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terminated its contract, or \$100, 000, whichever is greater.

[69 FR 78338, Dec. 30, 2004, as amended at 70 FR 4741, Jan. 28, 2005]

§ 422.760 Other applicable provisions.

The provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

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AUTHORITY: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

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1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

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1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and 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 (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means 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 means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means 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. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

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Service area (*Service area does not include facilities in which individuals are incarcerated.*) means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the

PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(v) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

§ 423.34 Enrollment of full-benefit dual eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans full-benefit dual eligible individuals who fail to enroll in a Part D plan.

(b) *Definition of full-benefit dual eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is:

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. ; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a).

(c) *Enrolling a full-benefit dual eligible individual.* Notwithstanding § 423.32(e), during the annual coordinated election period, CMS may enroll a full-benefit dual eligible individual in another PDP

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if CMS determines that the further enrollment is warranted.

(d) *Automatic enrollment rules*—(1) *General rule.* CMS must automatically enroll full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount (as defined in §423.780(b)). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals must be enrolled in such PDPs on a random basis.

(2) Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit. Full-benefit dual eligible individuals enrolled in an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be automatically enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a full-benefit dual eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under §423.38.

(f) *Effective date of enrollment.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual eligible individuals as of December 31, 2005;

(2) The first day of the month the individual is eligible for Part D under §423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under §423.30(a)(1) on or after January 1, 2006; and

(3) For individuals who are eligible for Part D under §423.30(a)(1) and subsequently become newly eligible for Medicaid on or after January 1, 2006,

enrollment is effective as soon as practicable after being identified as a newly full-benefit dual eligible individual, in a process to be determined by CMS.

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in §423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.*
(i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment

period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period*—(1) *For 2006*. This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years*. For coverage beginning 2007 or any subsequent year, the annual coordinated election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods*. A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of creditable prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had creditable prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous

because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.40 Effective dates.

(a) *Initial enrollment period*. (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar

month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods*—(1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.44 Involuntary disenrollment by the PDP.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment*—(1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment*—(1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) Reenrollment in the PDP. If an individual is

disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive behavior.* (i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual 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.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the require-

ments to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligibility.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies,

disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description

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of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.* (i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

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§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.*

(1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) 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.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(c) *Examples of marketing materials.* Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(6) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its

service area and no longer be offered in the area where a beneficiary resides.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval.* If CMS has not disapproved the distribution of a marketing material or form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

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(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D-22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under

§ 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified—

Actual cost means the 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 means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's for-

mulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either 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 means 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 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 fees means 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 consistent with § 423.153(c)(2), 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 in the previous sentence, 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 program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, 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 any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

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.

Incurred costs means costs incurred by a Part D enrollee for covered Part D drugs—

(1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.454); or

(iii) Under § 423.782.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg-91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means 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 means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that—

(1) Are available to beneficiaries at the point of sale at network pharmacies;

(2) Are reduced by those 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

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Person means 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 means 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 (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002-41 and Internal Revenue Notice 2002-45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for

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which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means 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 means coverage of Part D drugs under an MA-PD plan that consists of either—

- (1) Basic prescription drug coverage; or
- (2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

- (1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or
- (2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means 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 for a covered Part D drug.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plans.* A PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits.* The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

- (1) *Deductible.* An annual deductible equal to—
 - (i) *For 2006.* \$250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$5.

(2) *Cost-sharing under the initial coverage limit—(i) 25 Percent coinsurance.* Coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraph (d)(2)(i)(B) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit.* The initial coverage limit is equal to—

(i) *For 2006.* \$2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold.* Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (1) In 2006, \$2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* \$3,600.

(B) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage.

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For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(1) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(2) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(3) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP spon-*

sors. A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, 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

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.*

(i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug

coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices*—(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans.* The service area for a prescription drug plan other than a fallback prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions*—(1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to 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 prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access*—(1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area (as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban

areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D 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 written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide con-

venient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmaco-economic studies, outcomes research data, and other such information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) 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.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an adequate benefit. A Part D plan's formulary must—

(i) Except as provided in paragraph (b)(2)(ii) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) 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, the following—

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(3) *Transition Process.* A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes* (i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information—

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)(i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing

other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.*

Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A Part D sponsor must 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 as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs.* (1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician's office access. A Part D 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.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section 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 requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing re-

quirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including—

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, and appeals procedures.* All grievance, reconsideration, exceptions, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) Potential for contract termination. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits.* (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective

enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part, including for

covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy;

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section by providing such information to Part D plans for inclusion in the written explanations of benefits required under § 423.128(e); and

(2) Under other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Consumer satisfaction surveys of Part D plans.

