§ 160.426

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.

§ 160.426 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)).

Subpart E—Procedures for Hearings

Source: 71 FR 8428, Feb. 16, 2006, unless otherwise noted.

§ 160.500 Applicability.

This subpart applies to hearings conducted relating to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d-5.

§ 160.502 Definitions.

As used in this subpart, the following term has the following meaning:

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, who issue decisions in panels of three.

§ 160.504 Hearing 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.

- (b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 90 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.
- (c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states. the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty, except that a respondent may raise an affirmative defense under §160.410(b)(1) at any time.
- (d) The ALJ must dismiss a hearing request where—
- (1) On motion of the Secretary, the ALJ determines that the respondent's hearing request is not timely filed as required by paragraphs (b) or does not meet the requirements of paragraph (c) of this section;
- (2) The respondent withdraws the request for a hearing;
- (3) The respondent abandons the request for a hearing; or
- (4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§ 160.506 Rights of the parties.

- (a) Except as otherwise limited by this subpart, each party may—
- (1) Be accompanied, represented, and advised by an attorney;
- (2) Participate in any conference held by the ALJ;

- (3) Conduct discovery of documents as permitted by this subpart;
- (4) Agree to stipulations of fact or law that will be made part of the record:
- (5) Present evidence relevant to the issues at the hearing:
- (6) Present and cross-examine witnesses;
- (7) Present oral arguments at the hearing as permitted by the ALJ; and
- (8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.
- (b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.
- (c) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of 42 U.S.C. 406, which authorizes the Secretary to specify or limit their fees.

§ 160.508 Authority of the ALJ.

- (a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.
 - (b) The ALJ may—
- (1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;
- (2) Continue or recess the hearing in whole or in part for a reasonable period of time:
- (3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
- (4) Administer oaths and affirmations;
- (5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;
- (6) Rule on motions and other procedural matters;
- (7) Regulate the scope and timing of documentary discovery as permitted by this subpart;
- (8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;
 - (9) Examine witnesses;

- (10) Receive, rule on, exclude, or limit evidence:
- (11) Upon motion of a party, take official notice of facts;
- (12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and
- (13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.
 - (c) The ALJ-
- (1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must give deference to published guidance to the extent not inconsistent with statute or regulation;
- (2) May not enter an order in the nature of a directed verdict;
- (3) May not compel settlement negotiations;
- (4) May not enjoin any act of the Secretary; or
- (5) May not review the exercise of discretion by the Secretary with respect to whether to grant an extension under §160.410(b)(3)(ii)(B) of this part or to provide technical assistance under 42 U.S.C. 1320d-5(b)(3)(B).

§ 160.510 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 160.512 Prehearing conferences.

- (a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice, which may not be less than 14 business days, to the parties.
- (b) The ALJ may use prehearing conferences to discuss the following—
- (1) Simplification of the issues;