

## SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

### PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

#### Subpart A—General Provisions

Sec.

- 160.101 Statutory basis and purpose.
- 160.102 Applicability.
- 160.103 Definitions.
- 160.104 Modifications.

#### Subpart B—Preemption of State Law

- 160.201 Applicability.
- 160.202 Definitions.
- 160.203 General rule and exceptions.
- 160.204 Process for requesting exception determinations.
- 160.205 Duration of effectiveness of exception determinations.

#### Subpart C—Compliance and Investigations

- 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—Imposition of Civil Money Penalties

- 160.400 Applicability.
- 160.401 Definitions.
- 160.402 Basis for a civil money penalty.
- 160.404 Amount of a civil money penalty.
- 160.406 Violations of an identical requirement or prohibition.
- 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

- 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.
- 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's decision.
- 160.548 Appeal of the ALJ's decision.
- 160.550 Stay of the Secretary's decision.
- 160.552 Harmless error.

AUTHORITY: 42 U.S.C. 1302(a), 42 U.S.C. 1320d-1320d-8, sec. 264 of Public Law 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)), 5 U.S.C. 552; and secs.13400 and 13402, Public Law 111-5, 123 Stat. 258-263.

SOURCE: 65 FR 82798, Dec. 28, 2000, unless otherwise noted.

#### Subpart A—General Provisions

##### § 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104-191, section 264 of Public Law 104-191, section 13402 of Public Law 111-5, and section 13410(d) of Public Law 111-5.

[ 74 FR 56130, Oct. 30, 2009]

##### § 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

#### § 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

*Act* means the Social Security Act.

*ANSI* stands for the American National Standards Institute.

*Business associate*: (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in §164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and re-pricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information

from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

*CMS* stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

*Compliance date* means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

*Covered entity* means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

*Disclosure* means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

*EIN* stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing