

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which CMS has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing non-waived testing;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Facility administration and quality systems standards.

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

[57 FR 7185, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 60 FR 20051, Apr. 24, 1995; 68 FR 3714, Jan. 24, 2003]

PART 494 [RESERVED]

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 52 FR 22446, June 12, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 498 appear at 61 FR 32349, June 24, 1996.

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 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: