PRESCRIPTION DRUG COVERAGE FOR MEDICARE BENEFICIARIES

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

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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 (Notice of Proposed Rulemaking or NPRM) in the *Federal Register* (69 FR 46631) that contained the regulations to implement the Medicare Prescription Drug Benefit (Title I of the MMA). Public comments were due to CMS on October 4, 2004. Over 7,000 comments were received. CMS published the final rule on January 28, 2005 (70 FR 4194).

Given the high level of interest in the regulations for implementing the Medicare drug benefit, Health Policy Alternatives, Inc. prepared a summary of the NPRM for The Henry J. Kaiser Family Foundation, so that interested readers could obtain information about how CMS proposes to implement the drug benefit. This document has been revised to reflect the policies adopted in the Final Rule

Like the proposed rule, the final rule is divided into many 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, and indicates where CMS made changes from what was included in the proposed rule. The revised language is shown in bold print. (Provisions or language that were deleted in the final rule are shown as strike outs). This document also summarizes issues or clarifications discussed in the preamble to the final rule. Finally, the “Preamble” column identifies where CMS has indicated plans to issue additional guidance, reports, or other “sub-regulatory” instructions and information.

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Subpart A: General Provisions

FINAL RULE	PREAMBLE (FINAL RULE)
§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 (i.e., a drug marketed under a proprietary, trademark-protected name.) ***Cost plan*. A plan operated by a Health Maintenance Organization of Competitive Medical Plan in accordance with a cost-reimbursement contract.** ~~• *Fallback prescription drug plan*: a prescription drug plan (PDP) offered by a fallback entity that:~~ ~~○ Offers only standard prescription drug coverage;~~ ~~○ Provides access to negotiated prices; and~~ ~~○ Meets other requirements as specified by CMS in subpart Q.~~ **Definition moved to Subpart Q (§423.855).** • *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:~~ ~~○ Has coverage for the month under a PDP or MA-PD plan; and~~ ~~○ 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.~~ **Definition moved to Subpart P (§423.772).** • *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.~~ Has the meaning given the term in ***§*422.2.** • *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. • ***Monthly beneficiary premium:* the amount calculated under §423.286 for Part D plans other than fallback prescription drug plans, and §423.867(a) for fallback prescription drug plans.** • ***PACE Plan*: a plan offered by a PACE organization.** • ***Part D eligible individual*: an individual entitled to or enrolled in Medicare Part A and/or Part B.** • ***Part D plan or Medicare Part D plan*: a PDP, MA-PDP, PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.**	Final rule moves some definitions to relevant subparts and uses this section for definitions of terms used throughout. Also includes new definitions. Indicates that CMS may waive the service area requirement for employer-sponsored group prescription drug plans in appropriate cases. *Further details will be provided in separate CMS guidance.*

FINAL RULE	PREAMBLE (FINAL RULE)
• *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. **This includes fallback prescription drug plans.** • *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. o **For a fallback PDP, an area that meets the definition of a fallback service area (423.859(b)).** o **For a PACE plan, the plan's service area (described in §460.22 of this chapter).** o **For a cost plan, an area described in §417.1 of this chapter.** o **Service area does not include facilities in which individuals are incarcerated.** ~~• *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.~~ **Definition moved to Subpart J (§423.454).** • *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.	CMS is planning to develop a range of tools and strategies that will help beneficiaries make a choice that meets their needs.

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

FINAL RULE	PREAMBLE (FINAL RULE)
§423.30 ~~Eligibility to enroll.~~ ***Eligibility and Enrollment*** • **An individual is eligible for Part D, and may enroll in a PDP, if he or she is:** **entitled to Medicare benefits under Part A or enrolled in Medicare Part B;** **lives** in the service area of a Part D plan; and is not **enrolled in another Part D plan**. MA enrollees may not enroll in a PDP except for those in a PFFS or MSA plan. Enrollees in PACE plans that offer Part D coverage **must obtain Part D coverage through that plan.** • **Individuals entitled to Part A or enrolled in Part B with a retroactive effective date are Part D eligible as of the month in which a notice of entitlement for Part A or enrollment in Part B is provided.** • **Cost plan enrollees who elect to receive Part D coverage under the plan are ineligible to enroll in another Part D plan but an enrollee in a cost plan offering qualified coverage is eligible to enroll in a PDP if the individual does not elect that entity's Part D coverage.**	Beneficiaries in state mental institutions will be provided with a special enrollment period to enable them to join the appropriate Part D plan based upon their situation. *CMS expects to provide guidance on this issue.*
§423.32 Enrollment process. • To enroll, an individual must complete the PDP's enrollment form or other process permitted by CMS. o **Enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between HHS (or designees) and the PDP sponsor. I** o **Individuals who assist with enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.** o **Part D plan enrollees must provide information regarding reimbursement for Part D costs through other insurance, and consent to release of information provided by the individual on other insurance.** • PDP sponsors must: o **Provide an enrollment form and mechanism complying with CMS instructions relating to content and format.** o Enroll all eligible individuals who elect the plan during enrollment periods, o Provide prompt notice of acceptance or denial in a format and manner specified by CMS. • **Maintenance of enrollment: An individual remains enrolled until the individual:** o **Successfully enrolls in another PDP;** o **Voluntarily disenrolls from the PDP;** o **Is involuntarily disenrolled from the PDP;** o **The PDP is discontinued; or** o **The individual is enrolled by CMS in another PDP, in accordance with 423.35(c).** **Enrollees in cost or PACE plans with drug coverage as of December 31, 2005 remain enrolled in that plan as of January 1, 2006, and will receive Part D benefits offered by that plan until they disenroll.**	The final rule reorganizes some of the content in this subpart to provide for greater clarity. For example, the section on maintenance of enrollment is a modified version of that which appeared in 423.42 of the proposed rule. By not limiting type of enrollment mechanisms, CMS intending to allow flexibility and creativity. *CMS intends to issue operational guidance in the future.* Notes that a legal representative is included as "the part D eligible individual." This section has been revised to permit a person or entity to assist a beneficiary in completing and submitting applications to a PDP.
~~§423.34 Enrollment process.~~ 423.34 Enrollment of full-benefit dual eligible individuals.	

FINAL RULE	PREAMBLE (FINAL RULE)
~~To enroll, an individual must complete the PDP's enrollment form or other process permitted by CMS.~~ ~~PDP sponsors must:~~ ~~Enroll all eligible individuals who elect the plan during enrollment periods,~~ ~~Process the enrollment request according to CMS guidelines.~~ ~~Provide prompt notice of acceptance or denial in a format and manner specified by CMS.~~ • **CMS (and not the states) must ensure the enrollment into Part D plans of full-benefit dual eligibles who fail to enroll in a Part D plan.** • **Defines a full-benefit dual eligible individual as one who is determined eligible by the state for:** ○ **Medicaid under any eligibility category covered under the state plan or comprehensive benefits under a section 1115 waiver, or for medical assistance (medically needy).** • **CMS may enroll a full-benefit dual eligible individual in another PDP during the annual coordinated election period if CMS determines that such enrollment is warranted (e.g., the plan's premium rose above the low-income subsidy amount).** • **Auto enrollment: CMS must auto enrollment into a PDP offering basic prescription drug coverage in the area in which the individual resides that has a monthly premium that does not exceed the low-income premium subsidy amount. If there is more than one such plan, enrollment will be done on a random basis.** • **Full benefit duals may decline enrollment in Part D or may disenroll from the plan in which they were enrolled and elect to enroll in another plan during the special enrollment period (for full benefit duals, this is effectively at any time).** • **CMS will perform the autoenrollment as of January 1, 2006 for individuals who are full duals as of December 31, 2005. After 2006, full benefit duals will be enrolled into plans as soon as their Medicare eligibility is determined.**	CMS will facilitate full benefit dual eligible individuals who are MA enrollees into the MA-PD with the lowest Part D premium, even if the premium is not covered by the low-income premium subsidy amount. CMS may facilitate enrollment for all others deemed or determined eligible for the low-income subsidy, i.e., QMBs, SLMBs, or QI-Is), and others who qualify for low-income subsidies.
§423.36 Disenrollment process. • **To disenroll, an individual may:** ○ **Enroll in another PDP;** ○ **File a disenrollment request as prescribed by CMS; or** ○ **Disenroll through other CMS approved mechanisms.** • **PDP sponsors are responsible for:** ○ **Submitting disenrollment notices to CMS within specified timeframes;** ○ **Providing notice to the enrollee; and** ○ **Filing and retaining disenrollment requests for a CMS specified period.** • **Retroactive disenrollment may be granted by CMS if:** ○ **There was never a valid enrollment; or** ○ **A valid disenrollment request was not acted upon.**	The contents of this new subsection had appeared in §423.42 in the proposed rule. CMS initially envisions a paper disenrollment process but the rule retains the flexibility for other secure and convenient mechanisms to be approved in the future. Any such mechanism would be available at the option of each PDP sponsor. To address possibility that beneficiaries will enroll in a Part D plan and be disenrolled from an employer plan, CMS intends to establish a process for PDPs and MA-PDS to verify an enrollment request for individuals who have been identified as having been claimed by an employer group sponsor to receive the employer based subsidy.

FINAL RULE	PREAMBLE (FINAL RULE)
	CMS intends to issue operational guidance on beneficiary education process targeted to individuals who already have other drug coverage.
~~§ 423.36 Enrollment periods.~~ §423.38 Enrollment periods. Establishes initial enrollment periods: o November 15, 2005 through May 15, 2006, (for those first eligible prior to January 31, 2006). o November 15, 2005 through May 31, 2006 (for those first eligible for Part D in February 2006). o Upon becoming Medicare eligible in March 2006 and after, the same as the individual's initial Part B enrollment period (3 months before the month of eligibility, and 3 months following Part D eligibility). Establishes annual coordinated election period. For 2004, this begins November 15, 2005 and ends on May 15, 2006. For 2007 and subsequent years, it is November 15th through December 31st for coverage beginning the following calendar year. • Establishes special enrollment periods (SEPs) for: Involuntary loss of creditable coverage; Persons not adequately informed about the status of creditable coverage; Unintentional, inadvertent, or erroneous enrollment/nonenrollment due to federal employee action; Full benefit dual eligible individuals; Individuals who disenroll from an MA-PD plan during the first year of MA plan eligibility; Individuals enrolled in PDPs when PDP sponsor's contract is terminated **or no longer offered in area in which individual resides;** Individuals who no longer reside in PDP service area; and Individuals who experience a substantial breach of contract by their plan.	*CMS will issue guidance regarding the SEPs, including for those individuals: eligible for the low-income subsidy whose enrollment will be facilitated, in long-term care facilities, enrolled in, or desiring, to enroll in PACE, and enrolled in employer group plans. May establish additional SEPs in the future through operational guidance.* CMS may establish SEPs on a case-by-case basis, where warranted by an immediate exceptional circumstance, such as an individual with a life-threatening condition or illness.
~~§ 423.38Effective dates.~~ § 423.40 Effective dates Plan elections made: Prior to Medicare entitlement/enrollment will be effective the first day of the month of entitlement or enrollment. 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
~~**§ 423.42 Coordination of enrollment and disenrollment through PDPs.**~~ ~~• To disenroll, an individual may:~~ ~~○ Enroll in another PDP;~~ ~~○ File a disenrollment request as prescribed by CMS; or~~ ~~○ Disenroll through other CMS approved mechanisms.~~ ~~• PDP sponsors are responsible for:~~ ~~○ Submitting disenrollment notices to CMS within specified timeframes;~~ ~~○ Providing notice to the enrollee; and~~ ~~○ Filing and retaining disenrollment requests for a CMS specified period.~~ ~~• Retroactive disenrollment may be granted by CMS if:~~ ~~○ There was never a valid enrollment; or~~ ~~○ A valid disenrollment request was not acted upon.~~ ~~• Maintenance of enrollment: individuals remain enrolled until the individual:~~ ~~○ Successfully enrolls in another PDP;~~ ~~○ Voluntarily disenrolls from the PDP;~~ ~~○ Is involuntarily disenrolled from the PDP; or~~ ~~○ The PDP is discontinued.~~	See §423.36 Disenrollment process.
~~**§ 423.44 Disenrollment by the PDP.**~~ **§ 423.44 Involuntary disenrollment by the PDP.** • PDP sponsors may not involuntarily disenroll individuals or request or encourage disenrollment. • Exceptions when PDP may disenroll: ○ Nonpayment of premium in timely manner;* ○ Disruptive behavior by enrollee.* • Exceptions when PDP must disenroll: ○ Enrollee no longer resides in service area;* ○ Enrollee loses Medicare entitlement (CMS will notify the PDP); ○ Enrollee dies; ○ PDP sponsor terminates contract with CMS (enrollee notice required as specified by CMS);* ○ 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 refuse reenrollment until all past premiums are paid. • Disruptive behavior is behavior ~~that:~~ ~~○ Jeopardizes the health or safety of the person or others;~~ ○ Impairs sponsor's ability to furnish services to the person or other plan members. **An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.** ~~○ Does not comply with the material terms of the enrollment agreement.~~	*CMS intends to provide further guidance to PDPs on the process of disenrollment when an individual:* • *permanently moves out of the service area;* • *loses entitlement to Part A or Part B; or* • *materially misrepresents information on third-party coverage.* Revised rule to focus on behavior that substantially impairs a PDP sponsor's ability to arrange or provide care for the individual or plan members. Clarifies that a full-benefit dual eligible individual who is involuntarily disenrolled for disruptive behavior remains

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• PDP sponsor must document the behavior to CMS and efforts to resolve problems. **Must inform the individual of the right to use the PDP's grievance procedure. The person has a right to submit any information or explanation. CMS (using staff with appropriate clinical or medical expertise) decides, including conditions on future re-enrollment as specified by the PDP, within 20 working days. PDP required to provide a reasonable accommodation for person in exceptional circumstances that CMS deems necessary. CMS notifies PDP within 5 working days after making its decision.** • **CMS reserves right to deny a request from a fallback plan to disenroll an individual for disruptive behavior.** • Disenrollment is effective the first day of the following month. PDP may decline future enrollment by the person. ~~CMS may consider an expedited process in certain circumstances.~~	entitled to a special enrollment period.
§ 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.	*CMS is developing operational and system requirements to implement the late enrollment penalty process. Additional guidance will be given to PDPs and individuals.*
§ 423.48 Information about Part D. • Each plan must annually provide CMS specified information necessary (benefits and formularies; monthly premium; quality and performance; cost-sharing; and results of consumer satisfaction surveys, etc.) for beneficiaries to make informed decisions among plans.	CMS anticipates posting the maximum negotiated prices for prescription drugs as part of the beneficiary information made available on the Medicare.gov website. Beneficiaries will pay the lower of the negotiated or usual and customary price at the point of sale.
§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. ○ Plan sponsors meeting CMS performance requirements may use materials 5 days after submission if not disapproved (File & Use). ○ **Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.** • Marketing materials include materials that; ○ Promote the PDP; ○ Provide information on enrollment; ○ Explain benefits or rules; ○ Explain covered services. ○ Examples of marketing materials are provided. • CMS review guidelines include provision of adequate written: ○ Description of rules, benefits, fees; ○ Explanation of grievance and appeals process; ○ Other necessary information; ○ Appropriate notification of the public of the enrollment period;	*CMS intends to provide greater detail on marketing issues through future guidance. These will give greater detail on what is expected of PDP sponsors, including requirements to ensure appropriate information is available to beneficiaries, including those with low literacy, are disabled, etc. Also will address marketing by providers and pharmacies, remuneration offered to providers in exchange for providing to patients information about Part D plans, eligibility and performance requirements associated with the File& Use program, and model marketing materials for sponsors.* SPAPs will be prohibited from discriminating against PDPs (i.e., they cannot steer beneficiaries to specific PDPs). They may provide beneficiaries with comparable education on all available Part D plans. Any auto enrollment of full-benefit duals into PDPs

