

Dept. of Health and Human Services

§ 160.314

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.

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(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) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) 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.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of

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its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

(c) Consistent with §160.310(c)(3), testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 160.316 Refraining from intimidation or retaliation.

A covered entity or business associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

(a) Filing of a complaint under §160.306;

(b) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under this part; or

(c) Opposing any act or practice made unlawful by this subchapter, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of protected health information in violation of subpart E of part 164 of this subchapter.

[71 FR 8424, Feb. 16, 2006, as amended at 78 FR 5691, Jan. 25, 2013]