

entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the District Court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are non-public investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

§ 160.506 Basis for penalty.

The Secretary shall impose a penalty on a person who is a covered entity and who the Secretary determines in accordance with this subpart has violated a provision of—

(a) 42 U.S.C. 1320d-1320d-8, as amended;

(b) Section 264 of Pub. L. 104-191 (42 U.S.C. 1320d-2(note)); or (c) Parts 160, 162 or 164 of this subchapter.

§ 160.508 Amount of penalty.

The penalty imposed under §160.506 must be in accordance with 42 U.S.C. 1320d-5 and the applicable provisions of this part.

§ 160.510 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.512 [Reserved]

§ 160.514 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the act(s) or omission(s) with respect to which the penalty is proposed;

(3) The reason(s) why the act(s) or omission(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty;

(5) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty without the right to a hearing under §160.554 or a right of appeal under §160.568, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request therefor in accordance with §160.526 of this subpart.

§ 160.516 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §160.526, the Secretary must impose the proposed penalty or any less severe penalty permitted by 42 U.S.C. 1320d-5.

§ 160.518

The Secretary must notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty. The respondent has no right to appeal under § 160.568 with respect to a penalty with respect to which the respondent has not timely requested a hearing.

§ 160.518 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty must be collected by the Secretary.

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under 42 U.S.C. 1320a-7a(e) may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 160.520 [Reserved]

§ 160.522 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.514 of this subpart, within 6 years from the date on which the latest act or omission that is the subject of the action occurred.

§ 160.524 [Reserved]

§ 160.526 Hearing before an ALJ.

(a) The respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

- (1) The respondent; and
- (2) The Secretary.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination.

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The request for a hearing must be mailed within 60 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.

(d) The ALJ must dismiss a hearing request where—

- (1) The respondent's hearing request is not filed as required by paragraphs (b) and (c) of this section;
- (2) The respondent withdraws the request for a hearing;
- (3) The respondent abandons the request for a hearing; or
- (4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§ 160.528 Rights of parties.

(a) Except as otherwise limited by this part, each party may—

- (1) Be accompanied, represented, and advised by an attorney;
- (2) Participate in any conference held by the ALJ;
- (3) Conduct discovery of documents as permitted by this subpart;
- (4) Agree to stipulations of fact or law that will be made part of the record;
- (5) Present evidence relevant to the issues at the hearing;
- (6) Present and cross-examine witnesses;
- (7) Present oral arguments at the hearing as permitted by the ALJ; and
- (8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.