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○ Notice of potential plan termination; and ○ Materials that are not materially inaccurate or misleading; ○ 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: ○ Provide cash or other enrollment inducements; ○ Engage in discriminatory activity such as targeted marketing based on income; ○ Solicit door-to-door; ○ Confuse or mislead beneficiaries, including claiming they are recommended or endorsed by CMS; ○ Use providers or provider groups to distribute PDP comparison information unless all plans involved concur and CMS approves; ○ Accept enrollment forms where health care is delivered; ○ Use names that imply a plan is not open to all beneficiaries; and ○ Engage in other CMS prohibited marketing activities. • PDPs must: ○ Allocate marketing resources to the disabled population; and ○ Maintain a system for confirming enrolled beneficiaries and under the applicable rules.	will have to be done on a random basis. Providers and pharmacies will be allowed to provide prospective enrollees with information on the full range of Part D options available to them. In situations where plans want to use or disclose protected health information, for purposes of marketing, Part D plans must comply with HIPAA and obtain a written authorization from the beneficiary prior to using such information to market non-health related products and services.
§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; ○ PDP or MA-PD plans; ○ Medicaid; ○ Group health plans including FEHBP, and qualified retiree plans; ○ ~~Supplemental drug coverage programs;~~ State Pharmaceutical Assistance Programs ○ Veterans benefits; ○ Medigap; ○ TRICARE and military coverage; ○ ~~e~~ Individual health insurance; ~~and~~ ○ Indian health service benefits. ○ **Coverage provided by a PACE organization;** ○ **Cost-based HMO or CMP;** ○ **Coverage offered by state high-risk pools as defined under HIPAA; and** ○ **Other coverage as the Secretary may determine appropriate.** • All of the above except PDP or MA-PD plans, **and PACE or cost plans that provide Part D coverage,** 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: ○ Fact that the actuarial value does not meet requirements; ○ Limited periods for PDP enrollment; and ○ Possibility of late enrollment penalty. • These plans (with the exceptions noted above) must also disclose creditable coverage status to CMS.	The rule has been revised to require plans to apply the actuarial equivalence standard to each benefit option within its plan. (The proposed rule would have required to be applied to the coverage as a whole.) The rule has been revised to allow notices of creditable and noncreditable status to be provided as part of other required documents (e.g. HIPAA notices or summary plan descriptions) so long as the information is conspicuous and includes standard information elements. *CMS intends to issue guidance on the aspects of actuarial equivalence, and may issue guidance, if determined necessary, specifying additional sources of creditable coverage. Guidance also will be provided on the form, manner and timing of the required notice; on a method for determining creditable coverage for employer group sponsors not electing the retiree drug subsidy.*

FINAL RULE	PREAMBLE (FINAL RULE)
• **Notice must be given to Part D eligible individuals prior to initial enrollment period, prior to the effective date of enrollment in the drug coverage, upon any change that affects whether the coverage is creditable, prior to the commencement of the annual coordinated election period; and upon request by the individual.** • If an individual is not adequately informed, he/she may apply to CMS to have coverage treated as creditable for purposes of applying the late enrollment penalty	

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

FINAL RULE	PREAMBLE (FINAL RULE)
§423.100 Definitions. • ***Actual cost:*** **negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with §423.124(a.** • ***Affected enrollee:*** **a Part D enrollee currently taking a covered Part D drug that is either being removed from a Part D plan's formulary or whose preferred or tiered cost-sharing status is changing.** • *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. • ***Contracted pharmacy network:*** **pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.** • ***Covered Part D drug*****: a means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §423.566, §423.580, and §423.600, §423.610, §423,620, and §423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with §423.124.** • ***Dispensing Fee:*** **costs that: (1) are incurred at the point of sale and pay for costs in excess of the** • **Ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed; (2) include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee.** ○ **Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities, measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.** ○ **In the case of pharmacies owned and operated by a Part D plan itself, notwithstanding number (3) of this definition, dispensing fees are understood to be the equivalent of all reasonable costs discussed above, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy; and** **(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.** • ***Government–funded health plan*****: any program established, maintained, or funded, in whole or in part, by the Government of the U.S, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including**	Note that a "covered Part D drug" is one that is on a plan's formulary or is treated as being so as a result of a coverage determination or appeal. It is distinguished from a "Part D drug" which is a drug that may be covered under Part D.

FINAL RULE	PREAMBLE (FINAL RULE)
any of the following: an SCHIP plan, Medicaid or a 1115 waiver, the VA, the Indian Health Service program, and any other government-funded program whose principal activity is the direct provision of health care. • *Group health plan:* **for purposes of applying the definition of incurred costs in §423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart (see below).** • *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 health plan ~~(other than a group health plan) or program~~ that provides, or pays the cost of Part D drugs, including, but not limited, to any of the following: o Health insurance coverage as defined in HIPAA (42 U.S.C. 300gg-91(b)(1); o An MA plan; and a o PACE organization; ~~A program of all-inclusive care for the elderly (PACE)~~; But specifically excluding a personal health savings vehicle. ~~o An approved State child health plan (SCHIP);~~ ~~o Medicaid (including under a section 1115 waiver);~~ ~~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 medical institution** or nursing facility for which payment is made **for an institutionalized individual under Medicaid section 1919(a) 1902(q)(1)(B).** • *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 **that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale** and includes any dispensing fees. • *Network pharmacy:* a licensed pharmacy ~~(not a mail order pharmacy)~~ under contract with a PDP sponsor ~~or MA organization~~ **to provide covered Part D drugs to its Part D plan enrollees.** • *Non-preferred pharmacy:* a network pharmacy **that offers Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at 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. • *Or otherwise: through a government-funded health program.* • *Part D drug:* **(was "Covered Part D drug" under NPRM) includes** any of the following if used for a	CMS has expanded the definition of a LTC facility to encompass not only skilled nursing facilities but also any medical institution or nursing facilities as defined under section 1919(a) of Medicaid. This expansion includes ICFs/MR and inpatient psychiatric hospitals facility, provided those facilities meet the requirements of a medical institution that receives Medicaid payments for institutionalized individuals under section 1902(q)(1)(B) of the Medicaid.

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medically accepted indication (as defined under Medicaid in section 1927(k)(6) of the Act): ○ A drug that may be dispensed only upon a prescription (described in Medicaid sections 1927(k)(2)(A)(i) through (iii)); ○ A biological product (described in Medicaid sections 1927(k)(2)(B)(i) through (iii)); ○ Insulin (described in Medicaid section 1927(k)(2)(C)); ○ Syringes, needles, alcohol swabs, and gauze associated with insulin injection; or ○ A vaccine licensed under section 351 of the Public Health Service Act. • **Does not include:** ○ 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 ○ 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. *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. • ***Personal health savings vehicle*: a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following-(1) a Health Savings Account; (2) a Flexible Spending Account offered in conjunction with a cafeteria plan; and (3) an Archer Medical Savings Account; but specifically excluding a Health Reimbursement Arrangement (as described in Internal Revenue Service Rulings 2002-41 and 2002-45).** • *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. • ***Retail pharmacy:* any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.** • *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.	CMS clarifies that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication. Under medical supplies, test strips and lancets, which are covered under Part B, cannot be covered under Part D. Needle disposal systems are also not covered under Part D. With respect to vaccines, plans will need to develop explicit criteria that can be applied on a case-by-case basis to determine that the administration of Part D vaccine is "reasonable and necessary" and that the Part D vaccine is therefore a covered Part D drug. Presumably these will comply with any widely accepted practice guidelines. If such are not available for certain vaccines, Part D plans will need to develop criteria that they can support with sound clinical reasoning. Part D-covered vaccines administered in physicians' offices will be covered under the out-of-network access rules (423.124). Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by 1927(d)(2) of the Act, provided they otherwise meet the requirements of 1860D-2(e)(1) and are not otherwise excluded under 1860D-2(e)(2)(B). To the extent this is the case, and a drug is dispensed for a "medically accepted indication" as described in the statute, weight loss agents may be covered for the treatment of morbid obesity, and decongestant products for example, may be covered when used to treat allergies. However, CMS clarifies that Part D plans may establish utilization management processes in

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• *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. • *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 an out-of-network pharmacy *or* **a physician's office** charges a customer who does not have any form of prescription drug coverage.	establish utilization management processes in order to ensure that such drugs are being prescribed for medically accepted indications that are not excluded under section 1927(d)(2) of the Act (for example, decongestant products when used for "symptomatic relief of coughs and colds"). *The various issues raised by the drugs covered by Part B for the administration of the Part D drug benefit will be addressed in a forthcoming Congressionally mandated report.* *CMS will also provide more information and guidance on the relation between Part B and Part D coverage in separate guidance to Part D plans.* Payments out of HSAs, FSAs, and MSAs will count as costs incurred by the enrollee and thus count toward TrOOP. Payments out of HRAs will not be allowed to be counted.
§423.104 Requirements related to qualified prescription drug coverage. • A Part D ~~PDP~~ sponsor ~~offering a PDP or an MA organization offering an MA-PD plan~~ must: ○ 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. ○ Offer that plan to all eligible beneficiaries in the plan's service area ~~(except if the plan has capacity limits~~; ○ 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: ○ 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. ○ Cost-sharing under the initial coverage limit of: ▪ 25% coinsurance for **actual** costs above the deductible and up to the initial coverage limit; or ▪ Actuarially equivalent to an average coinsurance of no more than 25 percent of **actual costs**; or ▪ Tiered co-payments ~~without limit~~, consistent with an average 25% coinsurance.	*For calculations of the annual percentage increase, CMS will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to Part D sponsors prior to the deadline for bid submissions.*

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○ 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. ○ Coinsurance for costs that fall between the initial coverage limit and the annual out-of-pocket threshold that is equal to 100%. ○ 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. ○ 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. ○ 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: ○ Has an annual deductible that does not exceed the annual deductible specified in law; ○ Imposes cost-sharing no greater than that specified in law once the annual out-of-pocket threshold specified in law is met; ○ **Has a total gross value that is at least equal to the total or gross value of defined standard coverage; and** ○ 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 the coverage exceeds the actuarial value of the subsidy payments; and ○ 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: ○ Coverage of drugs other than covered Part D drugs; and/or ○ 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. ○ 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: ○ 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	In determining true out-of-pocket costs (TrOOP), a charity does not have to be a bona fide charity for its payments on behalf of a beneficiary's Part D cost-sharing to be counted towards TrOOP. Similarly, a manufacturer's patient assistance program does not have to be a bona fide charity. However, in all such cases, the payment arrangements must comply with Federal fraud and abuse laws, including Medicare's anti-kickback statute (1128(b)), and civil monetary penalty provision (1128A(a)(5)). Notes that under the new exception to the anti-kickback statute added by section 101(e) of the MMA, pharmacies are permitted to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for beneficiaries enrolled in a Part D plan eligible for the low-income subsidy, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. Waivers or reductions of Part D cost-sharing by pharmacies will count towards TrOOP.

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○ 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 cost contract plan electing qualified drug coverage may offer enhanced alternative coverage as an optional supplemental benefit only if the cost plan also offers basic coverage. Such a plan may not offer drug coverage that is not qualified. A cost contract plan that does not offer qualified coverage may offer drug coverage that is not qualified coverage.** • A plan must provide its enrollees with access to negotiated prices for drugs included in its formulary. ○ 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). ○ 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. ○ Information on negotiated prices disclosed to CMS is protected under the confidentiality provisions applicable under Medicaid section 1927(b) (3) (D). ○ CMS **and the Office of the Inspector General** 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.	Any coverage that supplements benefits under Part D that are provided to beneficiaries by Medicaid, Medicaid 115, Pharmacy Plus waivers, VA, IHS, ADAP, and local or state indigent care programs will not count toward TrOOP. (SPAP payments are an exception.) However, ADAPs, HIS, and other programs providing coverage that supplements Part D benefits may subsidize costs incurred against an enrollee's deductible costs for those patients unable to afford them. Such subsidies will not affect the enrollee's ability to satisfy the deductible and thus qualify for the reduced cost-sharing between the deductible and the initial coverage limit. Such entities may also pay the enrollee's cost-sharing above the out-of-pocket threshold the enrollee has accumulated incurred costs above that threshold. Regarding negotiated prices, CMS should be able to determine the proportion of total aggregate price concessions that are passed through to the Medicare program or enrollees. *CMS will specify in operational guidance the format and frequency of the required plan reporting as well as what constitutes direct or indirect remunerations, rebates and discounts.*
§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. ○ To the extent practicable, PDP regions are the same as MA regions. ○ CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to benefits for Part D eligible individuals. ○ CMS establishes a PDP region(s) for the territories. ○ 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.	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 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

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	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~~ Part D plan must have a contracted pharmacy network, ~~other than mail-order pharmacies~~, **consisting of retail 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. • **Part D plans may count I/T/U pharmacies and pharmacies operated by the Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies.** • A plan's contracted pharmacy network may be supplemented by ~~mail order pharmacies~~ **by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, providing the access requirements are met.** • **A plan's network must provide adequate access to home infusion therapy pharmacies consistent with CMS guidelines and instructions.** • **A plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with CMS guidelines and instructions.** • **A plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in it service area. The plan must provide convenient access to I/T/U pharmacies consistent with CMS guidelines and instructions.** • CMS waives the pharmacy access requirements in the case of: o An MA-PD plan **or cost plan** that provides its enrollees with access to covered drugs through pharmacies owned and operated by the MA organization or **cost plan**, 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 **standard** 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	Whereas the proposed rule applied the TRICARE access standards across in each region in which a plan operates, the final rule applies it across each state in which the plan operates for PDPs and regional MA-PD plans. Local MA-PD plans will have to meet the access standards in each service area (including multi-county services areas in which they operate, and cost plans in each geographic area in which they operate. *Anticipating plan problems in meeting access requirements in some rural areas, CMS expects to establish an exceptions process, to be outlined in operational guidance to Part D plans that will account for any problem areas and mitigate any disincentives plans may have to avoid doing business in parts of the country in which meeting the pharmacy access standards.* CMS has established in the final rule an "any willing pharmacy" requirement specifically for LTC pharmacies, coupled with a requirement that Part D plans develop standard contracting terms and conditions for such pharmacies, such that any pharmacy in a service area could become an eligible LTC pharmacy by certifying that it meets certain performance and service criteria for providing pharmacy services to LTC facilities. These criteria would be incorporated into a Part D plan's standard contracting terms and conditions for LTC pharmacies. *CMS will provide further detail regarding these criteria in operational guidance, but expects that they*

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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 any of its network retail pharmacies, provided the enrollee pays for any differential in the negotiated price for the drug at the retail pharmacy. ***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 **pharmaceutical manufacturers**, 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. ▪ **Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.** ▪ **Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.** ▪ Document in writing its decisions regarding formulary development and revision **and utilization management activities.** ▪ **Meet other requirements consistent with written policy guidelines and other CMS instructions.** o A plan's formulary must include: ▪ At least two drugs in each therapeutic category and class **that are not therapeutically equivalent and bioequivalent,** with different strengths and doses. ▪ Only one drug if the category or class includes only one covered Part D drug. ▪ **Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, that only two drugs are available in that category or class of Part D drugs; and that one drug is clinically superior to the other drug in that category or class of Part D drugs.** ▪ **Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.** ▪ **Be approved by CMS consistent with the requirements of §423.272(b) (2) relating to**	*in operational guidance, but expects that they will address access to urgent and emergency medications on a 24/7 basis, standardized prescribing systems, and the availability of one of several standard delivery packaging and delivery systems for routine medications.* CMS plans to review the reasonableness of Part D plans' standard contracting terms and conditions for LTC pharmacies. CMS will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure convenient access to prescription drugs for American Indian/ Alaskan Native enrollees within the service area, and plans to review the reasonableness of Part D plans' standard contracting terms and conditions for I/T/U pharmacies. CMS clarifies that standard terms and conditions particularly for pharmacy payment terms may vary to accommodate geographic areas or types of pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. CMS is interpreting law that P&T committee decisions regarding which drugs are placed on the formulary are binding. However, it sees P&T role in reviewing plan policies that guide exceptions and other utilization management processes (including cost-sharing tiers) as advisory. Part D plans may not include two dosage forms or strengths of the same drug, or a brand-name and generic equivalent, in a particular category or class and meet the r2 drug per category and class requirement.

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plan designs not substantially discouraging enrollment by certain Part D eligible individuals. ○ **A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions**. • A plan sponsor must: ○ 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, ○ ~~Periodically evaluate and analyze treatment protocols and procedures related to its plan's formulary.~~ ○ Provide at least ~~30~~ **60** days notice to CMS, SPAPs, **entities providing other prescription drug coverage** ~~affected enrollees~~, authorized prescribers, **network** pharmacies, and pharmacists prior to removing a drug from its formulary, or changing the tiered cost-sharing status. ○ **Provide direct written notice to affected beneficiaries at least 60 days prior to a formulary change becoming effective, or at the time an affected enrollee requests a refill, provide such enrollee with a 60-day supply of the drug under the same terms as previously allowed, and written notice of the formulary change.** ○ **The written notice must contain certain specified information: name of the affected covered Part D drug; whether the plan is removing it from the formulary, or changing its preferred or tiered cost-sharing status; the reason why the plan is removing the drug from the formulary, or changing its preferred or tiered cost-sharing status; alternative drugs in the same therapeutic category or class or cost sharing tier and expected cost-sharing for those drugs; and the means by which enrollees may obtain a coverage determination under §423.566 or exception under §423.578.** ○ **Sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the FDA or removed from the market by their manufacturer without meeting the 60-day notice requirements. Sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, SPAPs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists consistent with the notice requirements described above.** ○ 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~~ **60** days after the beginning of the contract year. ○ Establish policies and procedures to educate and inform providers and enrollees concerning its formulary. ○ 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.	The transition process will be revised as part of the CMS benefit package review process. It expects that a plan's transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Such a policy should also focus on particularly vulnerable populations, including dual eligibles and individuals with certain medical conditions (for example, enrollees with HIV/AIDS, mental illness, and those with other cognitive disorders). To the extent that Part D plans do not provide the required 60-day advance notice, they are required to provide such notice and a 60-day supply of the drug at the same terms covered previously when affected enrollees request refills of their prescriptions. Once notice is provide, enrollees will have a 60-day window to either switch to a therapeutically appropriate alternative or obtain a redetermination, reconsideration, etc. (see subpart M). Note that CMS published the "Final Guidelines For Reviewing Prescription Drug Plan Formularies And Procedures" on January 24. 2005. [www.cms.hhs.gov/pdps/FormularyGuidance.pdf]
§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	CMS expects that plans will guarantee out-of-network access in cases in which an enrollee: (1) is traveling outside his or her plan's service area, runs out of or loses his or her

FINAL RULE	PREAMBLE (FINAL RULE)
network pharmacy, **and do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.** . • **A plan sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.** • ~~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.~~ • **A plan sponsor that provides its Part D enrollees with other than defined standard coverage may require its enrollees accessing Part D drugs out-of-network to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the standard benefit coinsurance requirements, and the requirements for alternative coverage.** • **A plan sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.**	covered Part D drugs or becomes ill and needs a covered Part D drug, and cannot access a network pharmacy; (2) cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24/7 service; (3) must fill a prescription for a covered Part D drug, and that particular drug (for example, an orphan drug or other specialty pharmaceutical) is not regularly stocked at accessible network retail or mail-order pharmacies; and (4) is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting. Reasonable rules for limiting out-of-network access might limit the amount of covered Part D drugs dispensed at an out-of-network pharmacy, require that a beneficiary purchase maintenance medications via mail-order for extended out-of-area travel, or require a plan notification or authorization process for individuals who fill their prescriptions at out-of-network pharmacies. CMS will pay any out-of-network differential for appropriate non-routine use of out-of-network pharmacies (or providers) for full and other subsidy-eligible individuals as part of the low-income subsidy.
§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.	*CMS will be providing marketing guidelines so that plans know how to describe their benefit packages ("clear, accurate, and standardized form").* On the content of the plan description that must be provided (prospectively as well as annually), changes from the proposed rule,

FINAL RULE	PREAMBLE (FINAL RULE)
▪ Cost-sharing and cost-sharing for subsidy eligible individuals. ▪ Any other conditions associated with receipt or use of benefits. 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 Information about the plan's formulary, **including a list of drugs included on the plan's formulary** and 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. o **The fact that a sponsor may terminate or refuse to renew its contract, or reduce its services area and the effect that any of those actions may have on individuals enrolled in a Part D plan.** • 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.~~ **Appeals** ▪ **Exceptions** 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.	include: • plan description must be provided in written format via mail unless beneficiary explicitly consents by actively opting in to receive information electronically or via phone' • clarifies that description must include information about any utilization management, including prior authorization requirements; • clarifies that description must include a list of network pharmacies, with addresses, as well as the information about number and mix available; • plan description must include the actual formulary list showing any cost-sharing tiers or utilization management program requirements; and • plan description must include information about possible contract termination (moved from available upon request).

FINAL RULE	PREAMBLE (FINAL RULE)
• 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~~ **monthly**, and provides enrollees with at least ~~30~~ **60** 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 **specified by CMS** and easily understandable to enrollees, during any month when prescription drug benefits are provided **including for covered Part D spending between the initial coverage limit and the out-of-pocket threshold**, a **written** 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.	CMS has decided against requiring 24/7 toll-free customer call centers, and retains business hour requirement but notes that this is a floor and encourages longer hours, especially during annual open enrollment periods. Strongly recommends that plans provide access to 24/7 clinical advice hotlines. Requires that the explanation of benefits (EOB) be provided via mail. Plans may offer additional mechanisms (e.g., electronically), but only to extent that the enrollees affirmatively elect to receive them in such a manner. Clarifies that for low-income beneficiaries, the EOB will include CMS subsidy amounts that count toward incurred costs.
§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 that is **therapeutically equivalent and bioequivalent and** available at that pharmacy, unless the particular drug being purchased is the lowest-priced t**herapeutically equivalent and bioequivalent 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~~ **by providing such information to Part D plans for inclusion in the written explanation of benefits required under §423.128.**	Nothing in the statute would prohibit Part D plans from requiring their network pharmacies to provide pricing information about lower priced off-patent innovator drugs (which are sometimes less expensive than generic drugs). CMS encourages plans to do so in the interest of ensuring Part D enrollees get the best prices available for their covered Part D drugs.
§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:	The NPRM incorporated the HIPAA and other privacy protections by reference to 422.118. For clarity and emphasis, the final rule restates the provisions of 422.118 here.

FINAL RULE	PREAMBLE (FINAL RULE)
○ 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. The sponsor must safeguard the privacy of any information that identifies a particular enrollee and specify for what purposes the information is used within the organization and to whom and for what purposes it discloses the information outside the organization. ○ Ensure that medical information is released only in accordance with applicable Federal or State law; ○ Maintain records and information in an accurate and timely manner; and ○ Ensure timely access by enrollees to records and information pertaining to them.	

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

FINAL RULE	PREAMBLE (FINAL RULE)
§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~~ **reasonable and appropriate** 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, **and provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.** • A **quality assurance** program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use **that include all of the following:** ~~The program must establish processes for:~~ ~~○ Drug utilization review;~~ ~~○ Patient counseling; and~~ ~~○ Patient information record-keeping.~~ • **Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.** • **Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's plan, typically at the point-of-sale or point of distribution. At the minimum, such review must include: screening for potential drug therapy problems due to therapeutic duplication; age/gender-related contraindications; over-utilization and under-utilization; drug-drug interactions; incorrect drug dosage or duration of drug therapy; drug-allergy contraindications; and clinical abuse/misuse.** • **Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care.** • **Internal medication error identification and reduction systems.** **Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.** **Note that the fraud and abuse provisions have been consolidated in Subpart K.**	Because CMS has not identified sufficient performance measures for drug utilization management programs, it is not adopting specific requirements on plans. Thus, CMS has elected to give plans broad discretion in designing drug utilization management programs. To ensure that plans appropriately employ drug utilization management techniques, and to develop or adopt further drug utilization management performance measures, CMS has added a reporting requirement and will *specify the required information in separate guidance.* The requirement relating to pharmacy practice has been added in lieu of adopting additional practice-setting, specific Federal standards. CMS encourages plans and their network pharmacy providers to establish and agree upon additional quality assurance standards as necessary, including those required for accreditation by recognized accrediting organizations. Instead of requiring plans to report medication errors to CMS, it has added a requirement on plans to implement internal medication error identification and reduction systems. Also requiring plans to provide CMS with information concerning their quality assurance measures and systems, in accordance with CMS guidelines. Also encouraging plans to use the FDA Medwatch form for reporting adverse events, as well as educating prescribers and pharmacy providers about its availability.
§423.153 (d). Medicare therapy management program (MTMP). • **A medication therapy management program (MTMP):**	Because CMS has not identified sufficient performance measures for MTMPs, it is not adopting specific requirements on plans.

FINAL RULE	PREAMBLE (FINAL RULE)
○ Must assure that drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; ○ Must, for the targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions; ○ May be furnished by a pharmacist **or other qualified provider**; and ○ May distinguish between services in ambulatory and institutional settings. • Targeted beneficiaries for the MTMP are enrolled Part D eligible individuals who: ○ Have multiple chronic diseases; ○ Are taking multiple covered Part D drugs; and ○ 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 (CCIP). **Plan sponsors must provide drug claims data to CCIPs for those beneficiaries that are enrolled in them.** • An applicant to become a plan sponsor must: ○ 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. ○ 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). ○ **Provide CMS with information regarding the procedures and performance of its MTMP according to guidelines specified by CMS.**	CMS believes that at the outset, plans should have maximum flexibility to develop MTMPs that can achieve the goal of improving therapeutic outcomes. Plans are not required to make MTMP services available at non-network pharmacies. Plans can offer MTMP services to non-targeted enrollees for a fee. There is no cost sharing for MTMP services provided to targeted enrollees. Plans have discretion to define targeted enrollees except that CMS will set a specific cost threshold for drug expenditures that must be met. *This will be done in separate guidance.* MTMP services will be considered an administrative cost (included in the plan bid), incident to appropriate drug therapy and not an additional benefit. *CMS will specify the information to be reported by plans on their MTMP services in separate guidance.*
~~**§423.153(c) 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.~~	This section has been consolidated under Subpart K.
§423.156 Consumer satisfaction surveys. • CMS conducts consumer satisfaction surveys of ~~PDP and MA-PD~~ **Part D** enrollees similar to the surveys it conducts of MA enrollees.	

FINAL RULE	PREAMBLE (FINAL RULE)
§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~~ **initial** standards ~~promulgated by CMS as well as~~ and final standards established by CMS once final standards are effective. **Any payments must in compliance with applicable Federal and State laws relating to fraud and abuse including the physician self-referral prohibition (1877 of the SSA) and the federal anti-kickback statute.**	Permits a separate payment to participating physicians in MA-PD plans for using e-prescribing procedures. CMS published proposed initial e-prescribing standards in the *Federal Register* on February 4, 2005. *CMS will publish additional guidance on acceptable physician incentives for e-prescribing.*
§**423.162 Quality Improvement Organization (QIO) activities.** • Quality Improvement Organizations (QIOs) are required to offer providers, practitioners, ~~MA organizations,~~ and ~~PDP~~ **Part D** 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. **The provisions of part 480 [relating to the acquisition, protection, and disclosure of information used by the QIOs] apply to Part D sponsors in the same manner as such provisions apply to institutions under 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.''~~	CMS indicates that QIOs will be available to evaluate the effectiveness of MTMPs. *Data to be made available to QIOs will be identified in separate CMS guidance.* QIOs will not be involved in reviewing the appropriateness of plan formularies.
§ **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: ○ 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 ○ The accreditation organization uses the standards approved by CMS for the purposes of assessing the sponsor's compliance with Medicare requirements. • Deemable requirements: ○ Access to covered drugs under §423.120 and §423.124. ○ ~~Cost and~~ Drug utilization management, quality assurance, MTMP, and programs to control fraud, abuse, and waste, as provided under ~~§423.153~~ **§423.504**. ○ 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: ○ The date the accreditation organization is approved by CMS. ○ The date the plan sponsor is accredited by the accreditation organization.	The final rule adopts all the provisions of the proposed rule. Accrediting organizations in their application for deemed status must report the names of all individuals with an ownership or control interest in the organization. CMS notes that solicitation for deemed status applications will be subject to other agency priorities and that currently no accrediting organization can meet the standards imposed by Part D.

