

§ 498.2

42 CFR Ch. IV (10–1–20 Edition)

(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; 73 FR 36462, June 27, 2008]

§ 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, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.

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.

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

Prospective provider means any of the entities specified in the definition of provider under this section that seeks to be approved for coverage of its serv-

ices by Medicare 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.

Prospective supplier means any of the listed entities specified in the definition of supplier in this section that seek to be approved for coverage of its services by Medicare.

Provider means any of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

- (i) Hospital.
- (ii) Transplant center.
- (iii) Critical access hospital (CAH).
- (iv) Skilled nursing facility (SNF).
- (v) Comprehensive outpatient rehabilitation facility (CORF).
- (vi) Home health agency (HHA).
- (vii) Hospice.
- (viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

- (i) Clinic.
 - (ii) Rehabilitation agency.
 - (iii) Public health agency.
- (3) An entity that has in effect an agreement to participate in Medicare but only to furnish opioid use disorder treatment services.

Supplier means any of the following entities that have in effect an agreement to participate in Medicare:

- (1) An independent laboratory.
- (2) Supplier of durable medical equipment prosthetics, orthotics, or supplies (DMEPOS).
- (3) Ambulance service provider.
- (4) Independent diagnostic testing facility.
- (5) Physician or other practitioner such as physician assistant.
- (6) Physical therapist in independent practice.
- (7) Supplier of portable X-ray services.
- (8) Rural health clinic (RHC).
- (9) Federally qualified health center (FQHC).
- (10) Ambulatory surgical center (ASC).

(11) An entity approved by CMS to furnish outpatient diabetes self-management training.

(12) End-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

(13) A site approved by CMS to furnish intensive cardiac rehabilitation services.

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, Mar. 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; 71 FR 31054, May 31, 2006; 72 FR 15280, Mar. 30, 2007; 73 FR 36462, June 27, 2008; 74 FR 62014, Nov. 25, 2009; 84 FR 63204, Nov. 15, 2019]

§ 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/IID 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.

(iv) CMS's determination to impose sanctions on the individual who is the administrator of a NF for failure to comply with the requirements at § 483.75(r) of this chapter.

(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 or individuals:

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

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

(iii) Part 488, subpart E (§ 488.330(e)) and subpart F (§ 488.446)—for SNFs and NFs and their administrators.

(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 subpart 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/IID's approval to participate in Medicaid.