

**Dept. of Health and Human Services**

**§ 160.424**

payment of the penalty would be excessive relative to the violation.

[8 FR 5692, Jan. 25, 2013]

**§ 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) and 42 U.S.C. 299b-22(f)(3), a penalty imposed under this part is in addition to any other penalty prescribed by law.

[78 FR 5692, Jan. 25, 2013]

**§ 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 and a reference to the subparagraph of §160.404 upon which it is based.

(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 state-

ment 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.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56131, Oct. 30, 2009]

**§ 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 owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ, or in an appeal under 42 U.S.C. 1320a-7a(e), may not be raised as a defense in a civil action by the United States to collect a penalty under this part.