AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

§ 3.420 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;

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

(4) The amount of the proposed penalty;

(5) Any factors described in § 3.408 of this subpart 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 60 days permits the imposition of the proposed penalty without the right to a hearing under § 3.504 of this subpart or a right of appeal under § 3.548 of this subpart, 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 § 3.504 of this subpart.

§ 3.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 3.504 of this subpart and the matter is not settled pursuant to § 3.416 of this subpart, the Secretary may impose the proposed penalty or any lesser penalty permitted by sections 921 through 926 of the Public Health Service Act, 42 U.S.C. 299b–21 through 299b–26. 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 § 3.548 of this subpart with respect to which the respondent has not timely requested a hearing.

§ 3.424 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.

§ 3.426 Notification of the public and other agencies.

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: The appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1320a–7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).

§ 3.504 Hearings before an ALJ.

(a) A respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

(1) The respondent; and

(2) The officer(s) or employee(s) of HHS to whom the enforcement authority involved has been delegated.