

## § 160.308

(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.* (1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.

(2) The Secretary may investigate any other complaint filed under this section.

(3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.

(4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

[71 FR 8424, Feb. 16, 2006, as amended at 78 FR 5690, Jan. 25, 2013]

### § 160.308 Compliance reviews.

(a) The Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect.

(b) The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance.

[78 FR 5690, Jan. 25, 2013]

### § 160.310 Responsibilities of covered entities and business associates.

(a) *Provide records and compliance reports.* A covered entity or business associate 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 or business associate has complied or is complying

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with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity or business associate must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity or business associate to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity or business associate 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 administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity or business associate must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity or business associate 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 or business associate 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 administrative simplification provisions, if otherwise required by law, or if permitted under 5 U.S.C. 552a(b)(7).

[78 FR 5690, Jan. 25, 2013]

### § 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to §160.306 or a compliance review pursuant to §160.308

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indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity or business associate and provide the covered entity or business associate an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§160.408 and 160.410 of this part. The covered entity or business associate must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under §160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity or business associate of such finding in a notice of proposed determination in accordance with §160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to §160.306 or a compliance review pursuant to §160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

[78 FR 5690, Jan. 25, 2013]

### § 160.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas 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 or compliance review pursuant to this part. For purposes of this paragraph, a

person other than a natural person is termed an “entity.”

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) 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 entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person 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.