

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(b) [Reserved]

§ 423.1002 Definitions.

As used in this subpart—

Affected party means any Part D sponsor impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part, and “*party*” means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in 423.4.

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in 423.1004, has a right to a hearing before an ALJ in accordance with this subpart

and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 423.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 423.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with 423.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 423.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with 423.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.