

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 determina-

tion 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 ap-

plication 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