

deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any remaining defect or impropriety, or of any new defect or impropriety raised by the additional information, in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section. A Part D sponsor may not provide notice of a new deficiency or impropriety in the claim that could have been identified by the sponsor in the original claim submission under this paragraph.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) or contested by the Part D sponsor within the timeframe specified in paragraph (c)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment*—(1) *General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines, a Part D sponsor is not charged interest under paragraph (e)(1) in exigent circumstances that prevent the timely processing of claims, including natural disasters and other unique and unexpected events.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants*—(1) *General.* Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

[73 FR 54252, Sept. 18, 2008, as amended at 76 FR 54634, Sept. 1, 2011]

§ 423.521 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the Part D sponsor a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount for the contract that has been consolidated,

nonrenewed, or terminated, which may be one of the following:

- (i) An amount due to the Part D sponsor.
- (ii) An amount due from the Part D sponsor.
- (iii) \$0 if nothing is due to or from the Part D sponsor.

(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 423.522.

(b) *Request for an appeal.* A Part D sponsor that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 423.522.

(1) If a Part D sponsor agrees with the final settlement amount, no response is required.

(2) If a Part D sponsor disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.

(c) *Actions if a Part D sponsor does not request an appeal.* (1) For Part D sponsors that are owed money by CMS, CMS remits payment to the Part D sponsor within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For Part D sponsors that owe CMS money, the Part D sponsor is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS

conducts a review process under the process described at § 423.522.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 423.521(a), is issued to the Part D sponsor, CMS—

(1) No longer applies retroactive payment adjustments to the terminated, consolidated or nonrenewed contract; and

(2) There are no adjustments applied to amounts used in the calculation of the final settlement amount.

[89 FR 30838, Apr. 23, 2024]

§ 423.522 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If a Part D sponsor does not agree with the final settlement amount described in § 423.521(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the final settlement amount described in § 423.521(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date that CMS issued the notice of final settlement to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the Part D sponsor disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional 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 in writing.

(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 (a)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS's reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS's 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 is conducted in accordance with the following:

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

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(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 CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review.

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

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews 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.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS's calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The Part D sponsor bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If a Part D sponsor requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the Part D sponsor fails to request further review within the