpretation that risk adjustment be budget neutral to the risk of actual Part D enrollees.*

PROPOSED RULE	PREAMBLE
• The reinsurance payment amount for a Part D enrollee for a coverage year is equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the year after the individual has truly incurred costs that exceed the annual out-of-pocket threshold. o Reinsurance payments are based on a method as CMS determines. o CMS establishes a payment method by which monthly payments of reinsurance amounts are made during a year based on allowable reinsurance costs incurred in each month of the year. o CMS reconciles the payments to final actual allowable reinsurance costs. • CMS determines the amount of reinsurance payments for PFFS using a methodology that bases the amount on CMS' estimate of the amounts that are payable if the plan were an MA-PD plan, takes into account the average reinsurance payments made for populations of similar risk under MA-PD plans. • The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible enrollee for a coverage year is the amount described in Sec. 423.782. o Payments for low-income subsidies are based on a method that CMS determines. o CMS establishes an interim payment method during a year based on the low-income cost-sharing assumptions submitted with plan bids as negotiated and approved. o CMS reconciles the interim payments to actual incurred low-income cost-sharing costs.	*Seeks comments on different approaches for interim payments, including payments for projected reinsurance costs, discounted at the Treasury bill rate.* Allowable reinsurance costs will take into consideration any induced utilization effects from supplemental coverage. *Seeks comments on whether such an adjustment should be made and best method to account for effects.*
§**423.336 Risk-sharing arrangements.** • *Adjusted allowable risk corridor costs* means: the allowable risk corridor costs for the plan for the coverage year, reduced by the sum of the total reinsurance payments to the plan sponsor for the year; and the total non-premium subsidy payments made to the plan sponsor for the coverage year. • For each year, CMS establishes a risk corridor for each PDP and each MA-PD plan. The risk corridor for a plan for a year is equal to a range as follows: o The first threshold lower limit of the corridor is equal to the target amount for the plan; minus an amount equal to the first threshold risk percentage for the plan of the target amount. o The second threshold lower limit of the corridor is equal to the target amount for the plan; minus an amount equal to the second threshold risk percentage for the plan of the target amount. o The first threshold upper limit of the corridor is equal to the sum of the target amount; and an amount equal to the first threshold risk percentage for the plan of the target amount. o The second threshold upper limit of the corridor is equal to the sum of the target amount; and an amount equal to the second threshold risk percentage for the plan of the target amount. o The first threshold risk percentage is for: ▪ 2006 and 2007, 2.5 percent; ▪ 2008 through 2011, 5 percent; and ▪ 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent. o The second threshold risk percentage is for: ▪ 2006 and 2007, 5.0 percent; ▪ 2008 through 2011, 10 percent ▪ 2012 and after, a percentage CMS establishes, greater than in 2012, but not less than 10 percent. • A PDP sponsor may submit a bid that requests a decrease in first or second threshold risk percentages or	*Seeks comments on interpretation that adjustments include only non-premium low-income subsidies.* *Seeks comments on remedies when plan sponsors submit inadequate information regarding risk sharing and poses several options.*

PROPOSED RULE	PREAMBLE
an increase in the percents of risk assumed by the federal government. • Sponsors that offer a plan with supplemental drug benefits are at full financial risk for the provision of the supplemental benefits. • If the adjusted allowable risk corridor costs for the plan for the year are at least equal to the first threshold lower limit of the risk corridor but not greater than the first threshold upper limit, CMS makes no payment adjustment. • If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, CMS increases the total of the payments made to the sponsor by 50% (or, for 2006 and 2007, 75% or 90% if the conditions described below are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor. • If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor, CMS increases the total of the payments made to the plan sponsor by an amount equal to the sum of: o 50% (or, for 2006 and 2007, 75% or 90% if the conditions specified below are met) of the difference between the second threshold upper limit and the first threshold upper limit; and o 80% of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor. • The conditions for paying 90% are met for 2006 or 2007 if CMS determines that at least 60% of PDPs and MA-PD plans to which this paragraph applies have adjusted allowable risk corridor costs that are more than the first threshold upper limit; and the plans have at least 60% of enrollees in any plan. • If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, CMS reduces the total payments made to the plan sponsor (or otherwise recovers from the sponsor) an amount equal to 50% (or, for 2006 and 2007, 75%) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs. • If the adjusted allowable risk corridor costs for the plan for the year are less than the second threshold lower limit of the risk corridor for the plan for the year, CMS reduces the total of the payments made to the sponsor by an amount (or otherwise recovers from the sponsor) equal to the sum of 50% (for 2006 and 2007, 75%) of the difference between the first threshold lower limit and the second threshold lower limit; and 80% of the difference between the second threshold upper limit and the adjusted allowable risk corridor costs. • CMS makes payments after a coverage year after obtaining all of the cost data necessary to determine the amount of payment; CMS will not make payments if the plan sponsor fails to provide the cost data. • Within 6 months of the end of a coverage year, the plan sponsor must provide to CMS: o The gross covered prescription drug costs segregated by enrollee and date of service. o The allowable risk corridor costs for the coverage year. o The adjusted allowable risk corridor costs for the coverage year. o Costs incurred for supplemental benefits distinguished from those for basic coverage. o Other information stipulated by CMS. • CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the	

PROPOSED RULE	PREAMBLE
predetermined risk corridor thresholds in the coverage year. • No adjustment in payments made by reason of this section may affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.	
§423.343 Retroactive adjustments and reconciliations. • CMS makes the same calculations and adjustments in payments to PDP sponsors in the same manner as they apply to payments to MA organizations. • CMS makes adjustments to payments to account for updated health status risk adjustment data. o CMS may recover payments associated with health status adjustments if the plan sponsor fails to provide the required information. • CMS makes final payment for reinsurance after a coverage year after obtaining all necessary information. o Within 6 months after a coverage year, the plan sponsor must provide CMS with the following: ▪ The gross covered prescription drug costs segregated by enrollee and date of service. ▪ The allowable reinsurance costs segregated by enrollee and date of service. ▪ The costs incurred by the plan delineated separately from those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures. ▪ Costs incurred for supplemental benefits distinguished from those for basic coverage. ▪ Other information stipulated by CMS. o CMS at its discretion either makes lump-sum payments or adjusts monthly payments based on the difference between monthly reinsurance payments made during the coverage year and the amount payable for reinsurance for the coverage year. o CMS may recover payments through a lump sum recovery or by adjusting monthly payments if the monthly reinsurance payments made during the coverage year exceed the amount payable or if the plan sponsor does not provide the required data. • CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment. o Within 6 months after a coverage year, the plan sponsor must provide CMS the following: ▪ The gross covered prescription drug costs segregated by enrollee and date of service. ▪ The costs incurred by the plan delineated separately from those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures. ▪ Other information stipulated by CMS. o CMS at its discretion either makes lump-sum payments or adjusts monthly payments based on the difference between interim low-income cost-sharing subsidy payments and total eligible low-income cost-sharing subsidy costs submitted by the plan for the coverage year. o CMS may recover payments through a lump sum recovery or by adjusting monthly payments if interim low-income cost-sharing subsidy payments exceed the amount payable or if the plan sponsor does not provide the required data.	Claims paid after deadline would not be taken into account (ever) for determining payments or risk adjustment, but the plan would remain liable for payment. Rebates received for claims from coverage year after 4th quarter data submitted must be credited towards future year payments. *Seeks comments on timetable.*
§423.346 Reopening. • CMS may reopen and revise a final payment determination on the final amount of direct subsidy, final reinsurance payments, the final amount of the low income subsidy, or final risk corridor payments under the following circumstances:	

PROPOSED RULE	PREAMBLE
o For any reason, within 12 months of the date of the notice of the final determination to the plan sponsor; o Within 4 years of the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening; or o At any time when the determination or decision was procured by fraud or similar fault of the plan sponsor or any subcontractor of such sponsor. • CMS will find good cause if: o New and material evidence that was not readily available at the time the final determination was made is furnished; o A clerical error in the computation of payments was made; or o The evidence considered in making the determination clearly shows that an error was made. • CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart I: Organization Compliance With State Law and Preemption by Federal Law

PROPOSED RULE	PREAMBLE
§423.401 General requirements for PDP sponsors. Each sponsor of a PDP must meet the following requirements: • Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a PDP. If not commercially licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor. • Assume financial risk for benefits it offers under a PDP that are not covered by federal reinsurance. o May obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.	
§423.410 Waiver of certain requirements to expand choice. • The licensure requirement is waived if CMS determines that the State has: o Failed to implement a licensing process for PDP sponsors or to complete action on the licensing application within 90 days. o Denied the application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied to other similar business entities, or required, as a condition of licensure that the organization offer any product other than a PDP. o Denied the application on the basis of the sponsor's failure to meet solvency requirements or solvency documentation requirements that are different from CMS standards. o Applied any grounds other than those required under Federal law. • The grounds for waiver approval are deemed met if the State does not have a licensing process in effect with respect to PDP sponsors. • For plan years beginning before January 1, 2008, if the State has a PDP or PDP sponsor licensing process in effect, CMS grants a waiver of the licensure requirement upon a demonstration that a PDP sponsor has submitted a substantially complete licensure application to the State. • The following additional waiver may be requested for regions: o An applicant licensed as a risk bearing entity in at least one State in a region may receive a regional plan waiver for the States in the region in which it is not licensed. o The applicant must demonstrate that it filed the necessary applications with each State in the region for which it does not already have a license, unless CMS determines that the State does not have a licensing process for potential PDP sponsors. o The waiver will expire at the end of the time period that CMS determines is appropriate for timely processing of the application, but in no case will a waiver extend beyond the end of the calendar year. • The following rules apply to waivers (except for regional plan waivers): o The waiver applies only to that State, is effective only for 36 months and cannot be renewed. ▪ The 36 month deadline does not apply, and the waiver may continue in effect for a given State as long as the State does not have a PDP licensing process in effect. o CMS grants or denies a waiver application under this section within 60 days after a substantially complete waiver application is received by CMS.	CMS intends to develop reasonable standards through guidance, after consulting with the NAIC. The guidance would be issued by January 1, 2005. These would be considered interpretative guidance. *Seeks comments on this issue*. CMS also would establish an application and certification process for waiver applicants. Other single lines of business, such as dental only plans, can provide some possible models. CMS is also experienced with federally qualified HMOs. (CMS also refers to Medica and PacifiCare as two drug-only plans that could provide models except that they operate under existing insurance licenses.) Indicates that factors that may be considered in discussions with NAIC may include the ability of an organization to maintain assets greater than total unsubordinated liabilities and the ability of the organization to generate a surplus on a consistent basis as demonstrated by history or an acceptable financial plan. States would be expressly preempted from regulating in all areas except licensure and solvency. Additional requirements under section 1855(a) of the SSA, such as state consumer protection and quality standards, do not apply to and are not incorporated in these regulations.

PROPOSED RULE	PREAMBLE
§423.420 Solvency standards for non-licensed entities. • Entities with a waiver of licensure requirements must maintain reasonable financial solvency and capital adequacy in accordance with the standards established and published by CMS.	
§423.425 425 Licensure does not substitute for or constitute certification. • The fact that a PDP sponsor is State licensed or has an approved waiver application does not deem the sponsor to meet other requirements imposed under this part for a PDP sponsor.	
§423.440 Prohibition of State imposition of premium taxes; relation to State laws. • Any State law or regulation (other than State licensing or plan solvency laws) with respect to PDP and MA-PD plans is superseded by federal standards. • No premium tax, fee, or other similar assessment may be imposed by any State or territory with respect to any payment CMS makes on behalf of MA-PD plan or PDP enrollees; or with respect to any payment made to PDP or MA-PD plans by a beneficiary or by a third party on behalf of a beneficiary. • PDP sponsors are not exempt from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from Medicare Part D business, if that tax, fee, or payment is applicable to a broad range of business activity.	Regarding preemption of state law, CMS observes that in areas where it has neither the expertise nor authority to regulate, it does not believe state laws would be superseded or preempted. Gives illustration of such laws as environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights, and similar areas. On the other hand, would interpret areas where state laws explicitly apply — licensing and solvency – narrowly. Gives illustrations.

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart J: Coordination With Other Prescription Drug Coverage

PROPOSED RULE	PREAMBLE
§423.454 Definitions and Terminology. • *Part D plan or Medicare Part D plan:* a PDP or an MA-PD plan. • *Employer-sponsored group prescription drug plan*: a PDP under a contract between a PDP or MA-PD sponsor and employers, labor organizations, or the trustees of funds established by employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage. • *State Pharmaceutical Assistance Program (SPAP*): a State program (operated by or under contract with a State) that meets the requirements described under Sec. 423.464 below.	
§423.458 Application of Part D rules to MA-PD plans on and after January 1, 2006. • Except as otherwise provided, the requirements of this Part D apply to prescription drug coverage provided by MA-PD plans offered by Medicare Advantage (MA) organizations. • CMS waives any provision of this Part D as applied to MA-PD plans to the extent it determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA-PD plan under Part C or as may be necessary to improve coordination of Part D this part with Part C. o Any waiver will apply to other similarly situated organizations that meet the waiver conditions. • Organizations offering or seeking to offer an MA-PD plan may request from CMS in writing: o A waiver of those Part D requirements that are duplicative of, or are in conflict with provisions otherwise applicable to the MA-PD plan, or proposed MA-PD plan, under Part C. o A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided under Part C of Medicare with the benefits under Part D. • PDPs may request, in writing, a waiver or modification of Part D requirements that hinder the design of, the offering of, or the enrollment in, an employer-sponsored group prescription drug plan (including separate premium amounts for enrollees of the employer-sponsored group PDP and limitations on enrollment in such plan to individuals participating in the employment-based retiree health coverage). o Any waiver will apply to other similarly situated organizations that meet the waiver conditions. • CMS waives any Part D provision that duplicates, or is in conflict with, provisions otherwise applicable to HMO and Competitive Medical Plan (CMP) cost contract plans or Programs for the All-Inclusive Care for the Elderly (PACE) organizations or as necessary to improve coordination. o Any waiver will apply to other similarly situated organizations that meet the waiver conditions. • HMO/CMP cost contract plans or PACE organizations seeking to offer qualified prescription drug overage may request from CMS in writing: o A waiver of Part D requirements that are duplicative of, or that are in conflict with provisions otherwise applicable to HMO/CMP cost contract plans or PACE organizations. o A waiver of a Part D requirement, if such waiver would improve coordination of benefits.	*Seeks comments on the process for authorizing additional waivers and what additional waivers should or should not be permitted.* *Seeks comments on automatic waivers for PACE programs.* *Seeks comments on the process and manner for authorizing additional waivers for employer-sponsored PDPs.*
§423.462 Medicare secondary payer procedures. • Medicare secondary payer procedures apply to PDP sponsors in the same way as they apply to MA organizations.	

