

(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.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 80 FR 7964, Feb. 12, 2015]

§ 423.352 CMS-identified overpayments associated with payment data submitted by Part D sponsors.

(a) *Definitions.* For purposes of this section—

Applicable reconciliation date occurs on the later of either the annual deadline for submitting—

(1) Prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(2) Direct and indirect remuneration data.

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part D requirements.

Payment data means data submitted by a Part D sponsor to CMS and used for payment purposes, including enrollment data and data submitted under § 423.329(b)(3), § 423.336(c)(1), and § 423.343, and data provided for purposes of supporting allowable reinsurance costs and allowable risk corridor costs as defined in § 423.308, including data submitted to CMS regarding direct and indirect remuneration.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by a Part D sponsor, CMS may send a data correction notice to the Part D sponsor requesting that the Part D sponsor correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the Part D sponsor fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the Part D sponsor if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the Part D sponsor that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the Part D sponsor disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If a Part D sponsor does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for its disagreement. As part of its request for reconsideration, the Part D sponsor may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of

this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *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.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The

Part D sponsor may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' finding that the payment data submitted by the Part D sponsor are erroneous.

(2) The Part D sponsor bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

[79 FR 67032, Nov. 10, 2014]

§ 423.360 Reporting and returning of overpayments.

(a) *Definitions.* For the purposes of this section the following definitions are applicable:

Applicable reconciliation means the later of either the annual deadline for submitting—

(i) PDE data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(ii) Direct and indirect remuneration data.