

Dept. of Health and Human Services

§ 160.530

§ 160.524 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Board must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

§ 160.526 Computation of time.

(a) In computing any period of time under this subpart or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This

paragraph does not apply to requests for hearing under § 160.504.

§ 160.528 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

§ 160.530 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs

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caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

§ 160.532 Collateral estoppel.

When a final determination that the respondent violated an administrative simplification provision has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

§ 160.534 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b) (1) The respondent has the burden of going forward and the burden of persuasion with respect to any:

(i) Affirmative defense pursuant to § 160.410 of this part;

(ii) Challenge to the amount of a proposed penalty pursuant to §§ 160.404–160.408 of this part, including any factors raised as mitigating factors; or

(iii) Claim that a proposed penalty should be reduced or waived pursuant to § 160.412 of this part; and

(iv) Compliance with subpart D of part 164, as provided under § 164.414(b).

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability other than with respect to subpart D of part 164, and the existence of any factors considered aggravating factors in determining the amount of the proposed penalty.

(3) The burden of persuasion will be judged by a preponderance of the evidence.

(c) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.

(d)(1) Subject to the 15-day rule under § 160.518(a) and the admissibility of evidence under § 160.540, either party may introduce, during its case in chief, items or information that arose or became known after the date of the issuance of the notice of proposed determination or the request for hearing, as applicable. Such items and informa-

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tion may not be admitted into evidence, if introduced—

(i) By the Secretary, unless they are material and relevant to the acts or omissions with respect to which the penalty is proposed in the notice of proposed determination pursuant to § 160.420 of this part, including circumstances that may increase penalties; or

(ii) By the respondent, unless they are material and relevant to an admission, denial or explanation of a finding of fact in the notice of proposed determination under § 160.420 of this part, or to a specific circumstance or argument expressly stated in the request for hearing under § 160.504, including circumstances that may reduce penalties.

(2) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 160.518.

[71 FR 8428, Feb. 16, 2006, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5692, Jan. 25, 2013]

§ 160.536 Statistical sampling.

(a) In meeting the burden of proof set forth in § 160.534, the Secretary may introduce the results of a statistical sampling study as evidence of the number of violations under § 160.406 of this part, or the factors considered in determining the amount of the civil money penalty under § 160.408 of this part. Such statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitutes prima facie evidence of the number of violations and the existence of factors material to the proposed civil money penalty as described in §§ 160.406 and 160.408.

(b) Once the Secretary has made a prima facie case, as described in paragraph (a) of this section, the burden of going forward shifts to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Secretary will then be given the opportunity to rebut this evidence.

§ 160.538 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.