PROPOSED RULE	PREAMBLE
§423.464 Coordination of benefits with other providers of prescription drug coverage.	
• A plan sponsor must permit SPAPs to coordinate benefits with the PDP or MA-PD plan and must comply with all CMS administrative processes and requirements to ensure effective exchange of information and coordination between a Part D plan and an SPAP and other plans providing prescription drug coverage for: o Payment of premiums and coverage; and o Payment for supplemental prescription drug benefits (including payment to a Part D plan on a lump sum per capita basis) for enrollees in the Part D plan and the SPAP or other plan. • A Medicare Part D plan is always the primary payor relative to an SPAP. • CMS may impose user fees to ensure effective exchange of information and coordination between a Part D plan and an SPAP and other plans providing prescription drug coverage in a manner similar to the manner in which user fees are imposed for coordination with Medigap plans, except that CMS may retain a portion of user fees to defray costs in carrying out such procedures. o CMS will not impose user fees on an SPAP. • The requirements of this subpart do not prevent an organization sponsoring a Medicare Part D plan from using cost management tools (including differential payments) under all methods of operation.	*Seeks comment on method for imposing user fees and whether on a monthly or quarterly basis and whether CMS should require electronic payment.* *Seeks comments on how to prevent wrap-around coverage by SPAPs or other insurers from undermining cost management tools such as tiered copays, and how to administer this.*
Coordination with State Pharmaceutical Assistance Programs (SPAPs). • To qualify as , an SPAP for Part D (i.e., so that TROOP does not apply ad SPAP benefits accrue towards enrollees' out-of-pocket thresholds), the program must be operated by or under contract with a State and: o Provide financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals; o Not discriminate based upon the Part D plan in which an individual enrolls; o Meet the benefit coordination requirements specified in this part; and o Not follow or adopt rules that change or affect the primary payor status of a Part D plan. • The definition of SPAP excludes: o State Medicaid programs, section 1115 demonstration programs, and any other program where the majority of funding is from Federal grants, contracts, or other Federal sources. • A plan sponsor shall collect information on and apply expenditures made by SPAPs for costs of covered Part D drugs for purposes of reaching an enrollee's out-of-pocket threshold. • A card that is issued for use under a Medicare Part D plan may also be used in connection with coverage of benefits provided under an SPAP and may contain an emblem or symbol indicating such connection. • Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Medicare Part D plan.	*Seeks comments on coordination of benefits with SPAPs and whether SPAPs that provide wrap-around benefits should be required to report how much they actually paid on a claim.*
Coordination with other plans. • Other plans that provide prescription drug coverage include any of the following: o Medicaid programs, including a plan operating under a section 1115 waiver; o Group health plans; o The Federal employees' health benefits plan (FEHBP); o Military coverage (including TRICARE). o Other health benefit plans or programs that provide coverage or financial assistance for	*Seeks comments on benefit coordination between States and Part D plans, including administrative processes and requirements.* *Seeks comments on feasibility of Part B and Part D coordination of benefits and cross-over procedures. Seeks comments on Part D coverage of drugs denied coverage under*

PROPOSED RULE	PREAMBLE
prescription drugs as CMS may specify. • A PDP or MA-PD plan sponsor shall exclude expenditures made by other plans (except qualified SPAPs) to cover for costs of covered Part D drugs for purposes of reaching an enrollee's out-of-pocket threshold (i.e., true out-of-pocket costs (TROOP) applies). • A plan sponsor may not impose fees on other plans that are unrelated to the cost of the coordination of benefits.	*coverage of drugs denied coverage under Part B, and under what circumstances.* Discusses options for facilitating data exchange to track TROOP including voluntary and mandatory reporting: Option 1: PDPs are solely responsible. Option 2: CMS would procure a contractor to coordinate claims from all payers for TROOP. Considering mandating that enrollees provide third party payment information as part of the enrollment process, including consent for release of information. *Seeks comments on how best to administer the TROOP provisions.*

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart K: Application Procedures and Contracts with PDP Sponsors

PROPOSED RULE	PREAMBLE
§423.501 501 Definitions. • *Business transaction*: any of the following kinds of transactions: o Sale, exchange, or lease of property. o Loan of money or extension of credit. o Goods, services, or facilities furnished for a monetary consideration, including management services, but not including: ▪ Salaries paid to employees; or ▪ Health services furnished to the PDP sponsor's enrollees by pharmacies and other providers, or by any combination of those entities. • *Significant business transaction:* any business transaction or series of transactions that has a total value that exceeds the lesser of $25,000 or 5% of the PDP sponsor's total annual operating expenses. • *Downstream entity*: any party that enters into an acceptable written arrangement below the level of the arrangement between a PDP sponsor and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. • *First tier entity:* any party that enters into an acceptable written arrangement with a PDP sponsor to provide administrative services or health care services for a Medicare eligible individual under Part D. • *Party in interest:* (1) Any director, officer, partner, or employee responsible for management or administration of a PDP sponsor. (2) Any person who is directly or indirectly the beneficial owner of more than 5% of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5% of the organization. (3) In the case of a corporate nonprofit PDP sponsor, an incorporator or member of the corporation under applicable State corporation law. (4) Any entity in which a person specified in (1), (2), or (3) of this definition is an officer, director, or partner; or has the kind of interest described in (1), (2), or (3) of this definition. (5) Any person that directly or indirectly controls, is controlled by, or is under common control with the PDP sponsor. (6) Any spouse, child, or parent of an individual specified in (1), (2), or (3). • *Related entity:* any entity that is related to the PDP sponsor by common ownership or control and: o Performs some of the PDP sponsor's management functions under contract or delegation; o Furnishes services to Medicare enrollees under an oral or written agreement; or o Leases real property or sells materials to the PDP sponsor at a cost of more than $2,500 during a contract period.	
§423.502 Application requirements. In order to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, which includes documentation of appropriate State licensure or certification or a Federal waiver of licensure. • The authorized individual must describe thoroughly how the entity meets, or plans to meet, requirements.	

PROPOSED RULE	PREAMBLE
• CMS determines whether an entity qualifies as a PDP sponsor and meets the requirements of Part D. • An applicant submitting material that he or she believes is protected from disclosure under The Freedom of Information Act, or because of HHS regulations providing exceptions to disclosure, must label the material ``privileged'' and include an explanation of the applicability of an exception.	
§423.503 Evaluation and determination procedures for applications to be a sponsor. • CMS evaluates an application based on information in the application and any information that CMS obtains through on-site visits, publicly available information, and other appropriate procedures. • If the application is incomplete, CMS notifies the contract applicant and allows 10 days from the date of the notice for the contract applicant to furnish the missing information. • After evaluating relevant information, CMS determines whether the application meets requirements. • CMS may deny an application based on the contract applicant's failure to comply with a prior contract with CMS even if the contract applicant meets all of the current requirements. • CMS notifies each applicant of its determination on the application and the basis for the determination: o Approval of application. o Notice of intent to deny the application and a summary of the basis for this finding. ▪ The applicant has 10 days to respond in writing to the issues that were the basis for CMS's finding and may revise its application to remedy any defects CMS identified. o Denial of application with written notice to the contract applicant indicating: ▪ That the applicant does not meet the contract requirements under Part D; ▪ The reasons why the applicant does not meet the contract requirements; and ▪ The applicant's right to request reconsideration. • CMS oversees a PDP sponsor's continued compliance with the requirements for a PDP sponsor. o If a PDP sponsor no longer meets those requirements, CMS terminates the contract.	
§423.504 General contract provisions. • A PDP sponsor must enter into a contract with CMS, which may cover more than one PDP of the sponsor. • Any entity seeking to contract as a PDP sponsor must: o Complete an application. o Be organized and licensed under State law as a risk bearing entity or have a Federal waiver. o Meet the minimum enrollment requirements unless waived. o Have administrative and management arrangements demonstrated by at least the following: ▪ A policy making body that exercises oversight and control over policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees. ▪ Personnel and systems sufficient for the sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and/or utilization management programs, and the administrative and management aspects of the organization. ▪ At a minimum, an executive manager whose appointment and removal are under the control of the policy making body. ▪ Fidelity bond or bonds, procured and maintained by the sponsor, in an amount fixed by its	*Seeks comment on any provisions that should not apply or any that are not addressed including:* • *Type of business transactions which should be reported to CMS.* • *Proposed administrative and management arrangements and how these should apply to large companies.* • *Record maintenance requirements.*

PROPOSED RULE	PREAMBLE
policymaking body but not less than $100,000 for each officer and employee entrusted with handling of its funds. The bond may have deductibles, based upon the financial strength of the sponsor. ▪ Insurance policies or other arrangements, secured and maintained by the PDP sponsor and approved by CMS to insure the PDP sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks. o Have a compliance plan that consists of the following: ▪ Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards. ▪ A compliance officer and compliance committee accountable to senior management. ▪ Effective training and education between the compliance officer and employees. ▪ Effective lines of communication between the compliance officer and employees. ▪ Enforcement of standards through well-publicized disciplinary guidelines. ▪ Procedures for internal monitoring and auditing. ▪ Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a PDP sponsor. ▪ If the PDP sponsor discovers from any source evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that misconduct; ▪ If the PDP sponsor has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report it to the appropriate authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-kickback provisions, the civil monetary penalties authorities, or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office. ▪ The PDP sponsor must conduct corrective actions (e.g., repayment of overpayments and disciplinary actions against responsible employees) in response to potential violations. o The sponsor's contract must not have been non-renewed by the sponsor within the past 2 years unless there was a change in law or regulations that increased PDP sponsor payments in the payment area at issue; or CMS has otherwise determined that circumstances warrant special consideration. • CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program • CMS annually audits at least one-third of the PDP sponsors (including fallback plans) offering PDPs. • Each contract must provide that CMS, or any person or organization designated by CMS, has the right to: o Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the PDP sponsor's contract; o Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for the inspection; and	

PROPOSED RULE	PREAMBLE
o Audit and inspect any books, contracts, and records of the PDP sponsor that pertain to: ▪ The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or ▪ Services performed or determinations of amounts payable under the contract. o The contract must provide that, upon CMS' request, the contract could be amended to exclude any State-licensed entity, or a PDP plan specified by CMS; and a separate contract for any excluded plan or entity must be deemed to be in place when a request is made.	
§423.505 505 Contract provisions. • The contract between the PDP sponsor and CMS must contain an agreement by the sponsor: o To comply with all requirements and conditions set forth in Part D and in general instructions. o To process enrollments and disenrollments as required. o To comply with the prohibition on discrimination in beneficiary enrollment. o To provide the basic benefits and, to the extent applicable, supplemental benefits. o To disclose information to beneficiaries in the manner and the form specified by CMS. o To operate the required quality assurance, cost and utilization management, a Medication Therapy Management Program (MTMP), and fraud, abuse and waste programs. o To comply with all requirements governing coverage determinations, grievances, and appeals. o To comply with the reporting requirements for submitting drug claims and related information to CMS for its use in risk adjustment calculations. o Each contract under this part provides that: ▪ The PDP sponsor provides CMS with information necessary for payment, and that ▪ CMS has the right to inspect and audit any books and records of a PDP sponsor that pertain to the information regarding costs provided to CMS. o To be paid under the contract in accordance with the payment rules. o To submit its bid and all required information on premiums, benefits, and cost-sharing, by the due date. o That its contract may not be renewed or may be terminated. o To comply with the confidentiality and enrollee record accuracy. o To comply with State law and preemption by Federal law. o To comply with the coordination requirements with plans providing prescription drug coverage. o To provide benefits by means of point of service systems to adjudicate drug claims, except when necessary to provide access in underserved areas, I/T/U pharmacies, and long-term care pharmacies. o The PDP sponsor must be able to communicate with CMS electronically as required by CMS. • The PDP sponsor agrees to maintain, for 6 years, books, records, documents, and other evidence of accounting procedures and practices that are sufficient to do the following: o Accommodate periodic auditing of the financial records. o Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization. o Enable CMS to audit and inspect any books and records of the PDP sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or	

PROPOSED RULE	PREAMBLE
determinations of amounts payable under the contract. o Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs. o Establish the basis for the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered by the PDP. o Records of the following: o Ownership and operation of the PDP sponsor's financial, medical, and other record keeping systems. o Financial statements for the current contract period and 6 prior periods. o Federal income tax or informational returns for the current contract period and 6 prior periods. o Asset acquisition, lease, sale, or other action. o Agreements, contracts, and subcontracts. o Franchise, marketing, and management agreements. o Matters pertaining to costs of operations. o Amounts of income received by source and payment. o Cash flow statements. o Any financial reports filed with other Federal programs or State authorities. o All prescription drug claims for the current contract period and 6 prior periods. o All price concessions (including concessions offered by manufacturers) for the current contract period and 6 prior periods accounted for separately from other administrative fees. • The PDP sponsor agrees to the following conditions on access to facilities and records: o HHS, the Comptroller General, or their designee may evaluate, through inspection or other means the quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract; the facilities of the PDP sponsor; and the enrollment and disenrollment records for the current contract period and 6 prior periods. o HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the PDP sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of Part D activities. The PDP sponsor agrees to make available its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. o HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless: CMS determines there is a special need to retain a particular record(s) for a longer period and notifies the PDP sponsor at least 30 days before the normal disposition date; There is a termination, dispute, or allegation of fraud or similar fault by the PDP sponsor, in which case the retention may be extended to 6 years from the date of final resolution; or o CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the PDP sponsor at any time.	

