

§ 423.1968

binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.1088.

[72 FR 68726, Dec. 5, 2007, as amended at 85 FR 72909, Nov. 16, 2020]

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

[82 FR 5125, Jan. 17, 2017]

§§ 423.1970–423.1976 [Reserved]

§ 423.1978 Reopening determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or attorney adjudicator or the Council that is otherwise binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

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(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(3) Consistent with § 423.1978(b), the filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

(5) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for drug claims that were already reimbursed

by the Part D plan sponsor is not a re-opening.

(b) *Timeframes and requirements for re-opening coverage determinations and redeterminations initiated by a Part D plan sponsor.* A Part D plan sponsor may reopen its coverage determination or redetermination on its own motion:

(1) Within 1 year from the date of the coverage determination or redetermination for any reason.

(2) Within 4 years from the date of the coverage determination or redetermination for good cause as defined in § 423.1986.

(3) At any time if there exists reliable evidence as defined in § 405.902 of this chapter that the coverage determination was procured by fraud or similar fault as defined in § 405.902.

(c) *Timeframe and requirements for re-opening coverage determinations and redeterminations requested by an enrollee.*

(1) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

(2) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with § 423.1986.

(d) *Time frame and requirements for re-opening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.* (1) An IRE may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with § 423.1986. If the IRE's reconsideration was procured by fraud or similar fault, then the IRE may reopen at any time.

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or

attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for re-opening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.* (1) An enrollee who received a reconsideration or a Part D plan sponsor may request that an IRE reopen its reconsideration decision within 180 calendar days from the date of the reconsideration for good cause in accordance with § 423.1986.

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1982 Notice of a revised determination or decision.

(a) *When adjudicators initiate re-openings.* When any determination or decision is reopened and revised as provided in § 423.1980:

(1) The Part D plan sponsor, IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.