

## § 160.306

of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

### § 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity is not complying with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.

### § 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying 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.

## 45 CFR Subtitle A (10–1–03 Edition)

### § 160.310 Responsibilities of covered entities.

(a) *Provide records and compliance reports.* A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying 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.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements of this part 160 and the standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(c) *Permit access to information.* (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining 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. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection

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, consisting of §§160.500 through 160.572, was added, effective May 19, 2003 to Sept. 16, 2004.

**§ 160.500 Applicability.**

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