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• The PDP sponsor agrees to submit to CMS: o Certified financial information that includes information as CMS may require demonstrating that the organization has a fiscally sound operation and pertaining to the disclosure of ownership and control of the sponsor. o Information necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for beneficiaries to exercise choice, including the benefits covered under a PDP; the PDP basic and supplemental (if any) beneficiary premium for the plan; the service area of each plan; and plan quality and performance indicators including disenrollment rates for the previous 2 years; information on enrollee satisfaction; recent records regarding compliance of the plan with Part D requirements; and other information determined by CMS. o Information about beneficiary appeals and their disposition. o Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization. o Other information deemed necessary to CMS for administration or evaluation. • The PDP sponsor agrees to comply with the following beneficiary financial protection requirements: o Maintain arrangements to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the PDP sponsor by: ▪ Ensuring that all contractual or other arrangements prohibit the sponsor's contracting agents from holding any enrollee liable for payment of any such fees; and ▪ Indemnifying the enrollee for payment of any fees that are the legal obligation of the PDP sponsor for drugs furnished by non-contracting pharmacists ▪ To do this, the sponsor may use contractual arrangements; insurance; financial reserves; or other arrangement acceptable to CMS. • The PDP sponsor must agree to comply with: o Title VI of the Civil Rights Act of 1964. o The Age Discrimination Act of 1975. o The Rehabilitation Act of 1973. o The Americans with Disabilities Act. o HIPAA Administrative Simplification rules. o Other laws including those applicable to recipients of Federal funds. • PDP sponsors must inform all related entities, contractors and subcontractors that payments they receive are, in whole or in part, from Federal funds. • Notwithstanding any relationship(s) that the PDP sponsor may have with related entities, contractors, or subcontractors, the PDP sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. • The PDP sponsor agrees to require all related entities, contractors, or subcontractors to agree that: HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the PDP sponsor for 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later. • All contracts or written arrangements between PDP sponsors and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain enrollee protection provisions, and	

PROPOSED RULE	PREAMBLE
accountability provisions, as specified in regulations. • If any of the PDP sponsors' contract responsibilities is delegated to other parties, the following apply: o Written arrangements must specify delegated activities and reporting responsibilities. o Written arrangements must provide for revocation of the delegation or specify other remedies if CMS or the sponsor determines that the parties have not performed satisfactorily. o Written arrangements must specify that the sponsor monitors the performance of the parties. o All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions. • If a PDP sponsor delegates selection of its drug providers to another entity, the written arrangements must state that the sponsor retains the right to approve, suspend, or terminate the arrangement. • *Severability of contracts*. The contract must provide that, upon CMS's request: o The contract is amended to exclude any State-licensed entity, or PDP sponsor specified by CMS; and o A separate contract for any excluded entity is deemed to be in place when the request is made. *Certification of data.* • The PDP sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief): o The accuracy, completeness, and truthfulness of all data related to payment. o That each enrollee for whom payment is requested is validly enrolled with the organization and the information is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement. o That the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. ▪ If the claims data are generated by a related entity or subcontractor, the entity or subcontractor must similarly certify. o That the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms. o That the information provided on allowable costs, is accurate, complete, and truthful and acknowledge that this information will be used for obtaining Federal reimbursement. o That the information provided for price comparison is accurate, complete, and truthful.	
§423.506 Effective date and term of contract. • The contract is effective on the date specified in the contract between the PDP sponsor and CMS. • Each contract is for a period of 12 months. • Contracts are renewed annually only if CMS informs the PDP sponsor that it authorizes a renewal; and the PDP sponsor has not provided CMS with a notice of intention not to renew.	
§423.507 Nonrenewal of contract. • A PDP sponsor may elect not to renew its contract with CMS as of the end of the contract term for any reason provided it notifies: o CMS in writing by the first Monday of June in the year in which the contract ends;	

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o Each Medicare enrollee, at least 90 days before the effective date of the nonrenewal. This notice must include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA-PDs, and other PDPs, and must receive CMS approval prior to issuance; and o The general public, at least 90 days before the effective date of the calendar year, by publishing a notice in newspaper(s) in each community or county located in the sponsor's service area. • If a PDP sponsor does not renew a contract, CMS cannot enter into a contract with the organization for 2 years unless CMS determines there are special circumstances that warrant special consideration. • CMS may elect not to authorize renewal of a contract for any of the following reasons: o For any of the reasons that also permits CMS to terminate the contract. o The PDP sponsor has committed any acts that result in the imposition of intermediate sanctions or civil money penalties. • CMS provides notice of its decision whether to authorize renewal of the contract as follows: o To the PDP sponsor by May 1 of the contract year. o To the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year. o To the general public at least 90 days before the end of the current calendar year, by publishing a notice in newspaper(s) in each community or county located in the sponsor's service area. • CMS gives the PDP sponsor written notice of its right to appeal the decision to not renew.	
§423.508 Modification or termination of contract by mutual consent. • A contract may be modified or terminated at any time by written mutual consent. • If the contract is terminated by mutual consent, the PDP sponsor must provide notice to its Medicare enrollees and the general public as provided above. • If the contract is modified by mutual consent, the PDP sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.	
§423.509 Termination of contract by CMS. • CMS may terminate a contract for any of the following reasons if the PDP sponsor: o Substantially fails to carry out the terms of its contract with CMS; o Is carrying out its contract in a manner that is not effective or efficient; o No longer meets the requirements for being a contracting organization; o There is credible evidence that the sponsor participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data; o Experiences financial difficulties so severe that its ability to provide drug coverage is impaired to the point of posing imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists; o Substantially fails to comply with the requirements relating to grievances and appeals; o Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data; o Substantially fails to comply with the service access requirements; o Substantially fails to comply with the marketing requirements; o Substantially fails to comply with the coordination with SPAP and other plans and programs; or	

PROPOSED RULE	PREAMBLE
o Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements. • If CMS decides to terminate a contract it gives notice of the termination as follows: o CMS notifies the sponsor in writing 90 days before the intended date of the termination. o The sponsor notifies enrollees by mail at least 30 days before the effective date. o The PDP sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in newspaper(s) in each community or county located in the sponsor's service area. • For immediate terminations based on serious violations CMS notifies the PDP sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the PDP sponsor covering the period of the month following the contract termination. o CMS notifies the sponsor's enrollees in writing of the termination no later than 30 days after CMS notifies the plan of its decision and simultaneously informs the enrollees of alternative options for obtaining prescription drug coverage, including PDPs MA-PDs in the area. o CMS notifies the general public no later than 30 days after notifying the plan by publishing a notice in newspaper(s) in each community or county located in the sponsor's service area. • Before terminating a contract, CMS provides the PDP sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies. o If a contract is terminated for fraud or for severe financial difficulties that pose a risk to enrollees, the PDP sponsor does not have the opportunity to submit a corrective action plan. • If CMS decides to terminate a contract, it sends written notice to the PDP sponsor informing it of its termination appeal rights.	
§423.510 Termination of contract by the PDP sponsor. • A sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract and must give advance notice as follows: o To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the PDP sponsor is requesting contract termination. o To its enrollees, at least 60 days before the termination. Must include a written description of alternatives available for obtaining Medicare drug services within the service area. o To the general public, at least 60 days before the termination by publishing a notice in newspaper(s) in each community or county located in the sponsor's geographic area(c) o • The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the PDP sponsor's notice of intent to terminate. • CMS's liability for payment to the PDP sponsor ends as of the first day of the month after the last month for which the contract is in effect. • CMS will not contract with an organization that has terminated its contract within the preceding 2 years unless CMS determines there are special circumstances that warrant special consideration.	

PROPOSED RULE	PREAMBLE
§423.512 Minimum enrollment requirements. • CMS will not enter into a contract unless the following minimum enrollment requirement is met: o At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or o At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and it primarily serves individuals residing outside of urbanized areas; • A PDP sponsor must maintain the minimum enrollment for the duration of its contract, except CMS may waive during the first contract year for an organization in a region.	
§423.514 Reporting requirements. • Each PDP sponsor must develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires the following statistics: o The cost of its operations. o The patterns of utilization of its services. o The availability, accessibility, and acceptability of its services. o Information demonstrating that the PDP sponsor has a fiscally sound operation. o Other matters that CMS may require. • Each PDP sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following: • Each PDP sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following: o A description of significant business transactions between the PDP sponsor and a party in interest: ▪ Indication that the costs of the transactions do not exceed the costs that are incurred if these transactions were with someone who is not a party in interest; or ▪ If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements. o A combined financial statement for the PDP sponsor and a party in interest if either of the following conditions is met: ▪ 35% or more of the costs of operation of the PDP sponsor go to a party in interest. ▪ 35% or more of the revenue of a party in interest is from the PDP sponsor. • Requirements for combined financial statements: o Must display in separate columns the financial information for the PDP sponsor and each of the parties in interest. o Inter-entity transactions must be eliminated in the consolidated column. o Must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes. o Upon written request from a PDP sponsor showing good cause, CMS may waive the requirement. • Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA). o For any employees' health benefits plan that includes a PDP sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under ERISA.	

PROPOSED RULE	PREAMBLE
o The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ``administrator'' is defined in ERISA. • *Loan information*. Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities. • Each PDP sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.	
§423.516 Prohibition of midyear implementation of significant new regulatory requirements. • CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a PDP.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart L: Effect of Change of Ownership or Leasing of Facilities During Term of Contract

PROPOSED RULE	PREAMBLE
§423.551 General provisions. • The following constitute a change of ownership: o Removal, addition, or substitution of a partner, unless partners agree otherwise as permitted by State law. o Transfer of substantially all the assets of the PDP sponsor to another party. o The merger or consolidation with one or more corporations, resulting in a new corporate body. o Transfer of stock or merger with the PDP sponsor surviving, does not constitute a change. • Advance notice requirement: o A PDP sponsor considering a change in ownership must notify CMS at least 60 days prior and provide financial information and a discussion of the financial impact on the surviving entity. o Sponsor remains liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership if timely notice is not given. o *A novation agreement* is an agreement signed by the current owner of the PDP sponsor, the prospective new owner, and CMS that meets CMS requirements; and under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract. o Without a novation agreement the existing contract becomes invalid; and if the new owner wishes to participate in Medicare, it must apply for, and enter into, a contract with CMS. o With a novation agreement signed by CMS, the new owner becomes the successor in interest to the current owner's existing Medicare contract.	*Seeks comment regarding how these provisions could be modified to accomplish these objectives. In particular, seeks comments regarding: situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to change of ownership, the novation agreement provisions, and the provision related to the leasing of a PDP's facilities.* *Seeks comment on situations where a sponsor transfers to another party substantial assets, but less than substantially all of its assets. Wants the comments to describe the different scenarios that might develop.*
§423.552 Novation agreement requirements. • CMS approves a novation agreement if the following conditions are met: o Advance notification. o The PDP sponsor submits to CMS, at least 30 days before the change of ownership date, three signed copies of the novation agreement, and one copy of other required relevant documents. o CMS makes a determination that the proposed new owner is in fact a successor in interest to the contract, and recognizes that the new owner is in the best interest of the Medicare program, and meets the requirements to qualify as a PDP sponsor. o A valid novation agreement requires the following: ▪ Assumption by the new owner of all obligations under the contract. ▪ Waiver of right to reimbursement by the previous owner for the current contract period. ▪ Guarantee of performance by the previous owner; or posting a performance bond. o The previous owner must make its books and records and other necessary information available to the new owner and to CMS for a determination of final settlement costs of the contract period.	
§423.553 Effect of leasing of a PDP sponsor's facilities. • If all facilities are leased to another entity, the existing contract terminates and if the other entity wishes to be a PDP sponsor, it must apply for and enter into a new contract with CMS. • If part of a sponsor's facilities are leased to another entity, the contract with CMS remains in effect while CMS determines whether it continues to be in compliance with the applicable requirements and conditions.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart M: Grievance, Coverage Determinations, and Appeals

PROPOSED RULE	PREAMBLE
§423.560 Definitions. The following definitions apply for this subpart: • *Appeal:* Any procedures that deal with the review of adverse coverage determinations made by the PDP sponsor on the benefits under a drug plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage. These procedures include redeterminations by the PDP sponsor and, if necessary, appeals to an independent review entity (IRE), hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review. An appeal does not include a grievance or a request for an exception to a tiered cost-sharing structure or formulary. • *Grievance:* Any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. • *Reconsideration:* A review of an adverse coverage determination by an IRE, the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains. • Redetermination: A review of an adverse coverage determination by a PDP sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the PDP sponsor obtains.	Definitions are similar to those for the MA program but have been modified to reflect applicability to the Part D drug benefits.
§423.562 General provisions. • Plan sponsors must, for each PDP that it offers, establish and maintain: o A grievance procedure for addressing issues that do not involve coverage determinations; o A procedure for making timely coverage determinations; o A procedure for handling exceptions to a tiered cost-sharing structure; o A procedure for handling exceptions to a formulary; and o Redetermination and appeal procedures for issues that involve coverage determinations. • Plan sponsors must ensure that all enrollees receive written information about the grievance and appeals procedures available through the sponsor; and the Quality Improvement Organization (QIO) process. • If a PDP sponsor delegates any of these responsibilities to another entity or individual, the sponsor is ultimately responsible for ensuring that these responsibilities are carried out. • Enrollees have all of the following rights in relation to PDP sponsors: o To have grievances heard and resolved by the sponsor; o To have a timely coverage determination; o To request from the sponsor an expedited coverage determination; o To request an exception to a PDP's tiered cost-sharing structure or formulary; o If dissatisfied with any part of a coverage determination by a PDP sponsor, the right to: ▪ a redetermination; ▪ an expedited redetermination; ▪ the right to reconsideration by an IRE, if as a result of a redetermination, a sponsor affirms, in part or in whole, its adverse coverage determination; ▪ an ALJ hearing, if the amount in controversy meets the requirements specified by the Secretary;	Notes that if a PDP sponsor delegates any of its responsibilities under this subpart to another entity, or individual through which the sponsor provides drug benefits, the sponsor is ultimately responsible for ensuring that applicable grievance, coverage determination, and appeal requirements are met. Points out an enrollee has no appeal right when there is no payment liability, or when benefits have been provided by a non-network pharmacy except in those emergency situations in which, under subpart C of this rule, the PDP is obligated to cover such drugs.

