

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).