

Subpart A—General Provisions

§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e)-(f) [Reserved]

(g) Although § 1866(h) of the Act is silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act—

(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 HCFA (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), or hospice, that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation 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.

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), or end-stage renal disease (ESRD) treatment facility that is approved by HCFA 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]

§ 498.3 Scope and applicability.

(a) *Scope.* (1) This part sets forth procedures for reviewing initial determinations that HCFA 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) HCFA's determination to terminate an NF's Medicaid provider agreement.

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

(iii) HCFA'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 HCFA.* HCFA makes initial determinations with respect to the following matters:

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

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

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

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

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

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(7) 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.

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

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

(10) Whether to deny payment under § 409.19 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(11) 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.

(12) 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.

(13) The level of noncompliance found by HCFA 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 HCFA could collect (The