

§ 160.316 Refraining from intimidation or retaliation.

A covered entity 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.

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.

§ 160.402 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 if the Secretary determines that the covered entity has violated an administrative simplification provision.

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

(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 es-

tablished that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity.* 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, acting within the scope of the agency, unless—

(1) The agent is a business associate of the covered entity;

(2) The covered entity has complied, with respect to such business associate, with the applicable requirements of §§ 164.308(b) and 164.502(e) of this subchapter; and

(3) The covered entity did not—

(i) Know of a pattern of activity or practice of the business associate, and

(ii) Fail to act as required by §§ 164.314(a)(1)(ii) and 164.504(e)(1)(ii) of this subchapter, as applicable.

§ 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.

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

(1) 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) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on

§ 160.408

the nature of the covered entity'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 is in violation of the provision.

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

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

(a) The nature of the violation, in light of the purpose of the rule violated.

(b) The circumstances, including the consequences, of the violation, including but not limited to:

(1) The time period during which the violation(s) occurred;

(2) Whether the violation caused physical harm;

(3) Whether the violation hindered or facilitated an individual's ability to obtain health care; and

(4) Whether the violation resulted in financial harm.

(c) The degree of culpability of the covered entity, including but not limited to:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the covered entity.

(d) Any history of prior compliance with the administrative simplification provisions, including violations, by the covered entity, including but not limited to:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the covered entity has attempted to correct previous violations;

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

(4) How the covered entity has responded to prior complaints.

45 CFR Subtitle A (10-1-06 Edition)

(e) The financial condition of the covered entity, including but not limited to:

(1) Whether the covered entity 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 to continue to provide, or to pay for, health care; and

(3) The size of the covered entity.

(f) Such other matters as justice may require.

§ 160.410 Affirmative defenses.

(a) As used in this section, the following terms have the following meanings:

Reasonable cause means 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.

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.

(b) 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 violation is an act punishable under 42 U.S.C. 1320d-6;

(2) 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

(3) The violation is—

(i) Due to reasonable cause and not willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the date the covered entity liable for