

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 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 a contract determination or decision of a hearing officer or the Administrator.

(a) CMS may reopen and revise an initial determination upon its own motion.

(b) *Contract determination.* 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 re-

vise 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.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of communication activities to Medicare beneficiaries by a Part D plan sponsor, as defined by CMS.

(b) CMS may impose civil money penalties as specified in 423.760.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010; 83 FR 16753, Apr. 16, 2018]

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

(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 re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization 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.

(7) Except as provided under § 423.34, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(8) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(9) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance.

(10) Employs or contracts with any individual, agent, provider, supplier or

entity who engages in the conduct described in paragraphs (a)(1) through (9) of this section.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose the intermediate sanctions at § 423.750(a)(1) and (3).

(c) *Civil money penalties* (1) CMS. In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in either of the following:

(i) Section 423.760(b) for any of the determinations at § 423.509(a), except § 423.509(a)(4)(i).

(ii) Section 423.760(c) for any of the determinations in paragraph (a) of this section except § 422.752(a)(5) of this chapter.

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 423.752(a).

(ii) Determinations made pursuant to § 422.510(a)(4)(i) of this chapter.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19825, Apr. 15, 2010; 79 FR 29965, May 23, 2014; 83 FR 16753, Apr. 16, 2018]

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanctions, CMS—

(i) Sends a written notice to the Part D plan sponsor stating the nature and basis of the proposed intermediate sanction, and the Part D plan sponsor's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D plan sponsor 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at subpart N of this part.

(c) *Effective date and duration of sanctions—(1) Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

(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 an earlier date that CMS specifies.

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(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 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.

(C) During the limited time period, sanctioned Part D plan sponsors under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 423.750, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b), or terminate the contract in accordance with § 423.509.

(1) Decline to authorize the renewal of an organization's contract in accordance with § 423.507(b); or

(2) 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; 79 FR 29965, May 23, 2014; 83 FR 16753, Apr. 16, 2018]

§ 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 considers the following as appropriate:

- (1) The nature of the conduct.
- (2) The degree of culpability of the Part D sponsor.
- (3) The adverse effect to enrollees 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.
- (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 likelihood of adversely affecting) one or more Part D enrollees—up to \$25,000 as adjusted annually under 45 CFR part 102 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 as adjusted annually under 45 CFR part 102 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency .

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts—*(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by the Office of Management and Budget (OMB) annually.

(ii) *Calculation of penalty amounts.* (A) Per determination and per enrollee penalty amounts are increased by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts will be updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announce them on an annual basis.

(4) 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 as adjusted annually under 45 CFR part 102.

(5) 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 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or

\$100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than \$25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or (a)(5)(i), not more than \$100,000 as adjusted annually under 45 CFR part 102 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), \$15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

[72 FR 68735, Dec. 5, 2007, as amended at 74 FR 1548, Jan. 12, 2009; 79 FR 29966, May 23, 2014; 81 FR 61562, Sept. 6, 2016; 86 FR 6121, Jan. 19, 2021]

§ 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.

(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