FINAL RULE	PREAMBLE (FINAL RULE)
• A plan sponsor deemed to meet Medicare requirements must: ○ Submit to surveys by CMS to validate its accreditation organization's accreditation process; and ○ 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: ○ 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; ○ CMS withdraws its approval of the accreditation organization that accredited the plan sponsor; ○ 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.	
§423.168 Accreditation organizations. • CMS may approve an accreditation organization for a given standard under this part if it meets the following: ○ It applies and enforces standards that are at least as stringent as Medicare's requirements; ○ It complies with the application and reapplication procedures; ○ 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: ○ Announces CMS's receipt of the accreditation organization's application for approval; ○ Describes the criteria CMS uses in evaluating the application; and ○ 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: ○ 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	

FINAL RULE	PREAMBLE (FINAL RULE)
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. 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
▪ 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. 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~~ **Part D** 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	

FINAL RULE	PREAMBLE (FINAL RULE)
system. ○ 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. ○ 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. ○ 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. ○ A list of all currently accredited ~~PDP~~ **Part D** sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them. ○ A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS. ○ 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: ○ Written presentation demonstrating its ability to furnish CMS with electronic data in CMS compatible format. ○ A resource analysis that demonstrates adequate staffing, funding, and other resources. ○ 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: ○ States whether the request for approval has been granted or denied; ○ Gives the rationale for any denial; and ○ 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: ○ Has revised its accreditation program to correct the deficiencies on which the denial was based; ○ Can demonstrate that the plan sponsors that it has accredited meet or exceed applicable Medicare requirements; and ○ Resubmits the application in its entirety.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 FINAL RULE
Subpart F: Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

FINAL RULE	PREAMBLE (FINAL RULE)
§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 Part D plan 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:~~ ○ ~~Submitted a bid in the first year of a contract period to offer a fallback PDP in any PDP region;~~ ○ ~~Offers a fallback PDP in any PDP region during the year; or~~ ○ ~~Offered a fallback PDP in that PDP region during the previous year.~~ ○ ~~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 Part D sponsor must submit bids and supplemental information described in this section for each Part D 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: ○ 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. ○ 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. ○ Include costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits. ○ Not include costs for enrollee deductible, co-payments, coinsurance, **liability above the plan allowance for out-of-network claims**, or payments projected to be made by CMS for reinsurance, or other costs for which the sponsor is not responsible. ○ 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. ○ Include a description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing. ○ Provide the following information on bid components, as well as actuarial certification that the	*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 and costs for supplemental benefits must be identified separately. Administrative costs include: crossover fees to obtain data for TROOP; MTMP expenses; marketing & Sales; direct administration (e.g., customer service, billing, etc.); indirect administration (e.g. accounting, legal, etc.); net cost of private reinsurance; Medicare user fees; uncollected premiums; and return on investment. *CMS will provide guidance on format for bid submission and added information on administrative costs; is expecting to develop a fully automated process including electronic signatures. See draft PDP Bid Instructions and Pricing Tool at www.cms.hhs.gov/pdps/)* CMS will share data from FEHBP, MCBS, and Medicaid. More information available at www.cms.hhs.gov/pdps/default.asp.

FINAL RULE	PREAMBLE (FINAL RULE)
values are calculated according to CMS guidelines, including adjustment for the effect that 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.	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.* Information submitted with the bid and used to pay plans would be confidential. That submitted with the bid and not used for payment (e.g., formulary structure) would not be protected, although could be labeled "confidential" by the submitter under FOIA. CMS will not release information considered proprietary or that would stifle availability of manufacturer discounts or rebates. Any utilization effect of supplemental benefits would have to be loaded into the supplemental portion of the bid. Since the supplemental premium bid will be based on an average risk profile, CMS will negotiate with plans to allow the supplemental premium to adequately account for the risk of plan the plan's 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 **its general authority granted under the MMA and** authority similar to that of the Director of the Office of Personnel Management for federal employee health benefits. • CMS will approve the Part D 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) **or its utilization management program** 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.	CMS observes that it prefers to rely on competition rather than negotiation. CMS 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 Part D average premium is determined to account for assumptions about applying rebate savings to premiums.

FINAL RULE	PREAMBLE (FINAL RULE)
○ **A plan that adopts the USP categories and classes may nevertheless be found to discourage enrollment because it excludes drugs from the formulary.** • There is no limit on the number of full risk plans that CMS approves; CMS approves a limited risk plan if the access requirements are not otherwise met for a PDP region. ○ 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. ○ 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: ○ These plans are exempt from the review and negotiation process, and are not held to the revenue requirements standard; ○ These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements. ○ 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. • **For plans with bids sufficiently below the national average as to result in a negative enrollee premium, as either:** ○ **A reduction in the supplemental premium if the plan already submitted a bid with an enhanced alternative benefit, or** ○ **An addition of new enhanced alternative benefits of no less value than the amount of negative premium.**	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 review of plan formularies will include: reviewing categories and classes in relation to the USP model; assuring appropriate treatments are available for certain diseases; comparing utilization management tools to make sure they support treatment guidelines; and comparing formularies to identify outlier practices. 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. *CMS welcomes comments on evaluation.* CMS would consider anything below 10% as "de minimis" for limited risk plans.
§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. ○ The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each PDP and MA-PD plan. ○ The calculation does not include bids submitted for MSA plans, **fallback plans**, MA PFFS plans, specialized MA plans, PACE programs, and reasonable cost reimbursement contracts. • **For 2006, CMS assigns equal weighting to PDP plan sponsors and assigns MA-PD plans a weight based on prior enrollment (new MA-PD plans are assigned zero weight).** • 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. ○ CMS determines the weighted average for 2005 to be used for the 2006 calculation.	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 a specific date (e.g., 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

FINAL RULE	PREAMBLE (FINAL RULE)
• 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. o **CMS does not apply any geographic adjustment until an appropriate methodology is developed.**	of the sponsor in the region. No geographic adjustment will be made in the first years. Once developed, geographic adjustment factors will be announced in the 45-day notice in advance of bidding for a year and will be subject to notice and comment.
§423.286 Rules regarding premiums. • The monthly beneficiary premium for a Part D plan in a PDP region is the same for all part D eligible individuals enrolled in the plan. • The monthly beneficiary premium for a Part D 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: (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. ▪ **If a negative premium amount results, the beneficiary premium is zero and the excess amount is applied to supplemental Part D benefits.** 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~~ **of plan enrollees as determined based on negotiations between CMS and the sponsor.** o The base beneficiary premium is increased on a monthly basis by the amount of any applicable 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.	CMS estimates the base beneficiary premium, after taking into account reinsurance subsidies, will be 34% 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 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. Clarifies that SPAPs may pay premiums on behalf of enrollees.

FINAL RULE	PREAMBLE (FINAL RULE)
• 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.	
§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.~~ **Part D plan sponsors must charge enrollees a consolidated monthly premium equal to the sum of the premium for basic coverage (if any) and the premium for supplemental coverage (if any).** • 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: ○ 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. ○ 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 due to late enrollment penalties in the initial years.

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

FINAL RULE	PREAMBLE (FINAL RULE)
§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 **fees** ~~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 **fees** ~~of covered Part D drugs~~ during the **coverage** year and costs relating to the deductible. They equal: ○ 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 ○ 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 Part D plan, equals the total amount of payments (from CMS and **by or on behalf of** 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.	For allowable costs, CMS will require reporting of aggregate rebates at the product level on a quarterly basis. *Additional guidance on payments and rebate accounting rules will be issued.* For repackaged drugs, allowable costs must be an accurate reflection of the product and purchase price, and not a manipulation of the AWP. CMS will expect reporting of all rebate dollars with no allowance for separate administration fees (which are considered price concessions to the extent above fair market value for services rendered). Clarifies that covered Part D drug for gross covered drug costs means a drug that is included in a Part D plan's formulary or is treated as a formulary drug as a result of a coverage determination or appeal.
§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 **a monthly basis based on either estimated or** ~~an as-~~ incurred **costs** ~~basis~~ and final reconciliation to actual allowable reinsurance costs.	*CMS intends to conduct a reinsurance demonstration with an alternative payment*

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 **offering Part D coverage**, 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.~~	*approach that will be budget neutral. They will issue future guidance.*
§423.322 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.	Claims data must be submitted to CMS no less frequently than monthly. *Additional guidance will be released addressing QIO access to Part D data*. Since QIOs have authority to collect claims data, CMS believes it can share claims data with QIOs.
§423.329 Determination of payment. • CMS makes a direct subsidy payment for each eligible beneficiary enrolled in a Part D 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. o **The direct subsidy may be increased by the excess amount of a negative premium.** • 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, • The reinsurance payment amount for a Part D enrollee for a coverage year is equal to 80 percent of the	The risk adjustment methodology will be published in the 45-day notice for 2006 MA rates, with an opportunity for comment. Short term the method will be based on the relationship of drug utilization to diagnoses. Longer-term plan is to refine the model to predict risk based on medical and drug claims data. Allowable reinsurance costs will take into consideration any induced utilization effects from supplemental coverage.

FINAL RULE	PREAMBLE (FINAL RULE)
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 **estimated or incurred** 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.	
§**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.	If a plan does not submit data for determining risk corridor costs, CMS will assume its costs were 50% of the target amount. *Further guidance will be issued on the methodology for reconciliation for these payments.*

FINAL RULE	PREAMBLE (FINAL RULE)
• A PDP sponsor **(not an MA-PD, PACE, or cost plan sponsor)** may submit a bid that requests a decrease in first or second threshold risk percentages or 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: ○ 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 ○ 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 **information that CMS requires.** ~~○ The gross covered prescription drug costs segregated by enrollee and date of service.~~ ~~○ The allowable risk corridor costs for the coverage year.~~ ~~○ The adjusted allowable risk corridor costs for the coverage year.~~ ~~○ Costs incurred for supplemental benefits distinguished from those for basic coverage.~~	

FINAL RULE	PREAMBLE (FINAL RULE)
~~○ 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 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. ○ 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. ~~○~~ Within 6 months after a coverage year, the plan sponsor must provide CMS with **information that CMS requires.** ~~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.~~ ○ 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. ○ 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. ~~○~~ Within 6 months after a coverage year, the plan sponsor must provide CMS **with information that CMS requires**. ~~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.~~ ○ 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. ○ 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
§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: ○ For any reason, within 12 months of the date of the notice of the final determination to the plan sponsor; ○ Within 4 years of the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening; or ○ 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: ○ New and material evidence that was not readily available at the time the final determination was made is furnished; ○ A clerical error in the computation of payments was made; or ○ 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. • **A decision not to reopen is final and not subject to review.**	
§423. 350 Payment appeals. • **If CMS did not apply its payment methodology correctly a Part D plan sponsor may appeal:** ○ **The reconciled health status risk adjustment of the direct subsidy** ○ **The reconciled reinsurance payments;** ○ **The reconciled final payments for low-income subsidies; or** ○ **The final risk-sharing payments.** • **Payment information submitted to CMS is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.** • **Reconsiderations:** ○ **Requests for reconsiderations must be filed within 15 days of notice of an adverse determination.** ○ **Requests must specify findings or issues in disagreement and reasons. Documentary evidence, but not new payment data, ma be submitted.** ○ **CMS reviews the payment determination and any other evidence.** ○ **CMS informs the sponsor of the decision orally or through electronic mail and sends a written decision upon request of the sponsor;** ○ **A reconsideration decision is final and binding unless a hearing is requested.** • **Informal hearing:** ○ **A sponsor is entitled to an informal hearing after a reconsideration decision;** ○ **Request for hearing must be made in writing within 15 days of receipt of reconsideration**	New section added.

FINAL RULE	PREAMBLE (FINAL RULE)
decision; ○ **Request must include a copy of the decision and must specify issues and reasons for disagreement;** ○ **CMS provides written notice of time and place of hearing at least 10 days prior to the date;** ○ **CMS hearing officer conducts hearing limited to review of the record;** ○ **Hearing officer may request, but not require, a written statement from CMS explaining the decision. Failure of CMS to provide a written statement may not be taken into account by the hearing officer in reaching a decision.** ○ **Hearing officer decides the case and sends a written decision to the Part D sponsor;** ○ **Hearing officer decision is final and binding unless reversed or modified by the Administrator.** • **Review by the Administrator:** ○ **A Part D sponsor that has received a hearing officer decision may request review by the Administrator within 15 days of the receipt of the decision;** ○ **The Administrator may review the decision, any written documents and any other information included in the record and make a determination to uphold, reverse, or modify the hearing officer's decision;** ○ **The Administrator's decision is final and binding.**	

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

FINAL RULE	PREAMBLE (FINAL RULE)
§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. ○ 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: ○ Failed to implement a licensing process for PDP sponsors or to complete action on the licensing application within 90 days. ○ 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. ○ 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. ○ 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 rules apply to waivers (except for regional plan waivers):** ○ **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.** • **CMS grants or denies a waiver application under this section within 60 days after a substantially complete waiver application is received by CMS.**	*CMS will issue further guidance on how best to identify plans that are approved under waivers.* Plans seeking waivers must first obtain written notice from state licensing authorities that its application cannot be accepted.
§423.115 Temporary regional plan waivers • The following additional waiver may be requested for regions: ○ 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. ○ 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. ○ 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	CMS will establish the time period for processing waiver applications. In no case will temporary regional plan waivers extend beyond the end of the calendar year for which they are issued.

FINAL RULE	PREAMBLE (FINAL RULE)
year. • ~~The following rules apply to waivers (except for regional plan waivers):~~ • ~~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.~~ • ~~CMS grants or denies a waiver application under this section within 60 days after a substantially complete waiver application is received by CMS.~~	
§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.	CMS solvency standards are undergoing internal review and are expected to be published with the initial application forms for PDPs and plan reporting requirements.
§423.425 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.	CMS does not intend to preempt state laws unless they conflict with requirements under its regulations. Specifically, it does not intend to preempt state pharmacy laws dealing with the practice of therapeutic substitution.

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

FINAL RULE	PREAMBLE (FINAL RULE)
§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~~ **prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage approved by CMS as a PDP.** • *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(e)(1) 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 on or after January 1, 2006. • 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.	CMS will not waive formulary, P&T committee, or coverage determination and appeals requirements for MA-PD plans. *CMS will issue guidance on waivers that it will and will not consider regarding employer group plans. It will also issue guidance on the entities it will contract with, as well as how they will contract with them.*
§423.462 Medicare secondary payer procedures. • Medicare secondary payer procedures apply to PDP sponsors in the same way as they apply to MA organizations.	