(c) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

(d) Quality improvement organization (QIO) activities.

(e) Compliance deemed on the basis of accreditation.

(f) Accreditation organizations.

(g) Procedures for the approval of accreditation

organizations as a basis for deeming compliance.

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that—

(1) Includes incentives to reduce costs when medically appropriate;

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) 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 Part D plan,

typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) 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 among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP)*—(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes 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 under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media has the same meaning given this term in 45 CFR 160.103.

E-prescribing means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* 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 initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with

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applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

§ 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3) *Exemptions.* (i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(ii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require

the use of a HIPAA transaction standard within an organization.

(iii) Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(4) In accordance with section 1860D-4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(b) *Standards—(1) Prescription.* The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, or Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (i) Get message transaction.
- (ii) Status response transaction.
- (iii) Error response transaction.
- (iv) New prescription transaction.
- (v) Prescription change request transaction.
- (vi) Prescription change response transaction.
- (vii) Refill prescription request transaction.
- (viii) Refill prescription response transaction.
- (ix) Verification transaction.
- (x) Password change transaction.
- (xi) Cancel prescription request transaction.
- (xii) Cancel prescription response transaction.

(2) *Eligibility.* (i) The Accredited Standards Committee X12N 270/271-

Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1, for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill); the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company,

004010X092A1, and the National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record. You may inspect copies of these materials at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For information on the availability of this material at CMS, call 410-786-0273. For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

You may obtain a copy of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004 or the Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and fax (480) 767-1042 or <http://www.ncdp.org>. You may obtain a copy of the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, 004010X092A1, October 2002, from the Washington Publishing Company, 301 West North Bend Way, Suite 107, P.O. Box 15388, North Bend, WA 98045; Telephone (425) 831-4999; and fax (425) 831-3233 or <http://www.wpc-edi.com/>. You may obtain a copy of the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent

NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or <http://www.ncdp.org>.

Authority: Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e))

[70 FR 67593, Nov. 7, 2005, as amended at 71 FR 36023, June 23, 2006]

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS

for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) 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).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any Part D 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.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment—*(1) *Proposed notice.* CMS publishes a notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) 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.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by

CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) 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).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) 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.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* 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—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* 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:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D 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

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* 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):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) 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.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) 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.

(7) 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.

(8) 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.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's

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request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* 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.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) 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.

Subpart E [Reserved]

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

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission.* Not later than the first Monday in June, 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.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a

uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription 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(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must 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 or 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.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *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 under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This

provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *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 under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D-11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only 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 (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum

(determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* (i) 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.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for 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 limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under

reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) 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.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, 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, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(i)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. 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 the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved 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 of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section.

except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c) as a result of the late enrollment.

(c) *Collection of late enrollment penalty—(1) Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback

plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or 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 would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

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Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means 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 means those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal—

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1),

less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans—(1) Application of reinsurance.*

For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart 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. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 423.329 Determination of payments.

(a) *Subsidy payments—(1) Direct subsidy.* CMS makes a direct subsidy payment for each Part D 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 (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment—(1) Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount—(1) General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount—(1) General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk—(1) Adjusted al-*

lowable risk corridor costs. For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(1) 2006 and 2007, 2.5 percent;

(2) 2008 through 2011, 5 percent; and

(3) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments—(1) No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor—(i) Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section 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.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor*—(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* 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, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 **Retroactive adjustments and reconciliations.**

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* 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.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, 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.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations—(1) Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 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.

(b) *Request for reconsideration—(1) Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the adverse determination.

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its

contractors explaining CMS' determination, or CMS or its contractors 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 in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D 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 hearing officer's decision.

(2) 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.

(3) The Administrator's determination is final and binding.

Subpart H [Reserved]

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

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is 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 prescription drug plan. If not otherwise 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.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D-15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor 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.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a fully completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does

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not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is

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approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors.

