

§ 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.

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(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