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repayment for conditional or mistaken Medicare primary payments.

(b) Lack of acceptable documentation. If a GHP or LGHP fails to provide acceptable evidence or documentation that it has complied with the MSP prohibitions and requirements set forth in §411.110, CMS may make a determination of nonconformance for both the year in which the services were furnished and the year in which the request for information was made.

§411.114 Determination of nonconformance.

(a) Starting dates for determination of nonconformance. CMS's authority to determine nonconformance of GHPs begins on the following dates:

(1) On January 1, 1987 for MSP provisions that affect the disabled.

(2) On December 20, 1989 for MSP provisions that affect ESRD beneficiaries and the working aged.

(3) On August 10, 1993 for failure to refund mistaken Medicare primary payments.

(b) Special rule for failure to repay. A GHP that fails to comply with §411.110 (a)(1), (a)(2), or (a)(3) in a particular year is nonconforming for that year. If, in a subsequent year, that plan fails to repay the resulting mistaken primary payments (in accordance with §411.110(a)(4)), the plan is also nonconforming for the subsequent year. For example, if a plan paid secondary for the working aged in 1991, that plan was nonconforming for 1991. If in 1994 CMS identifies mistaken primary payments attributable to the 1991 violation, and the plan refuses to repay, it is also nonconforming for 1994.

§411.115 Notice of determination of nonconformance.

(a) Notice to the GHP or LGHP. (1) If CMS determines that a GHP or an LGHP is nonconforming with respect to a particular calendar year, CMS mails to the plan written notice of the following:

(i) The determination.

(ii) The basis for the determination.

(iii) The right of the parties to request a hearing.

(iv) An explanation of the procedure for requesting a hearing.

(v) The tax that may be assessed by the IRS in accordance with section 5000 of the IRC.

(vi) The fact that if none of the parties requests a hearing within 65 days from the date of its notice, the determination is binding on all parties unless it is reopened in accordance with §411.126.

(2) The notice also states that the plan must, within 30 days from the date on its notice, submit to CMS the names and addresses of all employers and employee organizations that contributed to the plan during the calendar year for which CMS has determined nonconformance.

(b) Notice to contributing employers and employee organizations. CMS mails written notice of the determination, including all the information specified in paragraph (a)(1) of this section, to all contributing employers and employee organizations already known to CMS or identified by the plan in accordance with paragraph (a)(2) of this section. Employers and employee organizations have 65 days from the date of their notice to request a hearing.

§411.120 Appeals.

(a) Parties to the determination. The parties to the determination are CMS, the GHP or LGHP for which CMS determined nonconformance, and any employers or employee organizations that contributed to the plan during the calendar year for which CMS determined nonconformance.

(b) Request for hearing. (1) A party's request for hearing must be in writing (not in facsimile or other electronic medium) and in the manner stipulated in the notice of nonconformance; it must be filed within 65 days from the date on the notice.

(2) The request may include rationale showing why the parties believe that CMS's determination is incorrect and supporting documentation.

(3) A request is considered filed on the date it is received by the appropriate office, as shown by the receipt date stamped on the request.

§411.121 Hearing procedures.

(a) *Nature of hearing*. (1) If any of the parties requests a hearing within 65 days from the date on the notice of the

determination of nonconformance, the CMS Administrator appoints a hearing officer.

(2) If no party files a request within the 65-day period, the initial determination of nonconformance is binding upon all parties unless it is reopened in accordance with §411.126.

(3) If more than one party requests a hearing the hearing officer conducts a single hearing in which all parties may participate.

(4) On the record review. Ordinarily, the hearing officer makes a decision based upon review of the data and documents on which CMS based its determination of nonconformance and any other documentation submitted by any of the parties within 65 days from the date on the notice.

(5) Oral hearing. The hearing officer may provide for an oral hearing either on his or her own motion or in response to a party's request if the party demonstrates to the hearing officer's satisfaction that an oral hearing is necessary. Within 30 days of receipt of the request, the hearing officer gives all known parties written notice of the request and whether the request for oral hearing is granted.

(b) Notice of time and place of oral hearing. If the hearing officer provides an oral hearing, he or she gives all known parties written notice of the time and place of the hearing at least 30 days before the scheduled date.

(c) *Prehearing discovery*. (1) The hearing officer may permit prehearing discovery if it is requested by a party at least 10 days before the scheduled date of the hearing.

(2) If the hearing officer approves the request, he or she—

(i) Provides a reasonable time for inspection and reproduction of documents; and

(ii) In ruling on discovery matters, is guided by the Federal Rules of Civil Procedure. (28 U.S.C.A. Rules 26–37)

(3) The hearing officer's orders on all discovery matters are final.