PROPOSED RULE	PREAMBLE
▪ Request a MAC hearing; ▪ Judicial review of the hearing decision, if the amount in controversy meets the requirements established by the Secretary . • If an enrollee has no further liability to pay for drugs furnished through a PDP, a determination regarding these items or services is not subject to appeal. If an enrollee seeks coverage of drugs received from a non-network pharmacy, except in those situations (such as an "emergency") in which the PDP is obligated to cover such drugs, a determination regarding the prescription drugs is not subject to appeal. • *When other regulations apply.* Unless provided otherwise under this subpart, the regulations relating to MA plans, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII of the SSA, and representation of parties under title XVIII of the SSA) and any interpretive rules or CMS rulings issued under these regulations, apply to the extent they are appropriate.	
§423. 564 Grievance procedures. • *In general.* Each PDP sponsor must provide meaningful procedures for timely hearing and resolving of grievances. Upon receiving a complaint, a PDP sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance or its appeal procedures. • For quality of care issues, an enrollee may file a grievance with the PDP sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the PDP sponsor must cooperate with the QIO in resolving the complaint. • *Expedited grievances*. A PDP sponsor must respond to an enrollee's grievance within 24 hours if: o The complaint involves a sponsor's decision to invoke an extension relating to a coverage determination or redetermination; or o The complaint involves a sponsor's refusal to grant an enrollee's request for an expedited coverage determination or expedited redetermination and the enrollee has not yet purchased or received the drug that is in dispute. • *Record keeping.* The PDP sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the PDP sponsor notified the enrollee of the disposition.	The MMA provides that federal law supersedes any state law or regulation (other than state licensing laws or state law relating to plan solvency) with respect to Part D plans. CMS says that aspects of state grievance laws, such as authorized representative matters, may be preempted and that it may need to reexamine federal grievance requirements. *Seeks comment on the preemption issue and the specific state grievance requirements that should be incorporated into federal requirements.*
§**423.566 Coverage determinations.** • Each PDP sponsor must have a procedure for making timely coverage determinations for basic and supplemental coverage and the amount, if any, that the enrollee is required to pay for a drug. The sponsor must have a standard procedure for making determinations and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function. • The following actions by a PDP sponsor are coverage determinations: o Failure to provide or pay for a covered Part D drug (including failure to pay because the drug is not on the plan's formulary, determined not to be medically necessary, furnished by an out-of-network pharmacy, or because the sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act) that the enrollee believes may be furnished by the PDP. o Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.	

PROPOSED RULE	PREAMBLE
o A decision on the amount of cost sharing for a drug. o A decision on whether a drug is a preferred drug for an enrollee. • *Who can request a coverage determination.* Individuals who can request a standard or expedited coverage determination are: o The enrollee, including his or her authorized representative; or o The prescribing physician, on behalf of the enrollee.	A prescribing physician need not be an appointed representative of the enrollee in order to assist in obtaining either a standard or an expedited coverage determination. *Seeks comment on any additional individuals or entities that should be able to request a coverage determination.*
§ **423.568 Standard timeframe and notice requirements for coverage determinations.** • *Timeframe for requests for drug benefit.* Initial coverage determinations *on requests for a drug (i.e., one that has not yet been provided)* must be made by the plan sponsor as expeditiously as the enrollee's health condition requires but not later than 14 days after receiving the request, except that the plan may extend the period an additional 14 days if the enrollee requests the delay or if the plan justifies how the delay is in the interest of the enrollee. If the sponsor extends the timeframe, it must notify the enrollee in writing of the reasons and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension. For extensions, the sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but not later than the expiration of the extension. • *Timeframe for requests for payment.* Initial coverage determinations *on requests for payment (after a drug is provided*) must be made by the plan sponsor within 30 days after the determination is requested • *Written notice for PDP sponsor denials*. If a sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination. • *Form and content of notice*. Such notice of denial must: o Use approved notice language in a readable and understandable form; o State the specific reasons for the denial; and o Inform the enrollee of his or her right to a redetermination. For coverage denials, the sponsor must describe both the standard and expedited redetermination processes. For payment denials, the sponsor must describe the standard redetermination process and the rest of the appeal process. • *Effect of failure to provide timely notice*. If the PDP sponsor fails to provide the enrollee with timely notice of a coverage determination, this failure itself constitutes an adverse determination and may be appealed.	
§423.570 Expediting certain coverage determinations. • *Request for expedited determination*. An enrollee or an enrollee's prescribing physician may request that a PDP sponsor expedite a coverage determination. This does not include requests for payment of drugs already furnished. • *How to make a request.* To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the sponsor, or if applicable, to the entity responsible for making the determination. A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination. • *How a sponsor must process requests.* The sponsor must establish and maintain specified procedures for processing requests for expedited determinations, including providing an efficient and convenient means for individuals to submit oral or written requests. For a request made by an enrollee, the plan must provide	

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an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. For a request made or supported by an enrollee's prescribing physician, the sponsor must provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. • *Actions following a denial*. If a sponsor denies a request for expedited determination, it must make the determination within the 14-calendar day timeframe for a standard determination. The 14-calendar day period begins with the day the PDP sponsor receives the request. In addition, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that: o Explains that the PDP sponsor must process the request using the 14-calendar day timeframe for standard determinations; o Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision not to expedite; o Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and o Provides instructions about the grievance process and its timeframes. • *Actions upon accepting requests for expedited determination.* If a sponsor grants a request for expedited determination, it must make the determination and give notice.	
§423.572 Timeframes and notice requirements for expedited coverage determinations. • A PDP sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. • The sponsor may extend the 72-hour timeframe by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a sponsor's decision to deny). When the sponsor extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension. The sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension. If the sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. • *Content of the notice of expedited determination.* The notice must state the specific reasons for the determination in understandable language. If the determination is not completely favorable to the enrollee, the notice must: o Inform the enrollee of his or her right to a redetermination; o Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination and the rest of the appeal process; and o Comply with any other requirements specified by CMS.	Clarifies that given the requirement that timing of determinations (and redeterminations) be based on an enrollee's health condition, the PDP sponsor has a responsibility to ensure that an enrollee's health situation and needs are fully considered in reviewing any requests (e.g., if an enrollee has a chronic condition that has necessitated ongoing use of the drug in question). However, if the enrollee already received the drug and the determination involves who should pay for the drug (or how much), there is generally no need for an expedited determination since the enrollee's health needs have been met.

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• *Effect of failure to provide a timely notice.* A failure by the sponsor to provide timely notice of an expedited coverage determination constitutes an adverse coverage determination and may be appealed.	
§423.576 Effect of a coverage determination. • A coverage determination is binding on the PDP sponsor and the enrollee unless it is reconsidered or is reopened and revised.	
§423.578 Exceptions process. • *Exceptions to tiered cost-sharing structure.* Each PDP sponsor using a tiered formulary must establish and maintain an exceptions process that addresses the following circumstances: (1) the enrollee is using a drug and the applicable tiered cost-sharing structure changes mid-year; (2) the enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; or (3) there is no pre-existing use of the drug by the enrollee. • The sponsor's exception criteria must include, but are not limited to: (1) a description of the criteria a sponsor uses to evaluate a determination made by the enrollee's prescribing physician, (2) consideration of the cost difference between the preferred drug and the requested drug that is the subject of the exceptions request; (3) consideration of whether the requested drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary. (Drug products evaluated as ``therapeutically equivalent'' can be expected to have equal effect and no difference when substituted for the requested drug); (4) consideration of the number of drugs on the sponsor's formulary that are in the same class and category as the requested prescription drug. • An enrollee, the enrollee's authorized representative, or the enrollee's prescribing physician may file a request for an exception. • A sponsor may require a written certification from the enrollee's prescribing physician that the preferred drug on the sponsor's formulary is not as effective for the enrollee as the requested drug, or that the preferred drug on the sponsor's formulary may have adverse effects for the enrollee, or both. • The sponsor may require the written certification to include only certain specific information that will enable the sponsor to evaluate the medical necessity of the exceptions request. • *Request for exceptions involving a non-formulary drug.* Each sponsor that provides drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain an exceptions process. Formulary use includes the application of a dose restriction that causes a particular drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular drug not to be covered until the requirements of the sponsor's coverage policy are met. The exceptions process must address the following circumstances: (1) coverage of a drug that is not covered based on the PDP sponsor's formulary; (2) continued coverage of a particular drug that the sponsor is discontinuing coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer; and (3) an exception to a sponsor's coverage policy that causes a drug not to be covered until the step therapy requirement is satisfied or not to be covered at the prescribed number of doses. • A PDP sponsor's exception procedures must include, but are not limited to: (1) a description of the criteria a sponsor uses to evaluate a prescribing physician's determination; (2) a process for comparing applicable	Under the statute, the standard for an exceptions process to a plan's tiered cost-sharing structure is that the prescribing physician determines that the preferred drug either would not be as effective for the individual or would have adverse effects for the individual, or both. CMS states that this standard should be regarded as a minimum threshold for granting an exception, and that plans can require more, subject to CMS guidance. CMS observes that this flexibility raises two key, intertwined questions: (1) to what extent should the Secretary limit a plan's discretion in establishing exceptions criteria? (2) How detailed must the criteria be? CMS considered including other exceptions criteria such as--(1) requiring sponsors to establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change in the tiering structure; (2) requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer designated as the `"preferred drug'' to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug; (3) requiring a sponsor to establish exceptions criteria that are specific to particular classes of covered Part D drugs, such as cholesterol-lowering drugs; and (4) requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis. CMS also contemplated the possibility of establishing criteria for the review process used to evaluate plan

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medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee; and (3) a description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug. • If the PDP sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold. • An enrollee, the enrollee's authorized representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception. • A sponsor may require a written certification from the enrollee's prescribing physician that the requested drug is medically necessary because: (1) there is not a drug on the formulary to treat the enrollee's disease or medical condition that is an acceptable clinical alternative; (2) the drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements has: (i) been ineffective in treating the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or (ii) has caused or, based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the enrollee; or (3) the number of doses available under a dose restriction for the drug has been ineffective in the treatment or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. • The PDP sponsor may require the written certification to include only certain specified information that is reasonable necessary to evaluate the medical necessity of the medical exceptions request. • *Requirements for exceptions determinations.* A sponsor's decision concerning an exceptions request constitutes a coverage determination as specified at §423.566. If the sponsor fails to make a decision on an exceptions request for continued coverage of a drug the sponsor is removing from its formulary and fails to provide notice of the decision within the required timeframe, the enrollee is entitled to have coverage for up to 1 month's supply of the drug that is the subject of the request. In addition, the sponsor must make a decision on the exceptions request before the enrollee's completion of the 1-month's supply. If the sponsor fails to make a decision on the exceptions request and provides notice of the decision before the enrollee's completion of the supply the sponsor must maintain coverage, unless: (1) there is a material change in the enrollee's terms of coverage or the applicable benefit limits have been exhausted; (2) the drug is no longer prescribed for the enrollee or is not considered safe for the treatment of the enrollee's disease or medical condition; or (3) a decision is made on the exceptions request and notice of that decision is provided. • *When an exceptions request is approved.* The sponsor must provide coverage for the approved prescription drug and must not: (1) require the enrollee to request approval for a refill or a new prescription to continue using the prescription drug after the refills for the initial prescription are exhausted, as long as the enrollee's physician continues to prescribe the drug, and the drug continues to be considered safe for treating the enrollee's disease or medical condition or (2) establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to drugs approved for coverage under this	review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria that are specific to particular classes of covered Part D drugs. Based on public comment and any additional information that is available at the time on the formulary structure, CMS may add further detail to these criteria or include additional criteria in the final rule. CMS observes that, unlike for the tiering exceptions, the statute does not specifically require that PDP sponsors develop an exceptions process to review requests for exceptions for non-formulary drugs. However, "we do not believe that the statute intends to preclude an enrollee from obtaining a coverage determination from a PDP sponsor absent a determination by the prescribing physician, or to require that the physician's determination alone should result in a favorable coverage determination by the PDP. Thus, we propose to require that PDP sponsors also establish exceptions criteria for addressing these situations. Requiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied. Additionally, requiring a similar exceptions process for conducting these types of reviews will help ensure that a PDP sponsor's formulary is based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs." Seeks comments and suggestions on the proposed rules relating to the exceptions process since "these provisions represent a critical component of the new prescription drug benefit…"

