



**HIPAA Enforcement
NPRM**

**HIPAA SUMMIT XI
September, 2005**

Susan A. Miller, JD

COO, CPO HealthTransactions.com

Eye on HIPAA Enforcement



Subpart C – Compliance and Investigations

Section

- 160.300 Applicability
- 160.302 Definitions
- 160.304 Principles for achieving compliance
- 160.306 Complaints to the Secretary
- 160.308 Compliance reviews
- 160.310 Responsibilities of covered entities.
- 160.312 Secretarial action regarding complaints and compliance reviews
- 160.314 Investigational subpoenas and inquiries
- 160.316 Refraining from intimidation or retaliation

Subpart D – Procedures for Hearings

Section

- 160.400 Applicability
- 160.402 Basis for a civil money penalty
- 160.404 Amount of a civil money penalty
- 160.406 Number of violations
- 160.408 Factors considered in determining the amount of a civil money penalty
- 160.410 Affirmative defenses
- 160.412 Waiver
- 160.414 Limitations
- 160.416 Authority to settle
- 160.418 Penalty not exclusive
- 160.420 Notice of proposed determination
- 160.422 Failure to request a hearing
- 160.424 Collection of penalty
- 160.426 Notification of the public and other agencies

Subpart E – Procedures for Hearings

Section

160.500 Applicability
160.502 Definitions
160.504 Hearing before an ALJ
160.506 Rights of the parties
160.508 Authority of the ALJ
160.510 Ex parte contacts
160.512 Prehearing conferences
160.514 Authority to settle
160.516 Discovery
160.518 Exchange of witness lists, witness statements, and exhibits
160.520 Subpoenas for attendance at hearing
160.522 Fees
160.524 Form, filing, and service of papers

Section

160.526 Computation of time
160.528 Motions
160.530 Sanctions
160.532 Collateral estoppel
160.534 The hearing
160.536 Statistical sampling
160.538 Witnesses
160.540 Evidence
160.542 The record
160.544 Post hearing briefs
160.546 ALJ decision
160.548 Appeal of the ALJ decision
160.550 Stay of the Secretary's decision
160.552 Harmless error

160.300 Applicability

- **Subpart C** applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with, ***and the enforcement of,***
 - the applicable requirements of part 160 and
 - the applicable standards, requirements, and implementation specifications of parts 162 and 164 of this subchapter

160.302 Definitions

As used in this subparts C, D and E, the following terms have the following meanings:

- **Administrative simplification provision** means any requirement or prohibition established by:
 - (1) 42 U.S.C. 1320d–1320d–4, 1320d–7, and 1320d–8;
 - (2) Section 264 of Pub. L. 104–191; or
 - (3) This subchapter
- **ALJ** means Administrative Law Judge
- **Civil money penalty or penalty** means the amount determined under § 160.404 of this part and includes the plural of these terms
- **Respondent** means a covered entity upon which the Secretary has imposed, or proposes to impose, a civil money penalty
- **Violation or violate** means, as the context may require, failure to comply with an administrative simplification provision

160.304 Principles for Achieving Compliance

- (a) **Cooperation:** The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable *administrative simplification provisions*
- (b) **Assistance:** The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable *administrative simplification provisions*

160.306 Complaints to the Secretary

(a) ***Right to file a complaint:*** A person who believes a covered entity is not complying with the *administrative simplification provisions* may file a complaint with the Secretary

160.306 Complaints to 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 person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s)*
 - (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***

160.306 Complaints to the Secretary

(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 violation

160.308 Compliance Reviews

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable *administrative simplification provisions*

160.310 Responsibilities of Covered Entities

- (a) **Provide records and compliance reports:** A covered entity must keep records and submit compliance reports, in time and manner and containing 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 *administrative simplification provisions*
- (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 the covered entity to determine whether it is complying with the applicable *administrative simplification provisions*

160.310 Responsibilities of Covered Entities

(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 administrative simplification provisions

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

160.310 Responsibilities of Covered Entities

(c) *Permit access to information:*

(2) If any information required of a covered entity 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 will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, or if otherwise required by law

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 indicates noncompliance, the Secretary will 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 inform the covered entity and, if the matter arose from a complaint, the complainant, in writing

160.312 Secretarial Action Regarding Complaints and Compliance Reviews

(a) Resolution when noncompliance is indicated:

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

- (i) Inform the covered entity and provide the covered entity an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410

The covered entity must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526) 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 of such finding in a notice of proposed determination in accordance with § 160.420

160.312 Secretarial Action Regarding Complaints and Compliance Reviews

(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 inform the covered entity and, if the matter arose from a complaint, the complainant, in writing

160.314 Investigational Subpoenas and Inquires

- (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 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*

160.314 Investigational Subpoenas and Inquires

- (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

160.314 Investigational Subpoenas and Inquires

- (b) Investigational inquiries are nonpublic 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

160.314 Investigational Subpoenas and Inquires

(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

160.314 Investigational Subpoenas and Inquires

- (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 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

160.314 Investigational Subpoenas and Inquires

(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 may not threaten, intimidate, coerce, 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

BE REASONABLE!



Questions?

- Susan.Miller@HealthTransactions.com
- TMSAM@aol.com

– (978) 369-2092

THANK YOU!