(b) *State premium taxes prohibited—(1) Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver—(1) General rule.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions

otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1934 of the Act, with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage

(described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii) (including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs—(1) Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) 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;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage—(1) Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health centers.* Rural health centers as defined under section 1861(aa)(2) of the Act.

(viii) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans; application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this

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subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

- (1) Sale, exchange, or lease of property.
- (2) Loan of money or extension of credit.
- (3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—
 - (i) Salaries paid to employees for services performed in the normal course of their employment; or
 - (ii) Health services furnished to the Part D plan 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.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) 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 means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

- (1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.
- (2) Any person who is directly or indirectly the beneficial owner of more than 5 percent 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 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (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 Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds \$25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan 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, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the requirements described in this part.

(c) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) 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.

(d) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an entity's application on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the application meets the applicable requirements specified in § 423.504 and § 423.505.

(b) *Use of information from a prior contracting period.* If a Part D plan sponsor fails to comply with the terms of a pre-

vious year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor and/or has not provided enough information to evaluate the application, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N.

(d) *Oversight of continuing compliance.* (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

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(2) If a Part D plan sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this Part, including those listed in § 423.505.

(2) 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 Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and

the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than \$100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v) Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(D) Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for effective internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

(I) If the Part D sponsor discovers 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 conduct;

(2) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(H) 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.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) 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.

(i) 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—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction.* For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA

organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority.* CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR 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.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) 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.

(a) *General rule.* The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q.

(11) Be paid under the contract in accordance with the payment rules in

subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(c) *Communication with CMS.* The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs,

and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan 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.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the Part D plan sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) 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 Part D plan sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regu-

latory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The Part D plan sponsor agrees to comply with—

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with related entities, contractors, or subcontractors, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D plan sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) 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 Part D plan sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between Part D plan sponsors and pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may

delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) 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.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment—(1) General rule.* As a condition for receiving a monthly payment

under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan 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 request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, 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) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with 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) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) 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, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on be-

half of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) 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 to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, 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) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, 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) that the information provided for purposes of price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with § 423.507 of this subpart, an entity is determined qualified to renew its contract annually only if—

(1) CMS informs the Part D plan sponsor that it is qualified to renew its contract; and

(2) The Part D plan sponsor has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract

under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans, and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision of whether a Part D plan sponsor is qualified to renew its contract as follows:

(i) To the Part D plan sponsor by May 1 of the current contract year.

(ii) If CMS decides that a Part D plan sponsor is not qualified to renew its contract, to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS determines that the Part D plan sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) The notice provisions in paragraphs (b)(2)(ii) and (iii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified to renew its contract in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any

changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the Part D sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the Part D sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an 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;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization manage-

ment, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan 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 newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in paragraph (a)(4) or paragraph (a)(5) of this section, CMS notifies the Part D plan 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 Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan*—(1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or

county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to 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, statistics indicating the following—

- (1) The cost of its operations.
- (2) The patterns of utilization of its services.
- (3) The availability, accessibility, and acceptability of its services.
- (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.
- (5) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan 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:

- (1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:
 - (i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
 - (ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.
- (2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:
 - (i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.
 - (ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) 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.

(e) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under §423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of §423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of §423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under §423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its

rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor’s facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D 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, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels 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 in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means 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 means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a

Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D 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 disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan

sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D-22(b) of

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the Act, 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.

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) 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

Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) 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.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D 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 enrollee was notified of the disposition.

§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug

benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, 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, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.* When a party makes a request for

a drug benefit, the Part D 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.

(b) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

(c) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

Use approved notice language in a readable and understandable form;

State the specific reasons for the denial;

Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process; and

Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (a) or (b) of this section, the failure constitutes an adverse coverage determination, and 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.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a Part D

plan sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee’s prescribing physician on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor, or if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee’s request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees or prescribing physicians.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, 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.

(ii) For a request made or supported by an enrollee’s prescribing physician, 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.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72 hour timeframe established in § 423.568(a) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives

the request for expedited determination, or, for an exceptions request, the physician’s supporting statement.

(2) Give the enrollee and prescribing physician prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician’s support; and

(iv) Provides instructions about the plan’s grievance process and its timeframes.

(3) Subsequently deliver, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a Part D 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 24 hours after receiving the request, or, for an exceptions request, the physician’s supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan 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.