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section. • Nothing in this section should be construed to allow an enrollee to use the exceptions processes to request coverage for a drug that is not a covered Part D drug.	
§423.580 Right to a redetermination. • An enrollee who has received a coverage determination may request that it be redetermined under the procedures in §423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of the enrollee) may request an expedited redetermination.	
§423.582 Request for a standard redetermination. • An enrollee must ask for a redetermination by making an oral or written request with the PDP sponsor that made the coverage determination. Generally, an enrollee must file such a request within 60 calendar days from the date of the notice of the coverage determination. However, if an enrollee shows good cause, the sponsor may extend the timeframe. If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame. Such a request must be in writing and state why the redetermination was not filed on time. Such a request may also be withdrawn by the person who filed it.	
§423.584 Expediting certain redeterminations. • An enrollee or an enrollee's prescribing physician may request that a PDP sponsor expedite a redetermination that involves coverage determination issues relating to failure to provide or pay for a drug or failure to provide a timely coverage determination but not requests for payment of drugs already furnished. (Also does not apply to a coverage determination on amount of cost-sharing or a decision on preferred status of drug). • To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request. • The PDP sponsor must establish and maintain specific procedures for processing requests for expedited redetermination, including those relating to handling requests and issuing prompt decisions. • If a sponsor denies expedited redetermination request, it must: (1) automatically transfer the request to the standard timeframe and make the determination within the required 30-day timeframe; (2) give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that: (a) explains that the sponsor processes the enrollee's request using the 30-day timeframe; (b) informs the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision not to expedite; (c) informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and (d) provided instructions about the grievance process and its timeframes. • If a sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice.	

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§423.590 Timeframes and responsibility for making redeterminations. • The PDP sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. • In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the PDP sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.	
§423.600 Reconsideration by an independent review entity (IRE). • An enrollee who is dissatisfied with the redetermination of a PDP sponsor has a right to a reconsideration by an IRE that contracts with CMS. An enrollee must file a written request for reconsideration within 60 days of the date of the sponsor's redetermination. • When the enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. • For an enrollee to request an IRE reconsideration of a sponsor's determination not to provide for a covered Part D drug that is not on the formulary, the physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition is not as effective for the individual as the nonformulary drug, has adverse effects for the individual, or both. • The IRE must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in its contract.	CMS is proposing that enrollees be required to request reconsideration by an IRE, as opposed to having these cases automatically forwarded to the IRE. *Seeks comment on this proposal.* The IRE's review of adverse redeterminations of exceptions requests would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question. If it determined that the PDP sponsor correctly applied its exceptions criteria, the PDP's determination would be upheld. Thus, the IRE would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary. (CMS would be responsible for evaluating and approving a PDP's exceptions criteria and formulary as part of the annual plan approval process.)
§423.602 Notice of reconsideration determination by the independent review entity (IRE). • When the IRE makes its reconsideration determination, it must mail a notice to the enrollee and PDP sponsor and send a copy to CMS. The notice must: o State the specific reasons for the IRE's decision in understandable language; o If the reconsideration does not completely reverse the sponsor's adverse coverage determination, inform the enrollee of his or her right to an ALJ hearing if the amount in controversy exceeds the thresholds established by the Secretary; o Describe the procedures to be followed to obtain an ALJ hearing; and o Comply with other requirements specified by CMS.	
§423.604 Effect of a reconsideration determination. • A reconsideration determination is final and binding on the enrollee and the PDP sponsor, unless the enrollee files a request for an ALJ hearing.	

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§423.610 Right to an ALJ hearing. • If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ. • If the basis for the appeal is the PDP sponsor's refusal to provide drug benefits, CMS will use the projected value of those benefits to compute the amount remaining in controversy. • Two or more appeals may be aggregated by one enrollee to meet the amount in controversy for an ALJ hearing if: o The appeals have previously been reconsidered by an IRE; o The request for the ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations have been received; and o The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee. • Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if: o The appeals have previously been reconsidered by an IRE; o The request for ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations have been received; and o The ALJ determines that the appeals the enrollees seek to aggregate involve the same drug.	
§423.612 Request for an ALJ hearing. • The enrollee must file a written request for a hearing. The IRE receives the request directly or from the sponsor and must then forward it to the appropriate ALJ office. Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. • If a request for a hearing clearly shows that the amount in controversy is less than the required threshold (as established by the Secretary), the ALJ must dismiss the request. • If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the required amount, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.	
§423.620 Medicare Appeals Council (MAC). • An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal	See the regulations for the Medicare Advantage program at §422.608 for more information on how the MAC process works.
§423. 630 Judicial Review. • An enrollee may request judicial review of an ALJ's decision if: o The ALJ denied the enrollee's request for review; and o The amount in controversy meets the threshold requirement established annually by the Secretary. • An enrollee may request judicial review of the MAC's decision if: o It is the final decision of CMS and o The amount in controversy meets the threshold established annually by the Secretary. To request	

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judicial review, the enrollee must file a civil action in a U.S. district court consistent with statute and rules established in 205(g) of the SSA and subpart M of the MMA rule (which begins at §422.560).	
§423.634 Reopening and revising determinations and decisions. • A coverage determination or reconsideration made by a PDP sponsor, a reconsideration made by the IRE, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in §422, subpart M of this chapter. • The filing of a request for reopening does not relieve the PDP sponsor of its obligation to make payment or provide benefits as otherwise required. • Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed. • A decision of a PDP sponsor or any other entity not to reopen is not subject to review.	
§423.636 How a PDP sponsor must effectuate standard predeterminations, reconsideration determinations, or decisions. • *Reversals by the PDP sponsor of a request for benefits*. If, on redetermination of a request for benefit, the sponsor completely reverses its coverage determination, the sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the PDP sponsor receives the request for redetermination (or no later than upon expiration of an extension). • *Reversals of a request for payment.* If, on redetermination of a request for payment, the PDP sponsor completely reverses its coverage determination, the sponsor must pay for the benefit no later than 60 calendar days after the date the PDP sponsor receives the request for redetermination. • *Reversals by the IRE of requests for benefits.* If, on reconsideration of a request for benefit, the sponsor's determination is reversed in whole or in part by the IRE, the sponsor must authorize the benefit under dispute within 72 hours from the date it receives notice reversing the determination, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The sponsor must inform the IRE that the sponsor has effectuated the decision. • *Reversals by the IRE of requests for payment.* If, on reconsideration of a request for payment, the sponsor's determination is reversed in whole or in part by the IRE, the sponsor must pay for the benefit no later than 30 calendar days from the date it receives notice reversing the coverage determination. The sponsor must inform the IRE that the sponsor has effectuated the decision. • *Other reversals.* If the IRE's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the PDP sponsor must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The sponsor must inform the IRE that the sponsor has effectuated the decision.	
§423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered determinations. • *Reversals by the PDP sponsor*. If, on redetermination of an expedited request for benefits, the sponsor completely reverses its coverage determination, it must authorize or provide the benefit under dispute as	

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expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date it receives the request for redetermination (or no later than upon expiration of an extension). • *Reversals by the IRE.* If the sponsor's determination is reversed in whole or in part by the IRE, the sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The sponsor must inform the IRE that the sponsor has effectuated the decision. • *Other reversals.* If the IRE's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The sponsor must inform the IRE that the sponsor has effectuated the decision.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart N: Medicare Contract Determinations and Appeals

PROPOSED RULE	PREAMBLE
§423.641 - 423.643 Contract determinations. • A contract determination is a CMS decision to deny, terminate, or not renew a contract. • When CMS makes a contract determination, it gives the PDP sponsor written notice of the reasons for the determination and the PDP sponsor's right to request reconsideration. • CMS mails notice 90 days before the effective date of termination, except in case of terminations for fraud or severe financial difficulties, CMS immediately notifies the sponsor of its decision on termination. • If CMS is not going to renew a contract, it mails a notice to the sponsor by May 1 of the current year. • The contract determination is final and binding unless it is reconsidered, a timely request for a hearing is filed, or the reconsideration decision is revised as a result of a reopening.	A single set of procedures for contract determinations and appeals applies to both MA and PDP sponsors.
§423.644 - 423.648 Reconsiderations. • CMS reconsiders a contract determination if an authorized official of the contract applicant files a written request with any CMS office within 15 days from the date of the notice of the initial determination. o The request may be withdrawn at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS. • CMS provides applicant and CMS reasonable opportunity to present as evidence any documents or written statements that are relevant and material to the matters at issue. • A reconsidered determination affirms, reverses, or modifies the initial determination and is based on a review of the initial determination and other written evidence submitted. • CMS gives the applicant written notice of the reconsidered determination, and informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied.	
§423.650 - 423.665 Hearing. • An applicant determined to be unqualified or a PDP sponsor whose contract is terminated or is not renewed is entitled to a hearing on a reconsidered contract determination. • An authorized official of the applicant or sponsor that was the party to the determination may file a request for a hearing in writing with any CMS office within 15 days after the date of the reconsidered determination. • The parties to a hearing include the applicant, CMS, and, at the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by a decision at the hearing. • CMS postpones the effective date of a termination (except for terminations for fraud or severe financial difficulty) until a hearing decision is reached and affirmed by the Administrator, and extends the current contract at the end of the contract period only if CMS finds that an extension is consistent with the purpose of Part D this part; and for the period as CMS and the PDP sponsor agree. A contract terminated for fraud or severe financial difficulty is immediately terminated and is not postponed if a hearing is requested. • CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ. o A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. o A party to the hearing may object to the hearing officer in writing at the earliest opportunity. o The hearing officer must consider the objections, and may either proceed or withdraw. o If the hearing officer does not withdraw, the objecting party may, after the hearing, present	

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objections and ask in writing that the decision be revised or a new hearing be held. • The hearing officer fixes a time and place for the hearing, not to exceed 30 days from the hearing request and sends written notice to the parties with information about the hearing procedure. o The hearing officer may change the hearing time and place or adjourn or postpone it. • A party may appoint as its representative anyone not disqualified as a representative before the Secretary or otherwise prohibited by law. The representative gives or accepts any notice pertinent to the proceedings; presents evidence; and obtains information to the same extent as the party. • The hearing is open to the parties and to the public. • The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible in a court under rules applicable to court procedures. • The hearing officer may examine the witnesses, and the parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties. • Prehearing discovery is permitted if the request is made before the beginning of the hearing. o A reasonable time for inspection and reproduction of documents is provided. o The hearing officer's order on all discovery matters is final. • The hearing officer may schedule a prehearing conference to more clearly define the issues. • A complete record of the hearing proceedings is made and transcribed and made available to all parties upon request. The record may not be closed until a hearing decision is issued. • The hearing officer issues a written decision that is based upon the evidence; and contains separately numbered findings of fact and conclusions of law. The hearing decision is final and binding unless it is reversed or modified by the Administrator or reopened.	
§423.666 Review by the Administrator. • A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision. • The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified. • The Administrator issues a written decision, and furnishes the decision to the person requesting review. • A decision by the Administrator is final and binding unless it is reopened and revised.	
§423.668 - 423.669 Reopening of a contract decision. • CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination. • A hearing decision of a hearing officer that is unfavorable to any party may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the hearing decision. • A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision. • The notice of reopening and any revisions is mailed to the parties and specifies the reasons for revisions. • The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart O: Intermediate Sanctions

PROPOSED RULE	PREAMBLE
§423.750 Kinds of sanctions. • The following intermediate sanctions and civil money penalties may be imposed on PDP sponsors: o Civil money penalties ranging from $10,000 to $100,000 depending upon the violation. o Suspension of enrollment of Medicare beneficiaries. o Suspension of payment to the PDP sponsor for Medicare beneficiaries who enroll. o Suspension of all PDP marketing activities to Medicare beneficiaries. • The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.	Sanctions are identical to those that may be imposed on MA plans. *Seeks comments on whether to generally rely on civil monetary penalties rather than closing enrollment because the latter may have implications for maintaining a choice of 2 plans in an area.*
§423.752 Basis for imposing sanctions. • CMS may impose any of the sanctions on any PDP sponsor that:: o Fails to provide an enrollee medically necessary services that it is required to provide and that failure adversely affects (or is substantially likely to adversely affect) the enrollee. o Imposes premiums in excess of the monthly basic and supplemental beneficiary premiums permitted. o Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part. o Engages in any practice that may have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services. o Misrepresents or falsifies information that it furnishes to CMS; or to an individual or to any other entity. o Employs or contracts with an individual or entity who is excluded from participation in Medicare (or with an entity that employs or contracts with an individual or entity) for the provision of any of the following: ▪ Health care. ▪ Utilization review. ▪ Medical social work. or ▪ Administrative services. o If CMS makes a determination that could lead to a contract termination, CMS may instead impose the intermediate sanctions suspending enrollment and marketing. o The PDP sponsor may also be subject to other applicable remedies available under law.	Violations subject to sanctions are the same as for MA plans except for two that are not applicable to drug benefits.
§423.756 Procedures for imposing sanctions. • Before imposing the intermediate sanctions suspending enrollment, payment and marketing, CMS sends a written notice to the PDP sponsor stating the nature and basis of the proposed sanction; and sends the Office of the Inspector General (OIG) a copy of the notice. • CMS allows the PDP sponsor 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements. o CMS may allow a 15-day extension of the deadline upon receipt of a written request. o The request must provide a credible explanation of why additional time is necessary and be	

