

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

(d) *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.

(e) *Notice to impose civil money penalties*—(1) *CMS notice to OIG.* If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement as described in 423.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon a Part D sponsor as specified at 423.752(c)(2).

(2) *CMS notice of civil money penalties to Part D plan sponsors.* If CMS makes a determination to impose a CMP described in 423.752(c)(1), CMS will send a written notice of the Agency's decision

to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The Part D sponsor's right to a hearing as specified under Subpart T of this part.

(vi) Information about where to file the request for hearing.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68735, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19825, Apr. 15, 2010]

**§ 423.758 Collection of civil money penalties imposed by CMS.**

(a) When a Part D plan sponsor does not request a hearing CMS initiates collection of the civil money penalty following the expiration of the time-frame for requesting an ALJ hearing as specified in subpart T.

(b) If a Part D sponsor requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68735, Dec. 5, 2007]

**§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.**

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under 423.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the Part D sponsor;

(3) The harm which resulted or could have resulted from the conduct of the Part D sponsor;

(4) The financial condition of the Part D sponsor;

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial

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likelihood of adversely affecting) one or more Part D enrollees—up to \$25,000 for each determination.

(2) 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 enrollees, CMS may calculate a CMP of up to \$25,000 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency .

(3) 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.

(4) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, \$250 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or \$100,000, whichever is greater.

[72 FR 68735, Dec. 5, 2007, as amended at 74 FR 1548, Jan. 12, 2009]

**§ 423.762 Settlement of penalties.**

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68735, Dec. 5, 2007]

**§ 423.764 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.

[70 FR 4525, Jan. 28, 2005. Redesignated at 72 FR 68735, Dec. 5, 2007]

**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.

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(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.

*Best available evidence* means evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual's low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.

*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