(c) Content of the notice of expedited determination.

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) 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

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan 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.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan 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 or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and

maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, 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, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) 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 infor-

mation generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan 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.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) 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;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) 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; or

(B) 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

(iii) The number of doses that is available under a dose restriction for the prescription 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.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) 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.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) 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.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing

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physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request—*(1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of 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 with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

- (i) Be in writing; and
 - (ii) State why the request for redetermination was not filed on time.
- (d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) 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 directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

- (i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;
- (ii) Informs the enrollee of the right to file an expedited grievance if he or

she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The Part D plan 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 Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *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 notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 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 7 calendar days from the date it

receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination—(1) Timeframe.* A Part D plan 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.

(2) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe

described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct 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 of the same specialty or subspecialty as the prescribing physician.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2) or (b)(2) of this section 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;

(i) 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;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60

days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. The IRE may solicit the views of the prescribing physician orally or in writing. A written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) 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.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) 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.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses 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.

(c) *Aggregating appeals to meet the amount in controversy*—(1) *Enrollee*. Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees*. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

The appeals have previously been reconsidered by an IRE;

The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request*. The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request*. 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. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020 of this chapter.

(c) *Insufficient amount in controversy*.

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable.

§ 423.630 Judicial review.

(a) *Review of ALJ's decision*. The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) How to request judicial review. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, 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 part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor—(1) Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor—(1) Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must 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 Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(a) *Reversals by the Part D plan sponsor.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor 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 the Part D plan sponsor receives the request for redetermination.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor 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 the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a

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PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

(c) Any favorable redetermination, including those resulting from a hearing or Administrator review, must be made by July 15 for the contract in question to be effective on January of the following year.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a

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contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) Exception: A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) 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.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a

representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

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(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for 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 as provided under § 423.665(b).

(b) *Review by the Administrator.* 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 ter-

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mination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* 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.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* 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.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from \$10,000 to \$100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

(b) 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.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, we may impose one, or more, of the sanctions specified in § 423.750(a)(2), (a)(3) or (a)(4) on any Part D sponsor that has a contract in effect. The Part D sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D-1 *et seq.* of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.750(a)(2) and (a)(4).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond*—(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section, CMS—

(i) Sends a written notice to the Part D sponsor stating the nature and basis of the proposed sanction; and

(ii) Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D 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 described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the Part D sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the Part D sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the Part D sponsor submits a

timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the Part D sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions—*(1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the Part D sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract

in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the Part D sponsor in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), CMS may impose civil money penalties on the Part D sponsor in the amounts specified in § 423.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.509(a), as described in § 423.752(b), excepting those determinations under § 423.509(a)(4), CMS may impose civil money penalties, in addition to, or in place of, the sanctions that CMS may impose under § 423.756(c), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D plan enrollees—up to \$25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to \$10,000 per week.

(c) If CMS makes a determination that a Part D sponsor has terminated its contract with CMS other than in a manner described in § 423.510 and that

the sponsor has therefore failed to substantially carry of the terms of the contract, \$250 per Medicare enrollee from the terminated Part D plan or plans at the time the Part D sponsor terminated its contract, or \$100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

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

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half 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 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means—

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is 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 Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* 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:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2) Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of \$10. The nearest multiple are rounded up if it is equal to or greater than \$5 and down if it is less than \$5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Recipient of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full subsidy eligible under this paragraph (c) of this section that he or she does not need to apply for the subsidies available under this subpart, and is deemed eligible for a full subsidy for a period up to one year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, \$10,000 if single or \$20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount

allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of \$10. The nearest multiple will be rounded up if it is equal to or greater than \$5 and down if it is less than \$5.

§ 423.774 Eligibility determinations, re-determinations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies

with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D-14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility—(1) Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* 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.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) *Multiple applications.* If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.* (1) The premium subsidy amount is equal to an amount which is the lesser of:

(i) Under the Part D plan selected by the beneficiary, the monthly beneficiary premium for a Part D plan other than a MA-PD plan that is basic prescription drug coverage, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan other than a MA-PD plan that is enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium as defined under section 1854(b)(2)(B) of the Act, or

(ii) The greater of the low-income benchmark premium amount for a PDP region as determined under paragraph (b)(2) of this section or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in this paragraph (b)(2)(ii) of this section, with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

(ii) *Premium amounts:* The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP

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that is enhanced alternative coverage; or,

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual eligible individuals who are institutionalized have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than \$1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or \$3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the

PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, 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 Part D drugs, rounded to the nearest multiple of \$1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed \$2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased 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.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* The Part D sponsor offering the Part D plan, 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, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The Part D sponsor offer-

ing the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of 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 incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or fallback entity means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity

that is or applies to become a non-fallback 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 or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100. An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area—(1) For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do

not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids—(1) Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year

cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids—*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a

contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. 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 PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* 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 (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on in-

vestment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* 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 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) *Scope.* This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs, in accordance with section 1860D-22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs that are actually paid (net any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf).

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or gross retiree costs means, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. §1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under

or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002-45, 2002-28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C. §1003(b), for governmental plans or church plans).

Part D drug is defined in §423.100 of this part.

Part D eligible individual is defined in §423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in §423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in §411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of

current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan 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 means an agreement by the sponsor to comply with the provisions of this subpart.

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General.* Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information.* The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclo-

sure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application*—(1) *Submitting an application.* The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information.* In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions.* To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iii) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor.* An authorized representative of the requesting 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.

(5) *Timing.* (i) *General rule.* An application for a given plan year must be submitted by 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 procedures established by CMS.

(ii) *Transition rule.* For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates.* The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information of the individuals submitted as qualifying covered retirees with the Medicare Beneficiary Database (MBD) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation-general.* The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial

value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription drug coverage (as defined at §423.100). The attestation must meet all of the following standards.

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for the plan year in question.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3) The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) *Methodology.* (i) *Basis of the attestation.* The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D-22(a) of the Act consistent with generally accepted

actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage.* (A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.* (A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by

paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(1) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(2) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year. The attestation, however, must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year otherwise, such valuation is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D for the upcoming calendar year.

(D) Example. If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the attestation for the year April 1, 2007–March 30, 2008 is based on the coverage limit, cost-sharing and out-of-pocket threshold that apply to defined standard prescription drug coverage under Part D in 2007 provided the attestation is submitted within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option

for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options for which the sponsor provided assurances under paragraph (d)(1)(i) of this section.

(6) Timing. (i) *Annual submission.* The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) *Submission following material change.* The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's plan that impacts the actuarial value of the coverage.

(e) *Disclosure of creditable prescription drug coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit.* The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the

calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision.* For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to \$250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to \$5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(d)(1)(ii) and (d)(5)(ii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as

elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data.* (i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section.

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require.

The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans.* (i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section, may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross prescription

drug costs incurred by the health insurance issuer (as defined in 45 CFR § 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4) of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section 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 audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative

or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section 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 liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

§ 423.890 Appeals.

(a) *Informal written reconsideration—*
(1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors 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 in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) 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 hearing officer's decision.

(2) 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.

(3) The Administrator's determination is final and binding.

(d) *Reopening—(1) Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless—

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, 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.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* 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.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* 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) 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 Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors 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 Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

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

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

- (1) State rate setting documentation for drug costs to the full dual eligible population;
- (2) State encounter and enrollment record databases including cost data; and
- (3) State managed care plan-specific financial cost data; and
- (4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D-2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals.

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process—(1) Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

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(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.*

(i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information.* States must 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.

§ 423.906 General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs.* States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-in-

come individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be provided.

(2) The low-income population (income less than 150 percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, \$28,125,000;

(2) For fiscal year 2007, \$37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment—(1) Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. 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 CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D.	\$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	\$100,000,000	CMS-64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	\$500,000,000	CMS-64
(iv) ...	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans.	\$1,600	(1) × [1 - (4)]
(vi) ...	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003.	\$1,500	To be Determined
(vii) ..	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans.	90,000	CY MSIS data
(viii) ..	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans.	10,000	CY MSIS data
(ix) ...	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	\$1,590	[(7) × (5) + (8) × (6)] ÷ [(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion).	0.4000	FEDERAL REGISTER
(xi) ...	Applicable growth factor (cumulative increase from 2003 through 2006).	50.0%	NHE projections
(xii) ...	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii) ..	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv) ..	Phased-down State contribution for the month	\$8,586,000	1 / 12 × (9) × (10) × [1 + (11)] × (12) × (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include

specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS-64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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