

§ 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

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.

§ 160.412 Waiver.

For violations described in § 160.410(b)(3)(i) that are not corrected within the period described in § 160.410(b)(3)(ii), the Secretary may waive the civil money penalty, in whole or in part, to the extent that payment of the penalty would be excessive relative to the violation.

§ 160.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.420, within 6 years from the date of the occurrence of the violation.

§ 160.416 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d-5(b)(1), a penalty imposed under this part is in addition to any other penalty prescribed by law.

§ 160.420 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

- (1) Reference to the statutory basis for the penalty;
- (2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed (except that, in any case where the Secretary is relying upon a statistical sampling study in accordance with § 160.536 of this part, the notice must provide a copy of the study relied upon by the Secretary);

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty;

(5) Any circumstances described in § 160.408 that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 90 days permits the imposition of the proposed penalty without the right to a hearing under § 160.504 or a right of appeal under § 160.548 of this part, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with § 160.504 of this part.

§ 160.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 160.504 of this part and the matter is not settled pursuant to § 160.416, the Secretary will impose the proposed penalty or any lesser penalty permitted by 42 U.S.C. 1320d-5. The Secretary will notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under § 160.548 of this part with respect to which the respondent has not timely requested a hearing.

§ 160.424 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary, subject to the first sentence of 42 U.S.C. 1320a-7a(f).

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later