

(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-

verse 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 all marketing activities to Medicare beneficiaries by a Part D plan sponsor.

(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]

§ 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

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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.

(b) *Suspension of enrollment and marketing.* 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 (a)(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 423.760, for any of the determinations at 423.509(a), except 423.509(a)(4).

(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 423.509(a)(4).

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19825, Apr. 15, 2010]

§ 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 from receipt of the notice to provide a written rebuttal. CMS considers receipt of 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 § 423.650 through § 423.662 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.