

§ 1005.21

granted under § 1005.21(a), except as provided in § 1005.22(a), the initial decision will become final and binding on the day following the end of the extension period.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.21 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB or to appeal to the DAB any interlocutory ruling by the ALJ, except on the timeliness of a filing of the hearing request.

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty, assessment or exclusion determined by the ALJ.

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(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k) (1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the Chief Counsel to the IG. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Chief Counsel to the IG receives two or more petitions within 10 days after the DAB issues its decision, the Chief Counsel to the IG will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

[57 FR 3350, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 65 FR 24419, Apr. 26, 2000]

§ 1005.22 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Quality Improvement Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 1006—INVESTIGATIONAL INQUIRIES

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AUTHORITY: 42 U.S.C. 405(d), 405(e), 1302 and 1320a-7a.

SOURCE: 57 FR 3354, Jan. 29, 1992, unless otherwise noted.

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector Gen-

eral, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. 6(a)(4), App. 3.

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual's name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.