PROPOSED RULE	PREAMBLE
received before the end of the original 15-day period. o No extension is granted if the sponsor's conduct poses a threat to enrollee health and safety. • If the sponsor submits a timely response to CMS' sanction notice, CMS conducts an informal reconsideration that reviews the evidence and gives a written decision. • If CMS affirms the determination, CMS may: o Require the PDP sponsor to suspend acceptance of enrollment applications; o Suspend payments to the PDP sponsor for enrollees in the sanctioned plan; and o Require the PDP sponsor to suspend all marketing activities for the sanctioned plan. • A sanction is effective 15 days after the date of notice or, if the sponsor seeks reconsideration in a timely manner, after the date specified in the notice of CMS' reconsidered determination. o If the sponsor's conduct poses a serious threat to enrollee health and safety, CMS may make the sanction effective on an earlier date. • The sanction remains in effect until CMS notifies the PDP sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur. • In addition to or as an alternative to the sanctions, CMS may decline to authorize the renewal of an organization's contract, or terminate the contract. • CMS notifies the OIG of sanctionable behavior, as well as when it reverses or terminates a sanction. • The OIG may impose civil money penalties on the PDP sponsor in addition to, or in place of, the sanctions that CMS may impose. • CMS may impose civil money penalties on the PDP sponsor in addition to, or in place of, other sanctions.	
§423.758 Maximum amount of civil money penalties imposed by CMS. • If CMS suspends enrollment and marketing for a deficiency that could be punished by contract termination, the maximum civil money penalty is: o If the deficiency on which the determination is based has directly adversely affected (or is likely to adversely affect) one or more enrollees--up to $25,000 for each determination. o For each week that a deficiency remains uncorrected --up to $10,000 per week. o If a PDP sponsor has terminated its contract with CMS in a manner other than that allowed --$250 per Medicare enrollee from the terminated PDP plan or $100,000, whichever is greater.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals

PROPOSED RULE	PREAMBLE
§423.772 Definitions • *Family size:* the applicant, spouse living in the same household, and individuals related to the applicant(s), living in the household who are dependent on the applicant(s) for at least 1/2 of their financial support. • *Federal poverty line (FPL):* has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by that section. • *Full benefit dual eligible individual:* an individual who, for any month: o Has coverage for the month under a PDP or MA-PD plan; and o Is eligible for full Medicaid benefits for the month under any eligibility category in the State plan or a Section 1115 demonstration (not including Pharmacy Plus demonstrations). Also includes any individual determined by the State to be eligible for medical assistance as medically needy for any month if the individual was eligible for medical assistance in any part of the month. • *Full subsidy eligible individuals:* individuals meeting the eligibility requirements under §423.773 below. • *Income*: income as described under Medicaid without use of any more liberal disregards. Includes income of the applicant and spouse living in the same household, regardless of whether the spouse is also an applicant. • *Institutionalized individual:* a full-benefit dual eligible who is an inpatient in a medical institution or nursing facility for which payment is made by Medicaid throughout a month. • *Other subsidy eligible individuals:* those individuals meeting the eligibility requirements described in §423.773 below, • *Personal representatives:* Individuals authorized to act on behalf of the applicant; if the applicant is incapacitated or incompetent, someone acting responsibly on their behalf, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative. • *Resources:* liquid resources of the individual (and spouse living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Social Security Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. • *State:* each of the 50 States and the District of Columbia. • *Subsidy eligible individuals*: individuals meeting the low-income subsidy eligibility requirements.	
§423.773 Requirements for eligibility. • *A subsidy eligible individual* is a Part D eligible individual residing in a State who is enrolled in a PDP or MA-PD plan and meets the following requirements: o Has income below 150 percent of the FPL applicable to the individual's family size. o Has resources at or below the resource thresholds. • *Full subsidy eligible individual* is a subsidy eligible individual who: o Has income below 135 percent of the FPL applicable to the individual's family size; and resources that do not exceed: ▪ For 2006: 3 times those allowed for SSI eligibility (i.e., $6,000 single, $9,000 couple) including the assets or resources of the individual's spouse. ▪ After 2006: the amount allowable for the previous year increased by the CPI (all items,	The Secretary is exercising the authority provided in the MMA to treat Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs) and Qualifying Individuals (QIs) (and not Qualified Disabled and Working Individuals (QDWIs)) as full subsidy eligible. The Secretary is not exercising the option to allow states to use the less restrictive rules allowed for QMB, SMB, and QI eligibility determinations. Therefore, all states will be

PROPOSED RULE	PREAMBLE
U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. o An individual must be treated as a full subsidy eligible individual if the individual is a: ▪ Full benefit dual eligible individual; ▪ Recipient of SSI benefits under title XVI of the Social Security Act; or ▪ Eligible for Medicaid as a QMB, SLMB, or a QI. The State agency must notify these individuals that they are eligible for a full subsidy of Part D premiums and deductibles and must either enroll in a PDP or MA-PD or be randomly assigned to one. • *Other low-income subsidy individuals* are subsidy eligible individuals who: o Have income less than 150 percent of the FPL; and o Have resources that do not exceed: ▪ For 2006: $10,000 single/$20,000 couple (including resources of the spouse). ▪ After 2006: the amount allowable for the previous year increased by the CPI (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10.	using the same resource methodologies.
§423.774 Eligibility determinations, redeterminations, and applications. • Determinations of eligibility for low-income subsidies are made by the State if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration, the Commissioner of Social Security. • Eligibility determinations are effective the first day of the month in which the individual applies, or January 1, 2006 if the application was taken before that date, and remain in effect for a period not to exceed 1 year. • Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan. • Redeterminations and appeals of eligibility determinations made by the Commissioner must be made in the manner specified by the Commissioner. • In order for low-income subsidy applications to be considered complete, individuals applying for the low-income subsidy, or personal representatives applying on the individual's behalf, must: o Complete all required elements of the application; o Provide any statements from financial institutions to support information in the application; and o Certify, under penalty of perjury as to the accuracy of the application information.	*Seeks comments on how best to implement the redetermination and appeals process so that State and Social Security processes produce the same outcome.* CMS is working with Social Security to develop a model application form. CMS' general policy on verification is to not spend more than the expected return. Will use an operations research strategy which maximizes the use of automated data matches and relies on profiling. *Seeks comments on this approach.* Paper copies of financial statements will not be required unless requested.
§**423.780 Premium subsidy.** • Full subsidy individuals are entitled to a premium subsidy equal to 100 percent of the ``premium subsidy amount,'' not to exceed the basic premium for coverage under the prescription drug plan selected by the beneficiary, and not to exceed the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region. (The premium subsidy determined in this way applies regardless of whether the individual enrolls in a PDP or MA-D.) In the event the low-income benchmark premium is less than the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in a PDP region, the premium subsidy will be equal to the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the PDP region.	*Seeks comments on the manner in which sliding scale premium subsidies would be calculated for those with incomes from 135% to 150% of FPL. Suggests a stepped scale with a decrease in subsidy for every 5% increase in income.* Clarifies that Part D-required co-payments for low-income individuals cannot be reduced or eliminated because any reduction must apply to all plan members. (A specialized MA plan

PROPOSED RULE	PREAMBLE
• The low-income benchmark premium amount for a region equals either: o If all PDPs in the PDP region are offered by the same PDP sponsor, the weighted average of the monthly beneficiary premiums for basic prescription drug coverage; or o If the PDPs in the region are offered by more than one PDP sponsor, the weighted average of the monthly beneficiary premiums for basic coverage for all PDP and MA-PD plans in the region (excluding cost contract plans, PACE plans, specialized MA plans, and private fee-for-service plans) and the portion of the monthly beneficiary premium for alternative prescription drug coverage attributable to basic prescription drug coverage for all PDPs and MA-PD plans in the region. Fallback plans will be treated the same as risk-bid plans for the calculation of the low-income benchmark premium. The weighted average is determined based on plan enrollment. • Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100% of the premium subsidy amount for individuals with incomes at or below 135% of the FPL, to 0% for those with incomes at 150% of the FPL. • Full subsidy eligible individuals subject to late enrollment penalties receive an additional premium subsidy of 80% of the penalty for the first 60 months and 100% of the penalty thereafter.	enrolling only dual eligibles could reduce or eliminate co-payments).
§423.782 Cost-sharing subsidy. • Full subsidy eligible individuals are entitled to the following: o Elimination of the annual deductible. o Reduction in cost-sharing for all drugs covered under the PDP or MA-PD plan below the out-of-pocket limit, including drugs obtained after the initial coverage limit, as follows: ▪ Co-payment amounts not to exceed the co-payment amounts specified in §423.104. This applies to those full benefit dual eligible individuals who are not institutionalized and who have income above 100% of the FPL. ▪ Institutionalized individuals have no cost-sharing for drugs covered under their plans. ▪ Non-institutionalized full benefit dual eligibles with incomes that do not exceed 100% of the FPL are subject to cost-sharing equal to the lesser of a co-payment amount of $1 for a generic drug or preferred multiple source drug or $3 for any other drug, or the amount charged to other individuals with income below 135% of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. These amounts are increased each year beginning in 2007 by the percentage increase in CPI, rounded to the nearest multiple of 5 cents or 10 cents, respectively. ▪ Non-institutionalized full benefit dual eligible individuals with incomes that exceed 100% of the FPL are subject to cost-sharing for covered drugs equal to the lesser of a co-payment amount of $2 for a generic drug or preferred multiple source drug or $5 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. ▪ Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit. • Other low-income subsidy eligible individuals are entitled to the following:	

PROPOSED RULE	PREAMBLE
o Reduction in the annual deductible to $50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of $1. o 15% coinsurance for all drugs covered under the individual's PDP or MA-PD plan obtained after the initial coverage limit, up to the out-of-pocket limit. o For covered drugs above the out-of-pocket limit, co-payments not to exceed $2 for a generic drug or preferred multiple source drug and $5 for any other drug. These amounts are increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.	
§423.800 Administration of subsidy program. • CMS notifies the plan sponsor in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy and the amount of the subsidy. • The plan sponsor in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions. o The plan sponsor must track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold. • CMS reimburses plan sponsors for reductions, or if the sponsor elects, on a capitated basis. • Cost-sharing subsidies may be reimbursed on a capitated basis, taking into account the actuarial value of the subsidies and making appropriate adjustments to reflect differences in the risks actually involved. • The plan sponsor must reimburse low-income subsidy eligible individuals for any out-of-pocket costs relating to excess premiums and cost-sharing paid between the date of notice of subsidy eligibility and the date subsidy eligibility is effective.	*Seeks comments on:* • *Process for CMS to notify a plan that an enrollee is subsidy eligible and amount of the subsidy.* • *Requirement that sponsors notify CMS that cost-sharing or premiums have been reduced and the amount of the reduction.* • *How best to reimburse individuals for excess premiums and cost-sharing incurred after they become subsidy eligible.* • *How to deal with premiums and cost sharing paid by charities or other programs during a period that the individual is subsidy eligible. Should the beneficiary have to reimburse the charity or government program?*

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart Q: Guaranteeing Access to a Choice of Coverage (Fallback Plans)

PROPOSED RULE	PREAMBLE
§423.855 Definitions. • *Eligible Fallback Entity or Fallback Entity*: an entity that, with respect to a particular contract period: o Meets all the requirements to be a PDP sponsor except that it does not have to be a risk-bearing entity; and o Does not submit a bid for any PDP for any PDP region for the first year of that contract period. An entity is treated as submitting a bid if the entity is acting as a subcontractor for an integral part of the benefit management activities of a PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor for a prescription drug plan. • *Fallback Prescription Drug Plan:* a plan offered by a fallback entity that: o Offers only actuarially equivalent standard prescription drug coverage; o Provides access to negotiated prices, including discounts from manufacturers; and o Meets other requirements as specified by CMS. • *Qualifying Plan:* a full-risk or limited-risk PDP or an MA-PD plan that either provides basic coverage, or alternative coverage for no additional premium due to a premium rebate under Part C as a credit against the supplemental premium. An MA-PD plan must be open for enrollment and under a capacity waiver.	*Seeks comments on using an "Indefinite delivery" model contract for a fallback plan in case there is no need to activate the plan in an area. This would allow the entity to contract for a PDP in the following year if the fallback plan was not activated.* *Seeks comments on requirements or exceptions from PDP requirements that should be considered for fallback plans.*
§423.859 Assuring access to a choice of coverage. • A choice of at least 2 qualifying plans in each area must be available to each Part D eligible individual. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. o At least 1 of the 2 qualifying plans must be a PDP. • If CMS determines that Part D eligibles in a PDP region, or a portion of the region, do not have available a choice of two qualified plans, CMS designates the region or portion of a region as a fallback service area. • If CMS determines that Part D eligibles in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of 2 qualifying plans due to a contract termination in the middle of a contract year CMS, designates the region or portion of a region as a fallback service area. • CMS may waive or modify requirements if necessary to secure access to qualified drug coverage for Part D eligible individuals residing in the territories; or if an entity seeking to become a PDP in a territory requests a waiver or modification in order to provide qualified coverage in a territory.	*Seeks comments on waivers needed to assure access to drug coverage in the territories.*
§423.863 Submission and approval of bids. • CMS solicits bids from eligible fallback entities separate from the PDP bidding process. o CMS will solicit bids for 2006 in order to allow enough time to prepare a bid. o After that, bids will be solicited on 3-year cycles, or annually as needed to replace contractors. o The form and manner for submission of fallback bids will be provided in separate guidance. • Generally, the same rules for the approval or disapproval of PDPs apply to fallback plans. • CMS will contract with only 1 fallback plan to serve all fallback service areas in a PDP region. • CMS will use competitive procedures to enter into a contract with a fallback plan. • CMS will approve a fallback PDP in a manner so that it is offered at the same time as PDPs are otherwise offered. For mid-year changes CMS approves a fallback PDP so that it is offered within 90 days of notice.	

PROPOSED RULE	PREAMBLE
• CMS may not contract with a single entity for the offering of fallback plans throughout the United States.	
§423.867 Rules regarding premiums. • The monthly beneficiary premium under a fallback PDP must be uniform for all fallback service areas in a PDP region (except for late enrollment penalties and low-income subsidies). • It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the region based on similar expenses of PDPs. • Premiums are collected in the same manner as Part B premiums (deducted from social security checks).	
§423.871 Contract terms and conditions. • In general the terms and conditions of contracts with eligible fallback entities offering fallback PDPs are the same as the terms and conditions for PDPs. • A contract with a fallback entity is in effect for a period of 3 years. However, a fallback PDP may be offered for any year within the contract period for a particular area only if the area is a fallback service area. • A fallback entity may not engage in any marketing or branding of a fallback PDP. • CMS issues guidance establishing performance measures for fallback PDPs based on the following: o Performance measures include at least measures for each of the following: ▪ Cost containment through mechanisms such as generic substitution and price discounts, including discounts from manufacturers. ▪ Quality programs that avoid adverse drug reactions and over-utilization and reduce medical errors. ▪ Timely and accurate delivery of services. ▪ Efficient and effective benefit administration and claims adjudication. • CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor experience nationwide during a base period, or changing program emphases or requirements. • A contract approved with a fallback entity includes terms for payment for: o The actual costs (taking into account negotiated price concessions of covered Part D drugs provided to enrollees in a fallback PDP offered by the entity); and o Management fees that are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract. • Each contract requires an eligible fallback entity to provide CMS with the information CMS determines is necessary, or as required by law. • Officers, employees and contractors of the DHHS may use information disclosed or obtained only for the purposes of, and as necessary for carrying out this part. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.	
§423.875 Payments to fallback plans. • The amount payable for a fallback PDP drug plan is the amount determined under the contract for the plan.	*Seeks comments on payment methods for fallback plans, especially in regard to prospective or retrospective rebate allocation.*

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart R: Payments to Sponsors of Retiree Prescription Drug Plans

PROPOSED RULE	PREAMBLE
§423.882 Definitions. • *Allowable retiree costs:* covered retiree plan-related prescription drug costs between the cost threshold and cost limit, as defined below, that are actually paid by either the qualified retiree plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions. • *Retiree drug subsidy amount:* the subsidy amount paid to sponsors of qualified retiree drug coverage. • *Employment-based retiree health coverage*: coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or the spouse or dependent of a retiree. The term includes voluntary insurance coverage, or coverage as a result of statutory or contractual obligation. • *Gross covered retiree plan-related prescription drug costs:* for a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for covered Part D drugs, paid for by the plan or the retiree, including costs directly related to dispensing. • *Group health plan:* as defined in section 607(1) of the Employee Retirement Income Security Act (ERISA) and also includes the following plans: o *Federal and State governmental plan* means a plan established or maintained for its employees by the Government of the United States, the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, including FEHBP. o *Collectively bargained plan:* a plan established by one or more collective bargaining agreements. o *Church plan:* a plan for employees or their beneficiaries of a church or by a convention or association of churches that is exempt from tax under section 501 of the IRS code. • *Qualified retiree prescription drug plan:* employment-based retiree health coverage that meets Part D requirements for a Part D eligible individual who is a participant or beneficiary under the coverage. • *Qualifying covered retiree:* a Part D eligible individual who participates in the qualified retiree prescription drug plan or the spouse or dependent of a participant, who is not enrolled in a PDP an MA-PD plan. • *Sponsor*: a plan sponsor as defined in section 3(16)(B) of ERISA, except that, for plans maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.	Employers have following options for providing drug coverage: • Provide drug benefits that do not qualify for subsidies; • Provide qualified drug benefits and get subsidies –Part D benefit and access provisions do not apply except actuarial equivalence; • "Wrap-around" Part D (TROOP applies); • Subsidize all or part of Part D premium; • Sponsor a PDP or MA-PD plan (TROOP applies). *Seeks comments on ways to maximize enhancements of employer benefits.* *Seeks comments on effective methods of outreach to employers and venues for outreach.*
§423.884 Requirements for qualified retiree prescription drug plans. A qualified retiree prescription drug plan must meet the following requirements: • The plan sponsor (or administrator) provides CMS an attestation that the actuarial value of the retiree plan drug coverage is at least equal to the actuarial value of Part D standard coverage. The attestation must: o Be provided annually, no later than 90 days prior to the start of the calendar year, except that for 2006, the attestation must be provided by September 30, 2005; o Be provided no later than 90 days before the implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage; o Certify that the values have been calculated according to established CMS actuarial guidelines based on generally accepted actuarial principles; o Be certified by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries;	*Seeks comments on attestation requirements and balance between beneficiary protections and undue burden on sponsors.* Approaches to establishing actuarial equivalence under consideration: • "Gross" value of the benefits is at least equal to Part D standard coverage (concern about potential windfall to employers if subsidies exceed what employer has paid vs. that paid through enrollee premiums) • Limit the amount of subsidy so it could not exceed the amount actually paid by the

PROPOSED RULE	PREAMBLE
o Be signed under the penalty of perjury; o State that the information is true and accurate to the best of the attester's knowledge; and o Acknowledge that the information being provided is being used to obtain Federal funds. • The sponsor must submit an application for the subsidy, signed by an authorized representative of the sponsor, to CMS by: o For the year 2006, September 30, 2005. o For all other years, 90 days prior to the start of the year. o For plans that begin coverage mid-year, 90 days prior to the date the coverage begins. o For new plans after September 30, 2005, 150 days prior to the start of the new plan. • The following information must be submitted with the application: o Employer Tax ID Number (if applicable). o Sponsor name and address. o Contact name and email address. o Actuarial attestation and supporting documentation for each of the sponsor's plans. o Full names of each qualifying retiree enrolled in each drug plan (including spouses and dependents, if Medicare-eligible), and Health Insurance Claim (HIC) number; birth date; sex; Social Security number; and relationship to the retired employee. • The sponsor must: o Agree to comply with all Federal laws and regulations, and the terms and conditions of eligibility for a subsidy payment, including audit of claims for subsidies and combating fraud and abuse; o Acknowledge that the information is being provided to obtain Federal funds; o Require that all subcontractors, including administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds; and o Sign any further certification that CMS may require. • An authorized representative of the sponsor must sign the completed application. • The sponsor (or the plan administrator) must provide updates to CMS of the required information in the manner and frequency specified by CMS. • Once the full application for the subsidy is submitted, CMS matches the names and identifying information of each retiree with the Medicare Data Base (MBD) to identify which retirees are qualifying covered retirees and provides to the sponsor (or plan administrator) the names of the sponsor's qualifying covered retirees. • The sponsor must disclose to all of its retirees and spouses and dependents in the plan who are Part D eligible individuals whether the coverage is creditable coverage. • The sponsor must allow CMS to audit and have access to records.	employer (but CMS uncertain concern about legal basis for such a policy); or • 2 prong test; combine "gross" value test with "net" value that reduces the value by the amount financed by enrollees. o Several variations on computing "net" value are proposed. *Seeks comments on these and other options. Seeks comments on deadlines and how they correspond to sponsors' open season. Seeks comments on the information required of sponsors.* *Seeks comments on whether to require a surety bond or preferred creditor status as part of the enrollment process in order to address situations of bankruptcy or termination prior to final reconciliation.* *Seeks comments on the format, placement, and timing of the notice of creditable coverage as well as methods for sponsors to notify CMS of creditable status of coverage.*
§423.886 Retiree drug subsidy amounts. • The sponsor receives a subsidy payment of 28% of the allowable retiree costs attributable to the gross prescription drug costs between the cost threshold and the cost limit for each qualifying enrollee in a plan year in which the retiree's gross retiree plan-related prescription drug costs exceeds the cost threshold. • The following cost threshold and cost limits apply: o For 2006 the cost threshold is $250 and the cost limit is $5,000. o For years after 2006, the cost limit and threshold are adjusted annually in the same manner as the	

PROPOSED RULE	PREAMBLE
annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted.	
§423.888 Payment methods, including provision of necessary information. • Payment is conditioned on provision of accurate and truthful information. The qualified retiree drug plan (or plan administrator or insurer must submit the information required to CMS as specified by CMS. • Officers, employees and contractors of DHHS, including the OIG, may use the information collected only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct necessary audits and evaluations. • The sponsor of the qualified retiree drug plan (or an administrator or insurer of the plan), as applicable, must maintain, and furnish to CMS or the OIG upon request, the following records, which must be maintained for 6 years after the plan year in which the costs were incurred: o Reports and working documents of the actuaries who wrote the attestation. o All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment, including the underlying claims data. • CMS or the OIG may extend the 6-year retention rule for ongoing investigation, litigation or negotiation.	*Seeks comment on whether to use plan year instead of calendar year as basis for subsidies. Lists options for using plan year.* *Seeks comments on subsidy payment process and periodicity. Suggests options:* *1. Pay after close of year.* *2. Make interim estimated payments throughout year subject to final settlement after end of year.* *3. Make payments based on experience. Reconcile on rebates, discounts after year end.* *Seeks comments on level of detail of cost data to be submitted to CMS.* *Seeks comments on the impact of privacy provisions where data provided CMS by plan would not be shared with the plan sponsor.* *Seeks comments on the 6 year retention rule.*
§423.890 Appeals. • A sponsor is entitled to an informal written reconsideration of an adverse initial determination regarding: o The amount of the subsidy payment. o The actuarial equivalence of the sponsor's retiree prescription drug plan. o If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or o Any other similar determination (as determined by CMS) that affects a subsidy payment. • An initial determination is final and binding unless a request for reconsideration is made in writing and filed with CMS within 15 days of the date on the notice of adverse determination. • The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements and may include additional documentary evidence. • CMS reviews the determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS, informs the sponsor of the reconsideration decision orally or by electronic mail and sends a written decision to the sponsor on the sponsor's request. • A reconsideration decision, oral or in writing, is final and binding unless a request for a hearing is filed. • A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing. o A written hearing request must be filed with CMS within 15 days of the reconsideration decision. o The request must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.	*Seeks comments on the 3 step appeals process (reconsideration, hearing, Administrator reviews). Discusses options:* • *Telephone hearing instead of in-person.* • *Hearing with no opportunity for oral testimony.*

PROPOSED RULE	PREAMBLE
o CMS provides written notice of the time and place at least 10 days before the informal hearing. o A CMS hearing officer conducts the hearing and is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations. o If CMS did not issue a written decision, the hearing officer may request, but not require, one from CMS explaining the determination, or CMS may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not be taken into account in reaching a decision. • The CMS hearing officer decides the case and sends a written decision to the sponsor. • The hearing officer decision is final and binding, unless it is reversed or modified by the Administrator. • A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the decision. • The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision. • The Administrator's determination is final and binding. • CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor: o Within 1 year of the date of the notice of determination for any reason. o Within 4 years for good cause. o At any time when the underlying decision was obtained through fraud or similar fault. • Notice of reopening and any revisions are mailed to the sponsor with reasons for any revisions. • The revision of an initial or reconsidered determination is final and binding unless: o The sponsor requests reconsideration; o A timely request for a hearing is filed; o The determination is reviewed by the Administrator; or o The determination is reopened and revised. • CMS finds good cause if: o New and material evidence not readily available for the initial determination is furnished; o A clerical error in the computation of payments was made; or o The evidence that was considered shows on its face that an error was made. • CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.	*Seeks comments on whether to allow reopening of decisions by hearing officer or Administrator.*
§423.892 Change in ownership. • Any of the following constitutes a change of ownership: o Partnership. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law. o Transfer of substantially all of the assets of the sponsor to another party. o The merger or consolidation of the sponsor's corporation with one or more other corporations, resulting in a new corporate body. • Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.	*Seeks comments on situations where a plan sponsor transfers substantial assets, but not all of its assets, to another party.* *Seeks comments on scenarios that might develop if more than one entity retains or acquires liability for drug costs as a result of change in ownership.*

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• A sponsor with a retiree drug subsidy agreement in effect considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. • When there is a change of ownership that results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner. • The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.	
§423.894 Construction. Nothing in this part must be interpreted as prohibiting or restricting: • A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a PDP or an MA-PD plan; • A sponsor or other person from paying all or any part of the monthly beneficiary premium for a PDP or MA-PD plan on behalf of a retiree (or his or her spouse or dependents); • A sponsor from providing supplemental coverage to Part D eligible individuals under employment-based retiree health coverage or coverage of higher actuarial value than that of standard coverage. • A sponsor from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to PDPs and MA-PD plans.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart S: Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