(d) *Conduct of hearing*. The hearing officer determines the conduct of the hearing, including the order in which the evidence and the allegations are presented.

(e) Evidence at hearing. (1) The hearing officer inquires into the matters at 42 CFR Ch. IV (10-1-02 Edition)

issue and may receive from all parties documentary and other evidence that is pertinent and material, including the testimony of witnesses, and evidence that would be inadmissible in a court of law.

(2) Evidence may be received at any time before the conclusion of the hearing.

(3) The hearing officer gives the parties opportunity for submission and consideration of evidence and arguments and, in ruling on the admissibility of evidence, excludes irrelevant, immaterial, or unduly repetitious evidence.

(4) The hearing officer's ruling on admissibility of evidence is final and not subject to further review.

(f) *Subpoenas*. (1) The hearing officer may, either on his or her own motion or upon the request of any party, issue subpoenas for either or both of the following if they are reasonably necessary for full presentation of the case:

(i) The attendance and testimony of witnesses.

(ii) The production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(2) A party that wishes the issuance of a subpoena must, at least 10 days before the date fixed for the hearing, file with the hearing officer a written request that identifies the witnesses or documents to be produced and describes the address or location in sufficient detail to permit the witnesses or documents to be found.

(3) The request for a subpoena must state the pertinent facts that the party expects to establish by the witnesses or documents and whether those facts could be established by other evidence without the use of a subpoena.

(4) The hearing officer issues the subpoenas at his or her discretion, and CMS assumes the cost of the issuance and the fees and mileage of any subpoenaed witness, in accordance with section 205(d) of the Act (42 U.S.C. 405(d)).

(g) Witnesses. Witnesses at the hearing testify under oath or affirmation, unless excused by the hearing officer for cause. The hearing officer may examine the witnesses and shall allow the parties to examine and cross-examine witnesses.

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(h) *Record of hearing*. A complete record of the proceedings at the hearing is made and transcribed in all cases. It is made available to the parties upon request. The record is not closed until a decision has been issued.

(i) Sources of hearing officer's authority. In the conduct of the hearing, the hearing officer complies with all the provisions of title XVIII of the Act and implementing regulations, as well as with CMS Rulings issued under §401.108 of this chapter. The hearing officer gives great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

§411.122 Hearing officer's decision.

(a) *Timing*. (1) If the decision is based on a review of the record, the hearing officer mails the decision to all known parties within 120 days from the date of receipt of the request for hearing.

(2) If the decision is based on an oral hearing, the hearing officer mails the decision to all known parties within 120 days from the conclusion of the hearing.

(b) Basis, content, and distribution of hearing decision. (1) The written decision is based on substantial evidence and contains findings of fact, a statement of reasons, and conclusions of law.

(2) The hearing officer mails a copy of the decision to each of the parties, by certified mail, return receipt requested, and includes a notice that the administrator may review the hearing decision at the request of a party or on his or her own motion.

(c) Effect of hearing decision. The hearing officer's decision is the final Departmental decision and is binding upon all parties unless the Administrator chooses to review that decision in accordance with §411.124 or it is reopened by the hearing officer in accordance with §411.126.

§411.124 Administrator's review of hearing decision.

(a) *Request for review*. A party's request for review of a hearing officer's decision must be in writing (not in facsimile or other electronic medium) and must be received by the Administrator within 25 days from the date on the decision.

(b) Office of the Attorney Advisor responsibility. The Office of the Attorney Advisor examines the hearing officer's decision, the requests made by any of the parties or CMS, and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to review the decision.

(c) Administrator's discretion. The Administrator may—

(1) Review or decline to review the hearing officer's decision;

(2) Exercise this discretion on his or her own motion or in response to a request from any of the parties; and

(3) Delegate review responsibility to the Deputy Administrator. (As used in this section, the term "Administrator" includes "Deputy Administrator" if review responsibility has been delegated.)

(d) Basis for decision to review. In deciding whether to review a hearing officer's decision, the Administrator considers—

(1) Whether the decision—

(i) Is based on a correct interpretation of law, regulation, or CMS Ruling;(ii) Is supported by substantial evi-

dence;

(iii) Presents a significant policy issue having a basis in law and regulations;

(iv) Requires clarification, amplification, or an alternative legal basis for the decision; and

(v) Is within the authority provided by statute, regulation, or CMS Ruling; and

(2) Whether review may lead to the issuance of a CMS Ruling or other directive needed to clarify a statute or regulation.

(e) Notice of decision to review or not to review. (1) The Administrator gives all parties prompt written notice of his or her decision to review or not to review.

(2) The notice of a decision to review identifies the specific issues the Administrator will consider.

(f) Response to notice of decision to review. (1) Within 20 days from the date on a notice of the Administrator's decision to review a hearing officer's decision, any of the parties may file with