FINAL RULE	PREAMBLE (FINAL RULE)
§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.	Even if a state is an authorized representative for its enrollees, it may not auto-enroll them in a select PDP and still meet the definition of an SPAP for Part D purposes. *CMS will provide guidance to SPAPs on activities they may undertake that will not discriminate among Part D plans.* SPAPs may not recommend Part D plans based on the SPAP's financial interest. State Kidney Programs may be considered SPAPs if they meet the criteria for an SPAP.
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; o Not follow or adopt rules that change or affect the primary payor status of a Part D plan; **and** o **Provides supplemental drug coverage based on financial need, age, or medical condition and not based on current or former employment status.** • 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.	Some or all of an SPAP's funding may come from private sources and may include some incidental federal funding.
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);	*CMS will be issuing further information on coordination requirements and processes by July 1, 2005.* CMS is considering facilitating TROOP tracking through a TROOP facilitation contractor, contractors, or other methods

FINAL RULE	PREAMBLE (FINAL RULE)
○ Military coverage (including TRICARE). ○ **Indian Health Service** ○ **Federally qualified health centers.** ○ **Rural health centers.** ○ Other health benefit plans or programs that provide coverage or financial assistance for prescription drugs as CMS may specify. • A PDP or MA-PD plan sponsor ~~sha~~ll **must** 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 Part D enrollee must disclose all these expenditures to the Part D plan.** • A plan sponsor may not impose fees on other plans that are unrelated to the cost of the coordination of benefits. • **If a Part D plan learns it has made an erroneous payment due to inaccurate TROOP information, that plan is authorized to recover such costs directly from the enrollee; the enrollee must reimburse the plan for these costs.**	contractor, contractors, or other methods. CMS expects to impose user fees on Part D plans of no more than $1 per enrollee per year (perhaps considerably less) for coordination of benefits system that tracks TROOP expenditures. Part D plans may charge user fees to SPAPs for coordination of benefits; fees must be reasonable and related on to actual coordination of benefits costs. After some experience with Part D, CMS will assess the need for appropriate crossover mechanisms to coordinate Part B and Part D drug coverage.

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

FINAL RULE	PREAMBLE (FINAL RULE)
§423.501 Definitions. • *Business transaction*: any of the following kinds of transactions: ○ Sale, exchange, or lease of property. ○ Loan of money or extension of credit. ○ 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, **by Part D plan sponsor staff, medical groups, or independent practice associations, 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: ○ Performs some of the PDP sponsor's management functions under contract or delegation; ○ Furnishes services to Medicare enrollees under an oral or written agreement; or ○ 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.	*CMS will issue separate guidance on the transition procedures for MA plans seeking to offer Part D benefits. Previously contracting MA organizations will have to complete an abbreviated version of the PDP application.*

FINAL RULE	PREAMBLE (FINAL RULE)
• The authorized individual must describe thoroughly how the entity meets, or plans to meet, requirements. • CMS determines whether an entity qualifies as a PDP sponsor and meets the requirements of Part D. • **A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.** • 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.	New MA organizations will have the relevant Part D provisions incorporated in the MA application. Price and cost information are generally protected from disclosure. Applicants must identify other information to be protected from disclosure and cite relevant exemption to FOIA.
§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 **or fails to complete a corrective action plan** 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: ○ Approval of application. ○ 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. ○ 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. ○ If a PDP sponsor no longer meets those requirements, CMS terminates the contract.	CMS will permit applicants to enter into the bid process without an executed contract. The contract will not be awarded until the applicant's bid is approved. Bid negotiations are not subject to appeal. CMS will attempt to notify applicants of missing information two days prior to issuing a notice of intent to deny an application. Once a notice of intent to deny has been issued, applicants have 10 days to remedy the application.
§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: ○ Complete an application. ○ Be organized and licensed under State law as a risk bearing entity or have a Federal waiver. ○ Meet the minimum enrollment requirements unless waived. ○ 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	

FINAL RULE	PREAMBLE (FINAL RULE)
quality assurance, medication 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 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 penalty 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. ▪ **A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.** 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 **within 6 months of a non-renewal notice;** or CMS has otherwise determined that circumstances warrant special consideration.	The provision mandating Part D plans to report violations of law, regulations, or other wrong-doing within 60 days is deleted from the final rule. A voluntary self reporting requirement should be included as a part of a comprehensive fraud and abuse plan. CMS recommends that plan sponsors adopt a compliance plan similar to the one in place for plans participating in the Federal Employees Health Benefits Program. CMS recommends that plans have in place mechanisms to screen for illegal prescription of narcotics. CMS recommends that plans monitor for aberrant or abusive behavior related to drug switching (e.g., brand to brand).

FINAL RULE	PREAMBLE (FINAL RULE)
• **For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.** • **CMS does not contract with 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:** **Submitted a bid for the year (as the first year of a contract period) to offer a fallback prescription drug plan in any PDP region**; **Offers a fallback prescription drug plan in any PDP region during the year; or** **Offered a fallback prescription drug plan in that PDP region during the previous year.** • 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 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 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 **and support e-prescribing**. o To comply with all requirements governing coverage determinations, **formulary exceptions**, and 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	

FINAL RULE	PREAMBLE (FINAL RULE)
▪ 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 **Contracts are approved by CMS and** 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 **To use a standard pharmacy contract that is available to any willing pharmacy**. o The PDP sponsor must be able to communicate with CMS electronically as required by CMS.	
• The PDP sponsor agrees to maintain, for **10** ~~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 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 **10** ~~6~~ prior periods. o Federal income tax or informational returns for the current contract period and **10** ~~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 **10** ~~6~~ prior periods. o All price concessions (including concessions offered by manufacturers) for the current contract period and **10**~~6~~ prior periods accounted for separately from other administrative fees.	Final rule revises the record retention and access requirements from 6 to 10 years to be consistent with the statute of limitations for the False Claims Act.

FINAL RULE	PREAMBLE (FINAL RULE)
• The PDP sponsor agrees to the following conditions on access to facilities and records: ○ 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 **10** ~~6~~ prior periods. ○ 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. ○ HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through **10** ~~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 ○ 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. • The PDP sponsor agrees to submit to CMS: ○ 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. ○ 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. ○ Information about beneficiary appeals and their disposition **and formulary exceptions**. ○ Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization. ○ **Information regarding any oversight findings by CMS.** ○ Other information deemed necessary to CMS for administration or evaluation. • **This information must be given to enrollees and, on request, the sponsor gives enrollees financial data.** • The PDP sponsor agrees to comply with the following beneficiary financial protection requirements: ○ 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	Final rule includes specific examples of other information that CMS may require to carry out an effective oversight program.

FINAL RULE	PREAMBLE (FINAL RULE)
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: • ~~Title VI of the Civil Rights Act of 1964.~~ • ~~The Age Discrimination Act of 1975.~~ • ~~The Rehabilitation Act of 1973.~~ • ~~The Americans with Disabilities Act.~~ o HIPAA Administrative Simplification rules. o **Federal fraud and abuse laws.** 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 **10** ~~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 accountability provisions, as specified in regulations **and must be consistent and comply with Part D requirements.** • 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 **ongoing** 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:~~ • ~~The contract is amended to exclude any State licensed entity, or PDP sponsor specified by CMS; and~~ • ~~A separate contract for any excluded entity is deemed to be in place when the request is made.~~	The final rule deletes specific references to federal laws that are not enforced by HHS. CMS suggests that plan sponsors also collect certifications from their downstream providers for any data reported.

FINAL RULE	PREAMBLE (FINAL RULE)
• **Additional contract terms and conditions as CMS deems necessary.** *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 acknowledges 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 **for risk corridors and reinsurance**, 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 intent~~ion~~ not to renew. • **Contract renewal contingent on agreement on bid negotiation with CMS (not subject to appeal).**	
§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; 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 **one or more newspapers in the region.** ~~each community or county located in the sponsor's 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. • **Sponsors must ensure timely transfer of data and records.** • CMS may elect not to authorize renewal of a contract for any of the following reasons:	Final rule modifies the public notice requirement from one or more newspapers in the county or community of the service area to at least one newspaper in the region or service area.

FINAL RULE	PREAMBLE (FINAL RULE)
○ For any of the reasons that also permits CMS to terminate the contract. ○ 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: ○ To the PDP sponsor by May 1 of the contract year. ○ To the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year **if the sponsor is not qualified for renewal.** ○ To the general public at least 90 days before the end of the current calendar year, by publishing a notice in **one or more newspaper(s) in the region** ~~in each community or county located in the sponsor's service area.~~ **if the sponsor is not qualified for renewal**. • CMS gives the PDP sponsor written notice of its right to appeal the decision to not renew **(except if the nonrenewal is based on the failure to reach an agreement during CMS/sponsor negotiations).**	
§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. • **If the contract is terminated by mutual consent, the sponsor must ensure timely transfer of data and files.**	
§423.509 Termination of contract by CMS. • CMS may terminate a contract for any of the following reasons if the PDP sponsor: ○ Substantially fails to carry out the terms of its contract with CMS; ○ Is carrying out its contract in a manner that is not effective or efficient; ○ No longer meets the requirements for being a contracting organization; ○ 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; ○ 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; ○ Substantially fails to comply with the requirements relating to grievances and appeals; ○ Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data; ○ Substantially fails to comply with the service access requirements; ○ Substantially fails to comply with the marketing requirements; ○ Substantially fails to comply with the coordination with SPAP and other plans and programs; or ○ 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: ○ CMS notifies the sponsor in writing 90 days before the intended date of the termination. ○ The sponsor notifies enrollees by mail at least 30 days before the effective date.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 **one or more** newspaper(s) **in the region**. ~~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 **one or more** newspaper(s) in the region. ~~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. • To the general public, at least 60 days before the termination by publishing a notice in **one or more** newspaper(s) in **the region.** ~~each community or county located in the sponsor's service area.~~ • 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.	
§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;	CMS reserves the right to increase the minimum enrollment numbers through future rule making if enrollments are too low for plans to obtain high enough discounts or to provide quality customer service.

FINAL RULE	PREAMBLE (FINAL RULE)
• A PDP sponsor must maintain the minimum enrollment for the duration of its contract, except CMS **waives the minimum enrollment requirement for the first contract year in a region**. ~~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: o A description of significant business transactions between the PDP sponsor and a party in interest: ▪ **Must show** ~~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 **to CMS**, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under ERISA. 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
§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 FINAL RULE
Subpart L: Effect of Change of Ownership or Leasing of Facilities During Term of Contract

FINAL RULE	PREAMBLE (FINAL RULE)
§423.551 General provisions. • The following constitute a change of ownership: ○ Removal, addition, or substitution of a partner, unless partners agree otherwise as permitted by State law. ○ Transfer of substantially all the assets of the PDP sponsor to another party. ○ The merger or consolidation with one or more corporations, resulting in a new corporate body. ○ Transfer of stock or merger with the PDP sponsor surviving, does not **ordinarily** constitute a change. • Advance notice requirement: ○ A PDP sponsor considering **or negotiating** a change in ownership must notify CMS at least 60 days prior and provide financial information and a discussion of the financial **and solvency** impact on the surviving entity. ○ 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. ○ *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. ○ 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. ○ With a novation agreement signed by CMS, the new owner becomes the successor in interest to the current owner's existing Medicare contract.	CMS will notify states in the case of any change of ownership of a plan sponsor.
§423.552 Novation agreement requirements. • CMS approves a novation agreement if the following conditions are met: ○ 60-day ~~A~~advance notification **including impact discussion**. ○ 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. ○ 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. ○ 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 post~~ing~~ a performance bond. ○ 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 FINAL RULE
Subpart M: Grievance, Coverage Determinations, and Appeals

FINAL RULE	PREAMBLE (FINAL RULE)
§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~~ **Part D** plan 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~~ **Part D plan** 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.~~ • ***Appointed representative.*** **An individual either appointed by an enrollee or authorized under State law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any level of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or dealing with any level of the appeals process.** • *Grievance:* Any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a ~~PDP~~ **Part D Plan** sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. • ***Projected value.*** **The charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.** • *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.	
§423.562 General provisions. • Plan sponsors must, for each ~~PDP~~ **Part D plan** that it offers, establish and maintain: ○ A grievance procedure for addressing issues that do not involve coverage determinations; ○ A procedure for making timely coverage determinations; **including determinations on request for exceptions to a tiered cost-sharing structure or to a formulary;** ○ ~~A procedure for handling exceptions to a tiered cost-sharing structure;~~ ○ ~~A procedure for handling exceptions to a formulary;~~ and ○ ~~Redetermination and~~ Appeal procedures that meet the requirements of this subpart 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. • **A plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they**	Point-of-sale transactions are not coverage determinations and thus do not trigger the notice requirements associated with adverse

FINAL RULE	PREAMBLE (FINAL RULE)
disagree with the information provided by the pharmacist. • If a ~~PDP~~ **Part D plan** 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 sponsors: ○ To have grievances heard and resolved by the sponsor; ○ To have a timely coverage determination; **including the right to request from the plan sponsor an exception to its tiered cost-sharing structure or formulary;** ○ To request from the sponsor an expedited coverage determination; ~~○ To request an exception to a PDP's tiered cost-sharing structure or formulary;~~ ○ 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~~ **if the amount in controversy meets the requirements of 423.610 and the IRE affirms the plan's adverse coverage determination in whole or in part;** ▪ Request a MAC hearing; if the ALJ affirms the IRE's adverse coverage determination, in whole or in part; ▪ Judicial review of the hearing decision**, if the MAC affirms the ALJ's decision in whole or in part and if the amount in controversy meets the requirements in 423.630**~~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. • ***Relation to ERISA Requirements.*** **Provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.**	determinations. But CMS requires plans to arrange that their network pharmacies notify enrollees of their right to receive a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. Plans may, for instance, require network pharmacies to post or distribute notices that instruct enrollees on how to contact their plans to obtain a coverage determination or request an exception when enrollees disagree with the information provided by the pharmacist. This provision will not take effect in the absence of regulations issued by the Secretary of Labor.
§423. 564 Grievance procedures. • *In general.* Each ~~PDP~~ **Part D plan 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. • *Quality of care issues*. An enrollee may file a grievance with the ~~PDP~~ plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the ~~PDP~~ **Part D plan** sponsor must cooperate with the QIO in resolving the complaint. • ***Method for filing a grievance.*** **An enrollee must file a grievance no later than 60 days after the event**	CMS has decided to implement the same

FINAL RULE	PREAMBLE (FINAL RULE)
or incident that precipitates the grievance. • ***Grievance disposition and notification.*** **The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance. The sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay. The sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:** o **All grievances submitted in writing must be responded to in writing.** o **Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.** o **All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.** • *Expedited grievances*. A ~~PDP~~ **Part D plan** 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~~ plan 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 sponsor notified the enrollee of the disposition.	guidelines for Part D grievances as proposed for M+C organizations in 2001. With respect to federal preemption of state grievance laws, CMS notes that enrollees still have access to various state remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan.
§**423.566 Coverage determinations.** • Each ~~PDP~~ **Part D plan** sponsor must have a procedure for making timely coverage determinations for basic and supplemental coverage and the amount, **including cost-sharing,** 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 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 plan. o Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee. o **A decision concerning an exceptions request;** o A decision on the amount of cost sharing for a drug.	Policies that a plan develops to encourage enrollees to use network pharmacies are not subject to appeal. The decision to place a medication on a prior authorization list is not a coverage determination and is not subject to appeal. However, when a plan processes a prior authorization request, the plan's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination that is subject to appeal. Also, if a plan denies a drug because the enrollee failed to seek prior authorization, that also constitutes a

FINAL RULE	PREAMBLE (FINAL RULE)
~~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~~ **appointed** representative; or o The prescribing physician, on behalf of the enrollee.	coverage determination subject to appeal.
§ **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.~~ **When a party makes a request for a drug benefits, the plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or for an exceptions request, the physician's supporting statement.** • *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~~ **72 hours** 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, including the right to, and conditions for obtaining an expedited redetermination and the rest of the appeals process. 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 sponsor fails to provide the enrollee with timely notice of a ~~coverage~~ determination, this failure itself constitutes an adverse **coverage** determination and ~~may be appealed~~ **the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.**	
§423.570 Expediting certain coverage determinations. • *Request for expedited determination*. An enrollee or an enrollee's prescribing physician may request that a 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	

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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~~ **for accepting** oral or written requests. For a request made by an enrollee, the plan must provide 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~~ **72- hour** timeframe for a standard determination. The ~~14-calendar day period~~ **72- hours** begins with the day the sponsor receives the request, **or for an exceptions request, the physician's supporting statement.** In addition, it must give the enrollee **and prescribing physician** prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that: ○ Explains that the sponsor must process the request using the ~~14-calendar day~~ **72-hour** timeframe for standard determinations; ○ Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision not to expedite; ○ Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and ○ 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 plan 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~~ **24** hours after receiving the request, **or for an exceptions request, the physician's supporting statement.** • ~~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.	

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• *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. • *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~~ **the sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.** .	
§423.576 Effect of a coverage determination. • A coverage determination is binding on the plan sponsor and the enrollee unless it is ~~reconsidered~~ **redetermined** or is reopened and revised.	
§423.578 Exceptions process. • *Exceptions to tiered cost-sharing structure.* Each ~~PDP~~ **Part D plan** 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~~ during the 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. T~~he 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)~~ **(2**) 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 prescribing physician must provide an oral or written supporting statement** that ~~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. **If the physician provides an oral statement, the sponsor may require a written one to demonstrate the medical necessity of the drug. The sponsor may require the physician to provide additional supporting medical documentation as part of the written follow-up.** • ~~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.~~ **In no case is the sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains**	CMS has elected not to establish specific exceptions criteria but to review the plans' exceptions criteria as part of the plan approval process, to ensure that the criteria are reasonable and complete.

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a separate tier dedicated to generic drugs. If a sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost drugs are not eligible for the tiering exception. • *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 procedures **subject to CMS' approval for receipt of an off-formulary drug. The sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician' statement and that the drug would be covered but for the fact that it is an off-formulary drug.** Formulary use includes the application of cost utilization tools such as 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, **or a therapeutic substitution requirement.** The exceptions process must address the following circumstances: (1) situations where a formulary changes during the year and situations where an enrollee is already using a given drug; ~~(2) continued 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 plan'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~~ **because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.** • A sponsor's exception ~~procedures~~ **criteria** 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 **gathering and** comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, **including safety information generated by an authoritative government body**; 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~~ **appointed** 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 **must provide an oral or written supporting statement** that the requested drug is medically necessary to treat the enrollee's disease or medical condition because: All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both. The drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements: ○ has been ineffective in the treatment of 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; ○ 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	CMS notes that the rule does not require that a plan specify the tier that must be applied when it approves an exceptions request involving non-formulary drugs. This means that plans will have the flexibility to determine which level of cost-sharing will apply.

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○ the number of doses that is available under a dose restriction for the drug has been ineffective in the treatment of 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. ~~(1) there is not a drug on the formulary to treat the enrollee's disease or medical condition that is an acceptable clinical alternative;~~ • If the physician provides an oral supporting statement, the sponsor may require the physician to subsequently provide a written supporting statement. ~~written certification to include only certain specified information that is reasonable necessary to evaluate the medical necessity of the medical exceptions request.~~ **The sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.** • *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 **and provide notice of the decision within the required timeframe, 24 or 72 hours as applicable, the failure constitutes as adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the adjudication timeframe**. ~~or 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 a **tiering** exceptions request is approved.* The sponsor must provide coverage for the approved prescription drug **at the cost-sharing level that applies for preferred drugs** and may 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; and (3) the enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year. ~~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 section.~~ • **When a non-formulary exceptions request is approved. The sponsor may not 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; the drug continues to be considered safe for treating the enrollee's disease or medical condition; and the enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year. The plan must not establish a special formulary tier or co-payment or other cost-sharing**	

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requirement that is applicable only to drugs approved for coverage under this section. An enrollee may not request a tiering exception for a non-formulary drug approved under 423.578(b). • **Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred tiered or cost-sharing status of such a drug, the sponsor must provide notice (see 423.120).** • **Nothing in this section should be construed to allow an enrollee to use the exceptions process to request or be granted coverage for a drug that does not meet the definition of a Part D drug.** • 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. **The sponsor may adopt a policy for accepting oral requests.** 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.	Examples of "good cause" for extending the timeframe include: (1) the enrollee was prevented by serious illness from contacting the plan in person, in writing, or through a friend, relative, or other person; (2) the enrollee had a death or serious illness in his or her immediate family; (3) important records were destroyed or damaged by fire or other accidental cause; (4) the plan, or its designated entity, gave the enrollee, appointed or authorized representative, or prescribing physician incorrect or incomplete information about when and how to request a redetermination; (5) the enrollee, appointed or authorized representative, or prescribing physician did not receive notice of the determination or decision; or, (6) the enrollee, appointed or authorized representative, or prescribing physician sent the request to another Government agency in good faith within the time limit and the request did not reach the correct plan until after the time period had expired. This is not meant to be an exhaustive list.

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§423.584 Expediting certain redeterminations. • An enrollee or an enrollee's prescribing physician may request that a 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;~~ **make the determination within a 7-day timeframe (established in §423.590) which begins when the sponsor receives the request for the expedited redetermination;** (2) give the enrollee prompt oral notice of the denial that (a) ~~and subsequently deliver, within 3 calendar days, a written letter that: of the denial that~~ **explains that the sponsor processes the enrollees' request within 7 days for standard redetermination;** (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) provides instructions about the grievance process and its timeframes. **(3) Subsequently, deliver, within 3 calendar days, equivalent written notice.** • If a sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice.	
423.586 Opportunity to submit evidence. • The ~~**Part D**~~ 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.	
§423.590 Timeframes and responsibility for making redeterminations. • *Standard redetermination, request for covered drug benefits.* (1) If the **Part D** plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor ~~must issue the~~ **must notify the enrollee in writing of its** redetermination as expeditiously as the enrollee's health condition requires, but no later than ~~30~~ **7** calendar days from the date it receives the request for a standard redetermination. (2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than ~~30~~ **7** calendar days from the date it receives	

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the request for a standard redetermination. ~~The sponsor may extend the timeframe by 14 days if the enrollee requests an extension or if the sponsor justifies a need for additional information. When the sponsor extends the timeframe, it must notify the enrollee, and inform him or her of the right to file an expedited grievance. For extensions, the sponsor must issue its determination expeditiously as the enrollee's health requires, but no later than the expiration of the extension~~ • *Standard redetermination--request for payment.* (1) If the sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination no later than ~~60~~ **7** calendar days from the date it receives the request for redetermination. (2) If the sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than ~~60~~ **7** calendar days from the date it receives the request for redetermination. • *Effect of failure to meet timeframe for standard redeterminations.* If the sponsor fails to provide the enrollee with a redetermination within the timeframes specified above, the failure constitutes an adverse redetermination decision, ~~and is subject to appeal to the IRE~~ **and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.** • *Expedited redetermination.* (1) Timeframe. ~~Except in the case of an extension,~~ a sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision 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 deadline by up to 14 calendar days if specific conditions are met. The sponsor must provide notice of the determination as expeditiously as the enrollee's health condition requires but no later than the expiration of the extension. When the sponsor extends the timeframe, it must notify the enrollee in writing of the reasons, and inform him or her of the right to file a grievance.~~ • *How sponsor must request additional information.* If the sponsor must receive medical information, it must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the sponsor requests additional information, it is responsible for meeting the timeframe and notice requirements. • ~~*Affirmation of an adverse expedited coverage determination.* If, as a result of its redetermination, the sponsor affirms, in whole or part, its adverse expedited coverage determination, the sponsor must give the enrollee (and prescribing physician as appropriate) notice of its decision as expeditiously as the enrollee's medical condition requires, but no later than 72 hours after receiving the request (or no later than the expiration of an extension.~~ • *Failure to meet timeframe for expedited redetermination.* If the sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described above, the failure constitutes ~~an affirmation of its adverse expedited coverage determination and is subject to appeal to the IRE~~ **an adverse redetermination decision, and the sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.** • ~~*Who must reconsider an adverse coverage determination.*~~ ***Who conducts the review of an adverse coverage determination.*** (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination. (2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be	

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of the same specialty or subspecialty as the prescribing physician. • ***Form and content of an adverse redetermination notice.*** **Notice of any adverse determination must: (1) use approved notice language in a readable and understandable form; (2) state the specific reasons for the denial; (3) inform the enrollee of his or her right to a reconsideration. For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and comply with any other notice requirements specified by CMS.**	
§423.600 Reconsideration by an independent review entity (IRE). • An enrollee who is dissatisfied with the redetermination of a ~~PDP~~ **Part D plan** 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 **orally or in writing. A written account of the physician's views (prepared by the physician or the IRE, as appropriate) must be contained in the IRE's record.** • 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~~ **would not be** as effective for the individual as the nonformulary drug, ~~has~~ **would have** 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, **including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.** • **When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.**	CMS considered but rejected a policy of automatically forwarding reconsiderations to the IRE. CMS notes that examining the record de novo using the plan's exceptions criteria, as approved by CMS, and making an independent medical necessity determination will form the basis for the IRE's decision. However, the IRE is prohibited from ruling on the validity of a plan's exceptions criteria or formulary. Only CMS can evaluate and decide whether to approve a plan's exceptions criteria and formulary as part of the annual 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 plan 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 is adverse, i.e., 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.	

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• A reconsideration determination is final and binding on the enrollee and the plan sponsor, unless the enrollee files a request for an ALJ hearing.	
§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 plan sponsor's refusal to provide drug benefits, CMS will use the projected value of those benefits to compute the amount remaining in controversy. **The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.** • 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 **with the entity specified in the IRE's reconsideration notice.** ~~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. **Time and place for a hearing before the ALJ will be set in accordance with §405.1020 of this chapter.** • 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.	The requirement relating to time and place of the hearing has not been finalized yet but CMS expects it be prior to January 1, 2006.
§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.	

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• An enrollee may request judicial review of an ALJ's decision if: o The MAC 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 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~~ **Part D plan** 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~~ **7** calendar days after the date the 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 sponsor ~~completely~~ reverses its coverage determination, the sponsor must ~~pay for the benefit~~ **authorize payment** for the benefit within ~~no later than 60~~ **7** calendar days after the date the sponsor receives the request for redetermination, **and make payment no later than 30 calendar days after the date the sponsor receives the request for redetermination.** • *Reversals by ~~the IRE~~ **other than the plan sponsor** of requests for benefits.* If, on ~~reconsideration~~ **appeal** of a request for benefit, the sponsor's determination is reversed in whole or in part by the IRE, **or at a higher level of appeal,** the sponsor must authorize **or provide** 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 **other than the plan sponsor** ~~the IRE~~ of requests for payment.* If, on ~~reconsideration~~ **appeal** 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~~ **authorize payment for the benefit within 72 hours but make payment** 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
• ~~*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~~ **Part D plan** sponsor*. If, on ~~redetermination of~~ an expedited **redetermination** or request for benefits, the sponsor completely reverses its coverage determination, it must authorize or provide the benefit under dispute as 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~~ **other than the plan sponsor.*** If the sponsor's **expedited** determination or **expedited red termination** is reversed in whole or in part by the IRE, **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 ~~72~~ **24** 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 FINAL RULE
Subpart N: Medicare Contract Determinations and Appeals

FINAL RULE	PREAMBLE (FINAL RULE)
§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. ○ 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. • **Any favorable reconsideration, including those resulting from a hearing or Administrator review, must be made by July 15 if it is to become effective for the contract in question on January 1 of the following year.**	
§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. ○ 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
○ A party to the hearing may object to the hearing officer in writing at the earliest opportunity. ○ The hearing officer must consider the objections, and may either proceed or withdraw. ○ If the hearing officer does not withdraw, the objecting party may, after the hearing, present 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. ○ 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. ○ A reasonable time for inspection and reproduction of documents is provided. ○ 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 FINAL RULE
Subpart O: Intermediate Sanctions

FINAL RULE	PREAMBLE (FINAL RULE)
§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.	CMS had sought comment in the NPRM 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. Final rule retains CMS ability to suspend marketing and enrollment but indicates reluctance to do so if it would reduce choice of plans below 2 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.	

FINAL RULE	PREAMBLE (FINAL RULE)
○ The request must provide a credible explanation of why additional time is necessary and be received before the end of the original 15-day period. ○ 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: ○ Require the PDP sponsor to suspend acceptance of enrollment applications; ○ Suspend payments to the PDP sponsor for enrollees in the sanctioned plan; and ○ 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. ○ 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: ○ 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. ○ For each week that a deficiency remains uncorrected --up to $10,000 per week. ○ 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 FINAL RULE
Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals

FINAL RULE	PREAMBLE (FINAL RULE)
§423.772 Definitions • ***Applicant: the Part D eligible individual applying for the low-income subsidies.*** • *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: ○ Has coverage for the month under a PDP or MA-PD plan; and ○ Is determined eligible by the state 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 or **Section 1115 demonstrations that provide pharmacy-only benefits**). 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: the subsidies available to full subsidy eligible individuals.*** • *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.~~	*The Social Security Administration (SSA) is publishing is own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to low-income subsidy eligibility*. These include counting items such as the cash surrender of life insurance and the value of IRAs and 401(k) plans.
§423.773 Requirements for eligibility. • *A subsidy eligible individual* is a Part D eligible individual residing in a State who is enrolled in, **or seeking to enroll in**, a Part D plan and meets the following requirements: ○ Has income below 150 percent of the FPL applicable to the individual's family size. ○ Has resources at or below the resource thresholds. • *Full subsidy eligible individual* is a subsidy eligible individual who: ○ Has income below 135 percent of the FPL applicable to the individual's family size; and resources that do not exceed:	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.

