

### Subpart D—Imposition of Civil Money Penalties

SOURCE: 71 FR 8426, Feb. 16, 2006, unless otherwise noted.

#### § 160.400 Applicability.

This subpart applies to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d-5.

#### § 160.401 Definitions.

As used in this subpart, the following terms have the following meanings:

*Reasonable cause* means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

*Reasonable diligence* means the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.

*Willful neglect* means conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

[74 FR 56130, Oct. 30, 2009, as amended at 78 FR 5691, Jan. 25, 2013]

#### § 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision.

(b) *Violation by more than one covered entity or business associate.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable

for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity or business associate.* (1) A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.

(2) A business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

[78 FR 5691, Jan. 25, 2013]

#### § 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section, and §§ 160.406, 160.408, and 160.412. These amounts were adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, (section 701 of Pub. L. 114-74), and appear at 45 CFR part 102. These amounts will be updated annually and published at 45 CFR part 102.

(b) The amount of a civil money penalty that may be imposed is subject to the following limitations:

(1) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty—

(i) In the amount of more than \$100 for each violation; or

(ii) In excess of \$25,000 for identical violations during a calendar year (January 1 through the following December 31);

(2) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty—

## § 160.406

(i) For a violation in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision,

(A) In the amount of less than \$100 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(ii) For a violation in which it is established that the violation was due to reasonable cause and not to willful neglect,

(A) In the amount of less than \$1,000 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than \$10,000 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31).

(3) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative sim-

## 45 CFR Subtitle A (10–1–23 Edition)

plification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56130, Oct. 30, 2009; 78 FR 5691, Jan. 25, 2013; 81 FR 61581, Sept. 6, 2016]

### § 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity or business associate is in violation of the provision.

[78 FR 5691, Jan. 25, 2013]

### § 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate:

(a) The nature and extent of the violation, consideration of which may include but is not limited to:

(1) The number of individuals affected; and

(2) The time period during which the violation occurred;

(b) The nature and extent of the harm resulting from the violation, consideration of which may include but is not limited to:

(1) Whether the violation caused physical harm;

(2) Whether the violation resulted in financial harm;

(3) Whether the violation resulted in harm to an individual's reputation; and

(4) Whether the violation hindered an individual's ability to obtain health care;

(c) The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity or business associate,