

other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 423.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with 423.1092.

(b) *Right to judicial review.* Section 423.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty.* Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-calendar day period for seeking judicial review.

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect—(1) ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is 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.

(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.