FINAL RULE	PREAMBLE (FINAL RULE)
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, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10 **(rounded up if equal to or greater than $5; down if less than $5).** 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.~~ • **CMS notifies these full subsidy eligible individuals that they do not need to apply for the subsidies and are deemed eligible for a period of up to one year.** • *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 **(rounded up if equal to or greater than $5; down if less than $5).**	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 using the same resource methodologies. Auto-enrollment of full-benefit dual eligibles is described in Subpart B. Drug coverage transition process is described in Subpart C. Full benefit dual eligibles will be deemed eligible through the rest of the calendar year regardless of a change in Medicaid status. Individuals that change state of residence will need to apply in the new state of residence or with SSA for low-income subsidies if their eligibility was determined by the state. Residents of the territories are not eligible for low-income subsidies. See Subpart S.
§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. • **In the case of multiple applications by an individual or their personal representative, the later application will be void if the response to the previous application was positive.**	*CMS is working with SSA to develop a model application form and to design a process so that states can determine if an individual has already filed an application with SSA and vice versa and will provide further guidance.* 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. Paper copies of financial statements will not be required unless requested. CMS is not implementing a presumptive eligibility process. *CMS will issue guidance on the notification of plans and SPAPs on low-income eligibility of enrollees.*

FINAL RULE	PREAMBLE (FINAL RULE)
§**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. • 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. • **Special rule for 2006: CMS will assign equal weighting to all PDP sponsors and assigns MA-PDs a weight based on prior enrollment. New MA-PD plans receive zero weight.** • 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 **as follows:** o **At or below 135% of FPL: 100% of premium subsidy amount;** o **135-140% of FPL: 75% of premium subsidy amount;** o **140-145%: 50% of premium subsidy amount;** o **145-150%: 25% of premium subsidy amount.** • 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.	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 enrolling only dual eligibles could reduce or eliminate co-payments). *CMS will issue operational guidance on process for when someone does not agree with the premium subsidy amount or the late enrollment penalty.*
§423.782 Cost-sharing subsidy. • Full subsidy eligible individuals are entitled to the following: 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.	Plans may not charge higher copayments to the low-income than provided in law. *CMS will issue guidance on how plans should address cases where an enrollee's institutional status is different than the information provided to them by CMS.*

FINAL RULE	PREAMBLE (FINAL RULE)
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: 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 Part D plan obtained after ~~the initial coverage limit~~ **annual deductible**, up to the out-of-pocket limit. 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 **and organizations paying cost-sharing on behalf of such individuals,** for any out-of-pocket costs relating to excess premiums and cost-sharing **paid after the effective date of the individual's eligibility for a low-income subsidy**. ~~between the date of notice of subsidy eligibility and the date subsidy eligibility is effective.~~	*CMS will issue guidance on: the issue of completeness and timeframe for processing applications; data system requirements; an oversight process for plan noncompliance with copayment requirements; and on the mechanism it will use to reimburse plans for expenses that the plan must reimburse for costs incurred before notification of subsidy eligibility.*

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

FINAL RULE	PREAMBLE (FINAL RULE)
§423.855 Definitions. • ***Actual costs*** **means the prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are actually paid by the sponsor.** • *Eligible Fallback Entity or Fallback Entity*: an entity that, with respect to a particular contract period: Meets all the requirements to be a PDP sponsor except that it does not have to be a risk-bearing entity; and 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: Offers only **standard coverage or** actuarially equivalent standard prescription drug coverage; Provides access to negotiated prices, including discounts from manufacturers; and Meets **all** other requirements as specified by CMS **in separate guidance documents.** • *Qualifying Plan:* a full-risk or limited-risk PDP or an MA-PD plan that ~~either~~ **provides required prescription drug** ~~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 **not** under a capacity waiver.	Final rule adds definition of actual costs to clarify basis for paying fallback plans. An MA-PD plan may also offer a fallback plan in the same region. Fallback plans may offer either standard coverage or actuarial equivalent defined drug coverage. Fallback plans must pass-thru all price concessions to the enrollee that are known at the point of sale.
§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.	
§423.863 Submission and approval of bids. • CMS solicits bids from eligible fallback entities separate from the PDP bidding process. CMS will solicit bids for 2006 in order to allow enough time to prepare a bid. After that, bids will be solicited on 3-year cycles, or annually as needed to replace contractors. 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 PDP~~s~~ **bids** apply to fallback plans.	CMS indicates that a risk plan may withdraw its bid prior to executing a contract if the plan does not wish to compete with a fallback plan. However, the CMS expectation is that risk plan bidders will enter the process in good faith with the full expectation of participating.

FINAL RULE	PREAMBLE (FINAL RULE)
• **CMS may approve limited risk plans first, and only if there remains an insufficient number of qualified plans, offer a fallback plan.** • 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. • CMS may not contract with a single entity for the offering of fallback plans throughout the United States.	*CMS will issue further guidance on performance measures used in the private sector as the basis for putting at risk a fallback plan's management fees.*
§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) **or paid directly to the fallback plan. Management fees due to a fallback plan are deducted from premiums collected from enrollees.**	
§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: 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: 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 Management fees **(covering administrative costs and return on investment)** that are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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 determining payments**. ~~carrying out this part.~~ This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations. • **The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).**	
§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.	*CMS will issue separate guidance on the methodologies for fallback plans that limit the amount of adjustments that must be made.*

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

FINAL RULE	PREAMBLE (FINAL RULE)
§423.882 Definitions.	
• *Allowable retiree costs:* **gross** covered retiree plan-related prescription drug costs as ~~between the cost threshold and cost limit,~~ ~~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.	*CMS may issue further guidance on what costs constitute gross retiree plan-related prescription drug costs.*
• **Benefit option: a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.**	
• *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.	*CMS will issue further guidance on account-based arrangements.*
• *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: ○ *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. ○ *Collectively bargained plan:* a plan established by one or more collective bargaining agreements. ○ *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. ○ ***Account-based medical plan:* a Health Reimbursement Arrangement(HRA), a flexible spending arrangement(FSA), a health savings account (HSA), or an Archer MSA to the extent they are subject to ERISA as employee welfare benefit plans (or would be except for the exclusion in ERISA for government and church plans).**	The Voluntary Data Sharing Agreement (VDSA) can help sponsors identify Medicare eligible individuals. See www.cms.hhs.gov/medicare/cob/employers/emp_vdsa.asp *CMS will issue guidance on waivers for sponsoring its own PDP or MA-PD.*
• *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 is a participant or the spouse or dependent of a participant; covered under a qualified retiree prescription drug plan, and not enrolled in a Part D plan. The determination of whether an individual is covered is the responsibility of the plan. An individual is presumed not to be covered if the person is receiving coverage by reason of current employment, whether or not Medicare secondary payer rules apply.**	
• *Retiree drug subsidy amount:* the subsidy amount paid to sponsors of qualified retiree drug coverage.	
• *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.	
• ***Sponsor agreement:* an agreement by the sponsor to comply with provisions of this subpart.**	

FINAL RULE	PREAMBLE (FINAL RULE)
§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:~~ ○ ~~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;~~ ○ ~~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;~~ ○ ~~Certify that the values have been calculated according to established CMS actuarial guidelines based on generally accepted actuarial principles;~~ ○ ~~Be certified by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries;~~ ○ ~~Be signed under the penalty of perjury;~~ ○ ~~State that the information is true and accurate to the best of the attester's knowledge; and~~ ○ ~~Acknowledge that the information being provided is being used to obtain Federal funds.~~ • **Employment-based retiree coverage is considered to be a qualified retiree prescription drug plan if the following are satisfied in accordance with the rules for this subpart:** ○ **An actuarial attestation is submitted;** ○ **Part D eligible enrollees in the plan are provided creditable coverage notices; and** ○ **Records are maintained and made available for audit.** • **The sponsor must have a written agreement with its health insurance issuer or group health plan regarding disclosure of information to CMS and the issuer or plan must disclose the necessary information to CMS.** • The sponsor **or its designee** must submit an application for the subsidy, signed by an authorized representative of the sponsor, to CMS **in a form and manner specified by CMS**. ~~by:~~ ○ ~~For the year 2006, September 30, 2005.~~ ○ ~~For all other years, 90 days prior to the start of the year.~~ ○ ~~For plans that begin coverage mid-year, 90 days prior to the date the coverage begins.~~ ○ ~~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 Employer Tax ID Number (if applicable). ○ Sponsor name and address. ○ Contact name and email address. ○ Actuarial attestation and supporting documentation for each of the sponsor's plans. ○ Full names of each qualifying retiree enrolled in each drug plan (including spouses and dependents, if Medicare-eligible), and Health Insurance Claim (HIC) **or Social Security number**; birth date; gender; and relationship to the retired employee. **(A sponsor may satisfy this by entering into a voluntary data sharing agreement with CMS):** ○ **A signed sponsor agreement;** ○ **Other information specified by CMS.** • The sponsor must specifically accept and agree to: ○ ~~Agree to C~~omply ~~with all Federal laws and regulations, and~~ the terms and conditions of eligibility	*CMS will provide further guidance on terms and conditions of the application.*

FINAL RULE	PREAMBLE (FINAL RULE)
for a subsidy payment **set forth in this regulation and subsequent CMS guidance**, ~~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 **and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief**. • **An application must be submitted no later than 90 days prior to the beginning of the plan year, unless a request for an extension has been filed and approved under CMS procedures.** o **For plan years that end in 2006 an application must be submitted by September 30, 2005, unless an extension has been filed and approved by CMS.** • The sponsor (or the plan administrator) must provide updates to CMS of the required information in the manner ~~and frequency~~ specified by CMS on a monthly basis or a 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~~ are not enrolled in a Part D plan and provides to the sponsor (or ~~plan administrator~~ a designee) 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.~~ • **Actuarial attestation: the sponsor must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree drug coverage is at least equal to that of Part D standard coverage and must meet the following standards:** o **Includes assurances that for the year in question:** ▪ **The actuarial gross value is at least equal to that of standard Part D coverage;** ▪ **The actuarial net value is at least equal to the net value of standard coverage;** ▪ **The actuarial values must be determined using the specified methods (below).** o **The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use outside actuaries who may submit the attestation directly to CMS.** o **The attestation must be signed by a qualified actuary and must state that it is true and accurate to the best of the attester's knowledge and belief.** o **The attestation must contain an acknowledgement that the information provided is being used to obtain Federal funds.** • **The attestation must be based on generally accepted actuarial principles and CMS guidelines.** • **Specific rules for determining actuarial value are:** o **The gross value must be determined using actual claims experience and demographic data for Part D eligible participants in the plan (sponsors without creditable data may use normative databases specified by CMS). Sponsors may use other approaches specified by CMS as an alternative.**	CMS will consider permitting the submission of entire enrollment files as updates. Each benefit option offered by a sponsor must meet the gross value test to qualify for the subsidies. The actuarial value of standard coverage in the actuarial value test takes TROOP into account, so that the sponsor's plan value is compared to standard coverage that an enrollee would receive if the retiree had wrap-around supplemental benefits (which delays reaching the out-of-pocket limit and thus reduces the value of standard coverage). The regulations allow each plan to determine the actuarial value of standard coverage using their own claims experience instead of CMS issuing a fixed numerical value to the coverage. *CMS will develop and publish simplified actuarial methods for comparing a sponsor's plan to standard coverage.* CMS will seek to determine if there is a level of public disclosure of attestation data that will enhance beneficiary confidence in the retiree subsidy program but will not deter sponsors from seeking the subsidy and maintaining their coverage.

FINAL RULE	PREAMBLE (FINAL RULE)
○ **The net value must be determined by reducing the gross value by the expected premiums paid by Part D eligible participants or their spouses/dependents. For sponsors with an integrated premium for drug and medical coverage, the attestation must allocate a portion of the premium using a method determined by the sponsor.** • **Rules for defining Part D defined standard coverage:** ○ **The gross value must be determined in the same manner as for the sponsor's plan (above).** ○ **The net value is determined by reducing the gross value by:** ▪ **The monthly beneficiary premiums expected to be paid for standard coverage;** ▪ **An amount reflecting the impact of any supplemental drug coverage provided by the sponsor. Sponsors may use alternative approaches specified by CMS.** ○ **The value of standard coverage is based on the initial coverage limit cost-sharing and out-of-pocket threshold in effect at the start of the plan year. However, the attestation must be submitted to CMS no later than 60 days after the publication of the limits for the upcoming year. Otherwise the limit and threshold for the upcoming year are used.** ○ **For employment-based coverage with 2 or more benefit options, the assurances must be provided separately for each option for which a subsidy is requested, except that the assurance for net value may be provided in the aggregate for all benefit options.**	
§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 plan year is the calendar, policy, or fiscal year on which records of the plan are kept.** • **For plan years beginning in 2005 and ending in calendar 2006, the subsidy is determined by taking into account all claims incurred in the plan year for determining which claims fall within the cost threshold and cost limit. The subsidy is paid only for costs incurred on or after January 1, 2006.** • The following cost threshold and cost limits apply: **For plan years that end** in 2006 the cost threshold is $250 and the cost limit is $5,000. **For plan years that end** after 2006, the cost limit and threshold are adjusted annually in the same manner as the 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. • **Payment can be made on a monthly, quarterly or annual basis as elected by the plan sponsor, unless CMS decides to restrict the options.** ○ **If the plan sponsor elects monthly or quarterly, it must provide data on a monthly or quarterly basis or as CMS requires. The data must include the gross plan-related drug costs incurred during the period and other data as required. It must also submit, using historical data and generally accepted actuarial principles, an estimate of its expected**	*CMS will issue further guidance on clarifying what are price concessions. In the meantime, performance guarantees that are not predicated on drug utilization but rather matters such as customer service are not likely price concessions for purposes of determining allowable costs.*

FINAL RULE	PREAMBLE (FINAL RULE)
costs based on expected rebates and price concessions. Final allocation of price concession data will occur at the end of year reconciliation. o **If the plan sponsor elects a one-time final annual payment, it must submit to CMS the total gross plan-related drug costs, actual rebate and other price concession data, and other data CMS requires within 15 months after the end of the plan year. As an alternative, the sponsor may elect an interim annual payment as for plans electing monthly or quarterly payments.** • **CMS makes payment after submission of cost data in a time and manner specified by CMS.** • **Sponsors who elect monthly, quarterly, or interim annual payments must submit to CMS within 15 months, or longer as specified by CMS, gross plan-related drug costs and actual rebate and price concession data.** o **CMS adjusts the payments made for the plan year as specified by CMS.** • **For insured plans, sponsors may choose to determine gross covered plan-related costs based on a portion of the premium paid by the sponsor, except that administrative and risk charges must be subtracted from the premium costs.** o **Final payments are determined from actual gross plan-related drug costs incurred by the insurer (or retiree) for each retiree and submitted for reconciliation.** o **CMS adjusts the payments made for the plan year 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~~ **designee)**, 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. o **Other records specified by CMS.** • **CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to)the use of electronic media.** • CMS or the OIG may extend the 6-year retention rule for ongoing investigation, litigation or negotiation **involving civil, administrative or criminal liability. The plan sponsor must maintain records longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative, or criminal activity.**	Privacy: Individual beneficiary authorization will not be required for disclosure of data to CMS for subsidy payments. However, plan sponsors may need to comply with state privacy laws that are more stringent than HIPAA. *Rebate information is confidential and CMS will issue further guidance on this.*
§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.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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. ○ A written hearing request must be filed with CMS within 15 days of the reconsideration decision. ○ 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. ○ CMS provides written notice of the time and place at least 10 days before the informal hearing. ○ 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. ○ 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: ○ Within 1 year of the date of the notice of determination for any reason. ○ Within 4 years for good cause. ○ 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: ○ The sponsor requests reconsideration; ○ A timely request for a hearing is filed; ○ The determination is reviewed by the Administrator; or ○ The determination is reopened and revised. • CMS finds good cause if: ○ New and material evidence not readily available for the initial determination is furnished; ○ A clerical error in the computation of payments was made; or ○ The evidence that was considered shows on its face that an error was made.	

