

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act—

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.

[52 FR 22446, June 12, 1987, as amended at 59 FR 56251, Nov. 10, 1994; 61 FR 32349, June 24, 1996]

§ 498.2 Definitions.

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and “party” means the affected party or CMS (or the OIG), as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or *Board* means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

OIG stands for the Department's Office of the Inspector General.

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), hospice, or religious nonmedical health care institution (RNHCI) that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, reha-

bilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and prospective provider means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

Supplier means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), Federally qualified health center (FQHC), ambulatory surgical center (ASC), organ procurement organization (OPO), an entity approved by CMS to furnish outpatient diabetes self-management training, or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services, and *prospective supplier* means any of the listed entities that seeks to be approved for coverage of its services under Medicare. (However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term *supplier* has the meaning specified in § 1001.2 of this title.)

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, March 1, 1988; 57 FR 24984, June 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 6579, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994; 61 FR 32350, June 24, 1996; 62 FR 46037, Aug. 29, 1997; 65 FR 18549, Apr. 7, 2000; 65 FR 83154, Dec. 29, 2000; 68 FR 66721, Nov. 28, 2003]

§ 498.3 Scope and applicability.

(a) *Scope.* (1) This part sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(2) The determinations listed in this section affect participation in the Medicare program. Many of the procedures of this part also apply to other determinations that do not affect participation in Medicare. Some examples follow:

(i) CMS's determination to terminate an NF's Medicaid provider agreement.

(ii) CMS's determination to cancel the approval of an ICF/MR under section 1910(b) of the Act.

(iii) CMS's determination, under the Clinical Laboratory Improvement Act (CLIA), to impose alternative sanctions or to suspend, limit, or revoke the certificate of a laboratory even though it does not participate in Medicare.

(3) The following parts of this chapter specify the applicability of the provisions of this part 498 to sanctions or remedies imposed on the indicated entities:

(i) Part 431, subpart D—for nursing facilities (NFs).

(ii) Part 488, subpart E (§ 488.330(e))—for SNFs and NFs.

(iii) Part 493, subpart R (§ 493.1844)—for laboratories.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under § 413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under § 413.65 of this chapter.

(3) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(4) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(5) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(6) Whether the services of a supplier continue to meet the conditions for coverage.

(7) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in sub-

part D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(8) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(9) CMS's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(10) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(11) [Reserved]

(12) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or continues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(13) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in § 488.406 of this chapter, except the State monitoring remedy.

(14) The level of noncompliance found by CMS in a SNF or NF but only if a successful challenge on this issue would affect—

(i) The range of civil money penalty amounts that CMS could collect (The scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter); or

(ii) A finding of substandard quality of care that results in the loss of approval for a SNF or NF of its nurse aide training program.

(15) The effective date of a Medicare provider agreement or supplier approval.

(16) The finding of substandard quality of care that leads to the loss by a SNF or NF of the approval of its nurse aide training program.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emer-

gency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF—(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by CMS as to the facility's level of non-compliance; and

(iii) The imposition of State monitoring.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial

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survey of a prospective provider or supplier.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

[52 FR 22446, June 12, 1987, as amended at 52 FR 27765, July 23, 1987; 53 FR 6551, March 1, 1988; 53 FR 6649, March 2, 1988; 54 FR 5373, Feb. 2, 1989; 56 FR 8854, Mar. 1, 1991; 56 FR 48879, Sept. 26, 1991; 57 FR 8204, Mar. 6, 1992; 57 FR 34021, July 31, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56251, Nov. 10, 1994; 60 FR 2330, Jan. 9, 1995; 60 FR 50120, Sept. 28, 1995; 61 FR 32350, June 24, 1996; 62 FR 43937, Aug. 18, 1997; 64 FR 24957, May 10, 1999; 64 FR 39937, July 23, 1999; 64 FR 43295, Aug. 10, 1999; 65 FR 18549, Apr. 7, 2000; 65 FR 62646, Oct. 19, 2000]

§ 498.4 NFs subject to appeals process in part 498.

A NF is considered a provider for purposes of this part when it has in effect an agreement to participate in Medicaid, including an agreement to participate in both Medicaid and Medicare and it is a—

(a) State-operated NF; or

(b) Non State-operated NF that is subject to compliance action as a result of—

(1) A validation survey by CMS; or

(2) CMS's review of the State's survey findings.

[59 FR 56252, Nov. 10, 1994]

§ 498.5 Appeal rights.

(a) *Appeal rights of prospective providers.* (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(b) *Appeal rights of providers.* Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) *Appeal rights of providers and prospective providers.* Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision.

(d) *Appeal rights of prospective suppliers.* (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) *Appeal rights of suppliers.* Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) *Appeal rights of suppliers and prospective suppliers.* (1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) *Appeal rights for certain practitioners.* A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) *Appeal rights for nonparticipating hospitals that furnish emergency services.* A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) *Appeal rights for suspended or excluded practitioners, providers, or suppliers.* (1) Any practitioner, provider, or supplier who has been suspended, or