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(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-

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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,

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consideration of which may include but is not limited to:

(1) Whether the current violation is the same or similar to previous indications of noncompliance;

(2) Whether and to what extent the covered entity or business associate has attempted to correct previous indications of noncompliance;

(3) How the covered entity or business associate has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity or business associate has responded to prior complaints;

(d) The financial condition of the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the covered entity or business associate had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity or business associate to continue to provide, or to pay for, health care; and

(3) The size of the covered entity or business associate; and

(e) Such other matters as justice may require.

[78 FR 5691, Jan. 25, 2013]

§ 160.410 Affirmative defenses.

(a) The Secretary may not:

(1) Prior to February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that the violation is punishable under 42 U.S.C. 1320d-6.

(2) On or after February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that a penalty has been imposed under 42 U.S.C. 1320d-6 with respect to such act.

(b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the

covered entity establishes that an affirmative defense exists with respect to the violation, including the following:

(1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or

(2) The violation is—

(i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(c) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity or business associate for a violation if the covered entity or business associate establishes to the satisfaction of the Secretary that the violation is—

(1) Not due to willful neglect; and

(2) Corrected during either:

(i) 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; or

(ii) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[78 FR 5692, Jan. 25, 2013]

§ 160.412 Waiver.

For violations described in § 160.410(b)(2) or (c) that are not corrected within the period specified under such paragraphs, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the