PROPOSED RULE	PREAMBLE
§423.902 Definitions. • *Actuarial value of capitated prescription drug benefits:* the estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. • *Applicable growth factor for each of 2004, 2005, and 2006:* the average annual percent change over the previous year in per capita prescription drug expenditures (based on the most recent National Health Expenditure projections). • *Growth factor for 2007 and after*: the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the U.S. for Part D eligible individuals for the 12 months ending in July of the previous year. • *Base year Medicaid per capita expenditures:* the monthly weighted average of: o The gross base year (2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and o The estimated actuarial value of drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible for 2003. • *Full-benefit dual eligible individual*: an individual who, for any month: o Has coverage under a PDP or MA-PD plan; and o Is eligible for full Medicaid benefits (including under a section 1115 waiver, but not under Pharmacy Plus demonstrations). o Also includes any individual who is eligible for Medicaid as medically needy if the individual was eligible for Medicaid in any part of the month. o For the 2003 baseline calculations, the full-benefit dual eligibles are those having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. • *Gross base year Medicaid per capita expenditures*: equal to the expenditures, including dispensing fees, made by the State during calendar year 2003 for Part D covered outpatient drugs, determined per full-benefit-dual-eligible-individual (excluding individuals receiving medical assistance for drugs through a Medicaid managed care plan). This amount is determined based on Medicaid drug claims paid during the four quarters of calendar year 2003 and the associated dual eligibility enrollment status of the beneficiary. • *Phased-down State contribution factor for a month:* 2006: 90 % 2007: 88 \1/3 % 2008: 86 \2/3 % 2009: 85 % 2010: 83 \1/3% 2011: 81 \2/3% 2012: 80 % 2013: 78 \1/3 % 2014: 76 \2/3 % 2015 and beyond: 75 %. • *Phased-down State contribution payment:* the State's' monthly payment to the Federal government to defray some of the Medicare drug expenditures for full-benefit dual eligibles equal to 1/12th of the product of the base year Medicaid per capita expenditures for Part D drugs for full-benefit dual eligibles multiplied by: o The State's Federal medical assistance percentage (FMAP) o The applicable growth factor; o The number of the State's full-benefit dual eligibles for the given month; and	

PROPOSED RULE	PREAMBLE
o The phased-down State contribution factor. • *Rebate adjustment factor*: equals the ratio for the State for the four quarters of calendar year 2003 of aggregate Medicaid rebate payments received by the State to the gross expenditures for covered outpatient drugs. • *State Medical Assistance Percentage:* the proportion equal to 100 percent minus the State's FMAP, applicable to the State for the fiscal year in which the month occurs.	
§423.904 Eligibility determinations for low-income subsidies. *States must*: • Make eligibility determinations and redeterminations for Part D low-income subsidies. • Inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS. • Screen individuals who apply for Part D subsidies for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing (i.e., QMB, SLMB, QI programs). • Offer Medicaid enrollment to those meeting the State plan eligibility requirements. • Notify deemed subsidy eligibles of their Part D subsidy eligibility. • Make available by no later than July 1, 2005: o Low-income subsidy application forms; o Information on the nature of, and eligibility requirements for, the subsidies under this section; and o Assistance with completion of low-income subsidy application forms. • Require an individual or personal representative applying for the low-income subsidy to: o Complete all required elements of the application and provide documents, as necessary; and o Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form. • Provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit. *States may require:* • Submission of financial statements for an application for low-income subsidies to be considered complete; and • That information be subject to verification in a manner the State determines to be most cost-effective and efficient.	CMS worked with the Social Security Administration on a simplified application form and process for the low-income subsidy program and developed uniform criteria for determining resources, income, and family size. *Seeks comments on ways to ease the administrative burden on States and to ensure a consistent eligibility determination process.*
§423.906. General payment provisions. • Regular Federal matching applies to the administrative expenses associated with eligibility determination and notification activities. • Medicare is the primary payer for covered drugs for Part D eligible individuals. • Federal Medicaid assistance is not available to full-benefit dual eligibles, effective January 1, 2006, including those not enrolled in Part D, for covered Part D drugs or Part D cost-sharing obligations. • States may elect to provide coverage, and receive federal matching funds, for drugs other than Part D drugs in the same manner as for non-Medicare full-benefit dual eligible individuals or through an arrangement with a PDP or an MA-PD plan.	
§423.907 Treatment of territories. • Part D enrollees in the territories are not eligible to receive low-income premium and cost-sharing subsidies. • A territory may submit a plan to the Secretary for providing medical assistance to low-income individuals for	

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covered Part D drugs. • Territories with approved plans will receive increased grants proportional to their Medicare population and the total grant funds available to the territories with approved plans. • Plans submitted to the Secretary must include a description of the medical assistance to be provided, the low-income population (income less than 150 % of FPL) to receive medical assistance, and assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.	
§423.910 State contribution requirements ("clawback"). • Each State and the District of Columbia is required to pay the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose drug coverage is assumed by Medicare Part D. • The State contribution payment is calculated by the Secretary on a monthly basis. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the state contribution payment is calculated using a methodology determined by the Secretary. • State payment must be made in a manner similar to that in which State payments are made for Medicare premiums, except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal SMI (Part B) Trust Fund. • If a State fails to pay, interest accrues at the rate applicable to Medicaid overpayments. The amount so owed, and applicable interest, must be immediately offset against amounts otherwise payable to the state for Medicaid. • States are required to provide accurate and complete coding to identify the numbers and types of dual eligibles beginning with calendar year 2003 MSIS reporting. 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004. • For each month (no later than 30 days after the end of each month), effective January 2006, States must submit, an electronic file identifying each full-benefit dual eligible enrolled in the State for each month with Part D coverage. • The Secretary performs those periodic data matches as necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment. • The Secretary establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during 2003 as reported on the CMS 64 Medicaid expenditure reports that were received by CMS on or before March 31, 2004. Rebates include Medicaid rebates and supplemental rebates. • The Secretary notifies each State by October 15 of each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.	

MEDICARE PRESCRIPTION DRUG BENEFIT – SUMMARY OF PROPOSED RULE
Subpart T: Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE and Medigap Requirements

PROPOSED RULE	PREAMBLE
§411. 351. Definition of outpatient prescription drugs for purposes of physician self-referral prohibition. • Proposing to add to the existing definition of drugs in the physician self referral regulations all drugs that are covered by Medicare Part D. (The regulation currently only includes drugs covered by Part B.)	This change is required to reflect the addition of Part D coverage in the physician self-referral regulations. Indicates that CMS believes that referrals for Part D drugs are subject to the same risk for over-utilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs. *Seeks comments on the proposed definition.*
§417.440 and §417.534. Cost-based HMOs and Competitive Medical Plans (CMPs) offering Part D coverage. • Would amend §417.440 to include Medicare Part D services to the extent that the HMO or CMP offers qualified prescription drug coverage under Part D and the enrollee is entitled to benefits under Part D. (A CMP is a plan that is not a Federally qualified HMO but meets the requirements to contract with Medicare. Under the MMA, Part D rules will generally apply to reasonable cost reimbursement HMOs and CMPs that contract under section 1876 of the Social Security Act and that offer qualified prescription drug coverage to Part D eligible enrollees in the same manner as such rules apply to local MA-PD plans.) • To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits will be reimbursed under this part. These costs instead will be reimbursed solely under the applicable provisions of then Part D regulations.	Cost contract plans are not permitted to operate freestanding PDPs. The Part D bids of such plans will not be included in the computation of the national average bid amount and the low-income benchmark premium amount. Notes that the waiver authority provided in §1860D-21(c) of the MMA would be available to cost contract HMOs and CMPs in the same manner as it is available to MA-PD plans. To the extent that a Part D requirement is in conflict with or duplicative of a section 1876 requirement, or to the extent that a waiver would promote coordination of Part A and Part B benefits with Part D benefits, a waiver would also be available to cost contract HMOs and CMPs. *Seeks comments on whether there are any Part D requirements otherwise applicable to MA-PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs.*
PACE Organizations offering Part D Coverage. • A PACE program may elect to provide qualified prescription drug coverage to its Part D eligible enrollees and Part D requirements would then apply in a manner that is similar to MA-local plans. However, the provisions of the MMA are to some extent in conflict with current law requirements on PACE organizations under §1894 and §1934 of the Social Security Act. For example, whereas Part D plans have required beneficiary cost-sharing (e.g., co-payments for drugs purchased under the catastrophic benefit), PACE organizations are not allowed to require enrollees to pay any co-payments for their prescription drugs. The	CMS notes that the MMA provides little specific guidance for implementing the prescription drug benefit for Part D eligible PACE enrollees. CMS notes that it does not believe that Congress intended to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided to enrollees. Therefore, CMS

PROPOSED RULE	PREAMBLE
preamble for subpart T proposes ways in which such conflicts may be resolved and discusses how PACE organizations may obtain waivers from the MMA requirement that they be treated similarly to MA-local plans for purposes of the Part D benefit.	is proposing that PACE organizations not be deemed as MA-PD local plans. Rather, PACE organizations would be treated in a manner that is similar to an MA-PD local plan for purposes of payment under Part D. This approach is consistent with section 1894(d)(1) of the Social Security Act that provides that payments will be made to PACE organizations in the same manner and from the same sources as payments are made to a Medicare+Choice (now MA) organization. It also specifies a set of proposed waivers for PACE organizations.
§403. 205 Medicare supplemental policy. • With the specific exceptions listed below, a Medicare supplemental or Medigap policy means a health insurance policy or other health benefit plan that: (1): a private entity offers to a Medicare beneficiary; and (2) is primarily advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare. • A "policy" refers to both a "policy form" and "policy." A p*olicy form* means the form of health insurance contract approved by and on file with the state agency for the regulation of insurance. A *policy* is the contract issued under the policy form and held by the policy holder. • "*Medicare supplemental policy."* Includes: (1) an individual policy; (2) a group policy; 3) a rider attached to an individual or group policy; or (4) as of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of a Medicare supplemental policy as defined in this section. • Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy. • *Exceptions.* A Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in §1882(g)(1) of the Social Security Act.	In order to reflect the addition of the Medicare drug benefit by the MMA, CMS proposes to revise the definition of a Medigap policy. CMS notes that some ambiguity had existed in the past about whether a policy that covered only prescription drugs, either as a separate, `"stand-alone'' policy or as a rider to another policy, met the definition of a Medigap policy. The ambiguity was created because there was no Medicare drug benefit to supplement. This has been resolved with the enactment of the Medicare drug benefit. Some confusion exists about whether a rider attached to a Medigap policy is considered part of the policy, and therefore subject to Medigap requirements. Accordingly, CMS proposes to revise the definition of a Medigap policy as stated in the proposed regulation. Notes that all the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, would apply to the rider. Thus, for instance, if an insurer offers an optional prescription drug rider that can be added to any other policies, addition of the rider would make the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies. Moreover,

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	any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy, would meet that definition as of January 1, 2006, when the prescription drug benefit takes effect, and new sales of these policies would be prohibited.
Additional provisions. §104 of the MMA requires that there be written disclosure notice that Medigap insurers must provide to their policy holders who have drug coverage. CMS specifies these disclosure provisions through the preamble (and not in the regulation itself). The MMA also requires that these disclosure standards be developed by the Secretary in consultation with the National Association of Insurance Commissioners (NAIC). As stated in the preamble, the purpose of the disclosure notice is to inform an individual who has a Medigap Rx policy about his or her Medigap choices once Part D goes into effect on January 1, 2006. On that date, the sale of new Medigap Rx policies will be prohibited, and drug coverage from Medigap Rx policies held by beneficiaries who enroll under Part D will have to be eliminated. The statute permits the renewal of Medigap Rx policies if the policy was purchased prior to January 1, 2006, and the individual does not enroll in Part D. In addition, beneficiaries who do not enroll in Part D during the Initial Enrollment Period, and choose to enroll later, will be charged higher Part D premiums unless they can establish that they had creditable prescription drug coverage prior to enrolling in Part D.	**(1) Timing and content of notice.** Issuers must send the disclosure notice during the 60-day period immediately preceding the initial Medicare Part D enrollment period (November 15, 2005 through May 15, 2006). Accordingly, Medigap issuers must send the written disclosure notice between September 16, 2005 and November 15, 2005. The written disclosure notice must inform the individual of his or her Medigap options if the individual does or does not enroll in Medicare Part D. **(2) Medigap policy as creditable coverage.** Medigap issuers will be responsible for determining whether the drug coverage under their policies is creditable drug coverage in accordance with the final rule implementing the Part D drug benefit. Medigap Plans H and I would not meet the actuarial equivalence standard, although it is possible to have a specific group for which the drug coverage in standardized Medigap Plan J would be creditable prescription drug coverage. Based on the distributions of drug utilization that the actuaries have seen so far, however, drug coverage in standardized Medigap Plan J would be unlikely to meet the definition of creditable prescription drug coverage. CMS cautions, however, that whether or not coverage is creditable cannot be determined until it has issued a final rule. **(3) Required disclosure notice.** The disclosure notice contains the basic language required to be included in all disclosure notices sent by Medigap issuers. It also proposes specific language to be included for policies that do not provide creditable

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	coverage (although CMS is not proposing exact language at this time). *Seeks comments on how the draft notice could be adapted for the types of policies that might provide creditable coverage.* The notice informing policyholders that they do have creditable coverage must advise them that they may be subject to late enrollment penalties under Part D if they eventually enroll in a Part D plan and have not maintained the creditable drug coverage they have under their Medigap policies. CMS also plans to work with the three states that have different Medigap standards (i.e., the "waiver states" of Massachusetts, Minnesota and Wisconsin) so that in the event the coverage offered in those States meets the definition of creditable coverage, there will be a required disclosure notice appropriate for use in those States. *Seeks comments on what to include in these potential model disclosure notices.* The preamble includes the language for a proposed disclosure notice for Medigap issuers to use for Medigap policies that do not have creditable drug coverage. Again, this group likely will include standardized Medigap Plans H, I, and J, as well as prestandardized Medigap plans, or plans sold in waiver states, that do not provide creditable drug coverage. The draft disclosure notice reflects consultation with the NAIC.

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