

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) *Special rules: Independent laboratories and suppliers of portable x-ray services.* If CMS determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) *Special rules: Nonparticipating hospitals that elect to claim payment for emergency services.* If CMS determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) *Other special rules.* Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.
Part 416—for ambulatory surgical centers.
Part 489—for providers, when their provider agreements have been terminated.

Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.

Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.

Part 1004—for sanctioned providers and practitioners.

(b) *Effect of initial determination.* An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* CMS reconsiders any initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. (None of the determinations made by the OIG are subject to reconsideration.)

(b) *Request for reconsideration: Manner and timing.* The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With CMS or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) *Content of request.* The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) *Extension of time to file a request for reconsideration.* (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of

§ 498.23

this section, it may file a written request with CMS, stating the reasons why the request was not filed timely.

(2) CMS will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before CMS mails the notice of reconsidered determination, and CMS approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, CMS—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) *Notice.* (1) CMS mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) *Effect.* A reconsidered determination is binding unless—

(1) CMS or the OIG, as appropriate, further revises the revised determination; or

42 CFR Ch. IV (10–1–05 Edition)

(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations

§ 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. CMS or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) *Notice.* (1) CMS or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) *Effect.* A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) CMS or the OIG further revises the revised determination.

Subpart D—Hearings

§ 498.40 Request for hearing.

(a) *Manner and timing of request.* (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with CMS or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of