

§ 160.312

with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution where noncompliance is indicated.* (1) If an investigation pursuant to §160.306 or a compliance review pursuant to §160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) *Resolution when no violation is found.* If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

Subpart E—Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings

SOURCE: 68 FR 18902, Apr. 17, 2003, unless otherwise noted.

EFFECTIVE DATE NOTE: At 68 FR 18902, Apr. 17, 2003, and corrected at 68 FR 22453, Apr. 28, 2003, subpart E was added, effective May 19, 2003, to Sept. 16, 2004. At 69 FR 55515, Sept. 15, 2004, the expiration date was extended from Sept. 16, 2004, to Sept. 16, 2005.

§ 160.500 Applicability.

This subpart applies to investigations conducted, penalties imposed, hearings conducted, and subpoenas

45 CFR Subtitle A (10–1–04 Edition)

issued, under the authority of 42 U.S.C. 1320d-5, relating to the imposition of civil money penalties.

§ 160.502 Definitions.

For the purposes of this subpart:

ALJ means Administrative Law Judge.

Entity means a legal person.

Penalty means the amount calculated under 42 U.S.C. 1320d-5, as determined in accordance with this part, and includes the plural of that term.

Person means a natural or legal person.

Respondent means the person upon whom the Secretary has imposed, or proposes to impose, a penalty.

§ 160.504 Investigational subpoenas and inquiries.

(a) The provisions of this paragraph govern subpoenas issued by the Secretary in accordance with 42 U.S.C. 405(d) and (e), 1320a-7a(j), and 1320d-5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation pursuant to this part.

(1) A subpoena issued under this paragraph must—

(i) State the name of the person to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the named entity must designate one or more natural persons who will testify on its behalf, and must state as to each person so designated that person's name and address and the matters on which he or she will testify. The person so designated must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the

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.