FINAL RULE	PREAMBLE (FINAL RULE)
• 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.	
§423.892 Change in ownership. • Any of the following constitutes a change of ownership: Partnership. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law. Transfer of substantially all of the assets of the sponsor to another party. 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. • 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 FINAL RULE
Subpart S: Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

FINAL RULE	PREAMBLE (FINAL RULE)
§423.902 Definitions. • *Actuarial value of capitated prescription drug benefits:* the estimated actuarial value of prescription drug benefits provided under a **comprehensive** capitated Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate, **among the following options:** • **State rate setting documentation for drug costs to the full dual eligible population;** • **State encounter and enrollment record databases including cost data; and** • **State managed care plan-specific financial cost data; and** • **Other appropriate data.** • *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. • **CMS provides further detail on sources of data and how the annual increase will be determined via operation guidance.** • *Base year Medicaid per capita expenditures:* the monthly weighted average of: ○ The gross base year (2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and ○ The estimated actuarial value of drug benefits provided under a **comprehensive** capitated Medicaid managed care plan per full-benefit dual eligible for 2003. **The per capita payments for dual eligibles with managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the MSIS.** • *Full-benefit dual eligible individual*: an individual who, for any month: ○ Has coverage under a Part D plan; and ○ **Is determined eligible by the state** for full Medicaid benefits (including under a section 1115 waiver, but not under Pharmacy Plus demonstrations **or pharmacy-only section 1115 demonstrations**). ○ 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. ○ 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 **as reported in MSIS**. • *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**~~ **MSIS** drug claims paid during the four quarters of calendar year 2003 and the associated dual eligibility enrollment status of the beneficiary. **MSIS drug claims with NDC codes that are excluded from Part D, and claims with Indian Health Service or Family Planning program codes will be excluded.**	CMS believes the Medicare Part D coverage will pay, on average, 96% of full-benefit dual eligibles' drug costs.

FINAL RULE	PREAMBLE (FINAL RULE)
• *Phased-down State contribution factor for a month:* • 2006: 90 % 2011: 81 \2/3% • 2007: 88 \1/3 % 2012: 80 % • 2008: 86 \2/3 % 2013: 78 \1/3 % • 2009: 85 % 2014: 76 \2/3 % • 2010: 83 \1/3% 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 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. *CMS intends to issue operational guidance to states on notification of eligibility and will monitor time periods and take action as appropriate. They expect time periods that are consistent with processing Medicaid applications*.

FINAL RULE	PREAMBLE (FINAL RULE)
§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 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~~ **CMS** 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~~ **CMS**. • **State payments begin January 2006 and are made on a monthly basis.** 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	*CMS will provide operational guidance on the process used to collect data from states.* Any changes a state makes in Medicaid payment, eligibility, or coverage because of the impact of the new Medicare benefit must be reflected in the state plan or the state risks losing its federal matching payments. CMS has developed a list of drug codes for drugs to be excluded from the baseline due to exclusion under Part D. *CMS will provide further operational guidance on sources of data and how the annual percentage increase will be determined.*

FINAL RULE	PREAMBLE (FINAL RULE)
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 FINAL RULE
Subpart T: Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE and Medigap Requirements

FINAL RULE	PREAMBLE (FINAL RULE)
§411. 351. Definition of outpatient prescription drugs for purposes of physician self-referral prohibition. • Adds 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 provision is required to reflect the addition of Part D coverage in the physician self-referral regulations.
§417.440 and §417.534. Cost-based HMOs and Competitive Medical Plans (CMPs) offering Part D coverage. • ~~Amends §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.~~ **With certain exceptions, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by an HMO or CMP in addition to the covered Part A and Part B services. (A CMP is a plan that is not a Federally qualified HMO but meets the requirements to contract with Medicare.) An HMO or CMS may elect to provide qualified prescription drug coverage under part D as an optional supplemental service. The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.** • 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.	Offering of Part D qualified drug coverage is optional for cost based HMOs. Plans electing to offer Part D coverage may do so only as an optional supplemental benefit. A HMO or CMP offering a cost plan may also apply to be a PDP sponsor and may, if approved, offer a separate Part D plan to eligible individuals enrolled in original Medicare who are not enrollees of its cost plan.
PACE Organizations offering Part D Coverage. • A PACE program may elect to provide qualified prescription drug coverage to its Part D eligible enrollees. In such a case, the Part D requirements would 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 preamble for subpart T 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.	Includes in Final Rule only the proposed waiver of 423.265(b) that would require that PACE organizations submit bids by first Monday of June. Indicates that new PACE organizations can submit at a later time but expects operational plans to meet deadline. *CMS intends to issue guidance listing additional Part D provisions that will be waived but applied then to all similarly situated PACE plans.*

FINAL RULE	PREAMBLE (FINAL RULE)
§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.	Notes that all the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, apply to any rider. Thus, for instance, if an insurer offers an optional prescription drug rider that can be added to any other policies, the addition of the rider makes the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies. Moreover, any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy will meet that definition as of January 1, 2006, when the prescription drug benefit takes effect, and new sales of these policies are 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, and CMS does not believe Plan H will meet it. (3) Required disclosure notice. The notice informing policyholders that they do have

FINAL RULE	PREAMBLE (FINAL RULE)
	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 plans to publish model disclosure notices for creditable and non-creditable coverage.*

Implementation of Part D: CMS Planned Guidance and Reports[1]

The Centers for Medicare and Medicaid Services (CMS) has indicated in the Final Rule for Part D that separate guidance or information regarding numerous aspects of the Part D program is forthcoming or is being issued separately. This memorandum identifies where CMS has indicated the intent to provide such additional guidance, organized by subpart of the implementing regulations. Please note that for a few of the subparts (M, N, and O), no separate guidance was indicated.

Subpart A. General Provisions

§423.4. Definitions -- CMS may waive the service area definition for employer-sponsored group prescription drug plans in appropriate cases. Further details will be provided in separate CMS guidance.

§423.6 Cost-sharing in beneficiary education and enrollment-related costs -- CMS is planning to develop a range of tools and strategies that will help beneficiaries make a choice that meets their needs.

Subpart B. Eligibility and Enrollment

§423.30 Eligibility to enroll -- beneficiaries in state mental institutions will be provided with a special enrollment period to enable them to join the appropriate Part D plan. CMS expects to provide guidance on this issue.

§423.32 Enrollment process -- operational guidance on the enrollment process.

§423.36 Disenrollment process -- operational guidance on beneficiary education process targeted to individuals who already have other drug coverage to avoid need for disenrollments.

§423.38 Enrollment periods -- guidance regarding the Special Election Periods (SEPs), including for those individuals: eligible for the low-income subsidy whose enrollment will be facilitated, in long-term care facilities; enrolled in, or desiring, to enroll in PACE; and enrolled in employer group plans. May establish additional SEPs in the future through operational guidance.

§423.44 Involuntary disenrollment -- further guidance on the process of disenrollment when an individual: permanently moves out of the service area; loses entitlement to Part A or Part B; or materially misrepresents information on third-party coverage.

§423.46 Late enrollment penalty -- Operational and system requirements are being developed to implement the late enrollment penalty process. Additional guidance will be given to plans and individuals.

§423.50 Marketing -- Future guidance will provide greater detail, including requirements to ensure appropriate information is available to beneficiaries, including those with low literacy, those who are disabled, etc. Also will address marketing by providers and pharmacies,

[1] Information is from the preamble to the final rule for title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, *Federal Register*, January 28, 2005.

remuneration offered to providers in exchange for providing to patients information about Part D plans, eligibility and performance requirements associated with the File& Use program, and model marketing materials for sponsors.

§423.56 Procedures to determine and document creditable status of prescription drug coverage -- Guidance on aspects of actuarial equivalence, and may issue guidance, if determined necessary, specifying additional sources of creditable coverage. Guidance also on the form, manner and timing of the required notice of creditable coverage; and on a method for determining creditable coverage for employer group sponsors not electing the retiree drug subsidy.

Subpart C. Benefits and Beneficiary Protections

§423.100 Definitions -- various issues raised by the drugs covered by Part B for the administration of the Part D drug benefit to be addressed in a forthcoming Congressionally mandated report. More information and guidance on the relation between Part B and Part D coverage in separate guidance to Part D plans.

§423.104 Requirements related to qualified prescription drug coverage -- For calculations of the annual percentage increase, CMS will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to Part D sponsors prior to the deadline for bid submissions. Also, operational guidance to be provided on the format and frequency of the required plan reporting on negotiated prices as well as what constitutes direct or indirect remunerations, rebates and discounts.

§423.120 Access to Covered Part D Drugs -- Further detail regarding criteria for long-term care pharmacies in operational guidance. Anticipating plan problems in meeting access requirements in some rural areas, CMS expects to establish an exceptions process, to be outlined in operational guidance to Part D plans that will account for any problem areas and mitigate any disincentives plans may have to avoid doing business in parts of the country in which meeting the pharmacy access standards.

§423.128 Dissemination of plan information -- CMS will be providing marketing guidelines so that plans know how to describe their benefit packages (“clear, accurate, and standardized form”).

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§423.150 - §423.153(c) Cost and utilization management, quality assurance, medication therapy management programs (MTMP) -- To ensure that plans appropriately employ drug utilization management techniques, and to develop or adopt further drug utilization management performance measures, CMS has added a reporting requirement and will specify the required information in separate guidance.

§423.153 (d). Medicare therapy management program (MTMP) -- Plans have discretion to define targeted enrollees except that CMS will set a specific cost threshold for drug expenditures that must be met. This will be done in separate guidance. Information to be reported by plans on their MTMP services also specified in separate guidance.

§v423.159 Electronic prescription program -- Additional guidance on acceptable physician incentives for e-prescribing.

§423.162 Quality Improvement Organization (QIO) activities -- Data to be made available to QIOs will be identified in separate CMS guidance.

Subpart F: Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§423.265 Submission of bids and related information -- 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). It will also provide guidance on format for bid submission and added information on administrative costs. For actuarial valuation processes and methods, data sources, methods, assumptions and other techniques, and formats will be specified in further guidance.

Subpart G: Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

§423.308 Definitions -- For allowable costs, CMS will require reporting of aggregate rebates at the product level on a quarterly basis. Additional guidance on payments and rebate accounting rules will be issued.

§423.315 General payment provisions -- CMS intends to conduct a reinsurance demonstration with an alternative payment approach that will be budget neutral. Guidance forthcoming.

§423.322 Requirement for disclosure of information -- Additional guidance will be released addressing QIO access to Part D data**.**

§423.336 Risk-sharing arrangements -- If a plan does not submit data for determining risk corridor costs, CMS will assume its costs were 50% of the target amount. Further guidance will be issued on the methodology for reconciliation for these payments.

Subpart I: Organization Compliance with State Law and Preemption by Federal Law

§423.410 Waiver of certain requirements to expand choice -- Further guidance on how best to identify plans that are approved under waivers.

§423.420 Solvency standards for non-licensed entities -- CMS solvency standards are undergoing internal review and are expected to be published with the initial application forms for PDPs and plan reporting requirements.

Subpart J: Coordination with Other Prescription Drug Coverage

§423.458 Application of Part D rules to MA-PD plans on and after January 1, 2006 -- Guidance on waivers that CMS will and will not consider regarding employer group plans. Also guidance on the entities CMS will contract with, as well as how CMS will contract with them.

§423.464 Coordination of benefits with other providers of prescription drug coverage -- Guidance to SPAPs on activities they may undertake that will not discriminate among Part D plans. Further information on coordination requirements and processes will be provided by July 1, 2005.

Subpart K: Application Procedures and Contracts with PDP Sponsors

§423.502 Application requirements -- Separate guidance to be issued on the transition procedures for MA plans seeking to offer Part D benefits

Subpart P: Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§423.772 Definitions -- The Social Security Administration (SSA) is publishing is own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to low-income subsidy eligibility.

§423.774 Eligibility determinations, redeterminations, and applications -- CMS is working with SSA to design a process so that states can determine if an individual has already filed an application with SSA and vice versa and will provide further guidance. Guidance on the notification of plans and SPAPs on low-income eligibility of enrollees.

§423.780. Premium subsidy -- Operational guidance on process for when someone does not agree with the premium subsidy amount or the late enrollment penalty.

§423.782 Cost-sharing subsidy -- Guidance on how plans should address cases where the institutional status is different that the information provided to them by CMS.

§423.800 Administration of subsidy program -- CMS will address the issue of completeness and timeframe for processing applications through additional guidance. It will also issue on data system requirements, and on an oversight process for plan noncompliance with copayment requirements. Guidance also to be issued on the mechanism it will use to reimburse plans for expenses that the plan must reimburse for costs incurred before notification of subsidy eligibility.

Subpart Q: Guaranteeing Access to a Choice of Coverage (Fallback Plans)

§423.863 Submission and approval of bids -- Further guidance on performance measures used in the private sector as the basis for putting at risk a fallback plan's management fees.

§423.875 Payments to fallback plans -- Separate guidance on the methodologies for fallback plans that limit the amount of adjustments that must be made.

Subpart R: Payments to Sponsors of Retiree Prescription Drug Plans

§423.882 Definitions -- CMS may issue further guidance on what costs constitute gross retiree plan-related prescription drug costs; and on account-based arrangements.
CMS will issue guidance on waivers for group health plans sponsoring PDPs or MA-PDs.

§423.884 Requirements for qualified retiree prescription drug plans -- Further guidance on terms and conditions of the application for the employer subsidy. It will also develop and publish simplified actuarial methods for comparing a sponsor's plan to standard coverage.

§423.888 Payment methods, including provision of necessary information -- Further guidance on clarifying what are price concessions.

Subpart S: Special Rules for States – Eligibility Determinations for Subsidies and General Payment Provisions

§423.904 Eligibility determinations for low-income subsidies -- Operational guidance to states on notification of eligibility and will monitor time periods and take action as appropriate.

§423.910 State contribution requirements ("clawback") -- Operational guidance on the process used to collect data from states; also on sources of State drug cost data and how the annual percentage increase will be determined.

Subpart T: Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE and Medigap Requirements

PACE Organizations offering Part D Coverage -- Guidance listing Part D provisions that will be waived but applied then to all similarly situated PACE plans.

§403.205 Medicare supplemental policy -- CMS plans to publish model disclosure notices for creditable and non-creditable coverage.

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