§ 489.2

which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The sections of the Act specified in paragraphs (a)(1) through (a)(4) of this section are also pertinent.

- (1) Section 1861 of the Act defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.
- (2) Section 1864 of the Act provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.
- (3) Section 1865(a)(1) of the Act provides that an entity accredited by a national accreditation body found by the Secretary to satisfy the Medicare conditions of participation, conditions for coverage, or conditions of certification or requirements for participation shall be treated as meeting those requirements. Section 1865(a)(2) of the Act requires the Secretary to consider when making such a finding, among other things, the national accreditation body's accreditation requirements and survey procedures.
- (4) Section 1871 of the Act authorizes the Secretary to prescribe regulations for the administration of the Medicare program
- (b) Although section 1866 of the Act speaks only to providers and provider agreements, the following rules in this part also apply to the approval of supplier entities that, for participation in Medicare, are subject to a determination by CMS on the basis of a survey conducted by the SA or CMS surveyors; or, in lieu of an SA or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with the requirements of part 488 of this chapter at the time of the accreditation survey and accreditation decision, in accordance with the following:
- (1) The definition of immediate jeopardy at § 489.3.
- (2) The effective date rules specified in §489.13.
- (3) The requirements specified in §489.53(a)(2), (13), and (18), related to termination by CMS of participation in Medicare.

(c) Section 1861(o)(7) of the Act requires each HHA to provide CMS with a surety bond.

[75 FR 50418, Aug. 16, 2010, as amended at 80 FR 29839, May 22, 2015]

§ 489.2 Scope of part.

- (a) Subpart A of this part sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare. Subpart B of this part specifies the basic commitments and limitations that the provider must agree to as part of an agreement to provide services. Subpart C specifies the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, blood, and services that must be part of the provider agreement. Subpart D of this part specifies how incorrect collections are to be handled. Subpart F sets forth the circumstances and procedures for denial of payments for new admissions and for withholding of payment as an alternative to termination of a provider agreement.
- (b) The following providers are subject to the provisions of this part:
 - (1) Hospitals.
 - (2) Skilled nursing facilities (SNFs).
 - (3) Home health agencies (HHAs).
- (4) Clinics, rehabilitation agencies, and public health agencies.
- (5) Comprehensive outpatient rehabilitation facilities (CORFs).
 - (6) Hospices.
 - (7) Critical access hospital (CAHs).
- (8) Community mental health centers (CMHCs).
- (9) Religious nonmedical health care institutions (RNHCIs).
- (10) Opioid treatment programs (OTPs).
- (11) Rural emergency hospitals (REHs).
- (c)(1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.
- (2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

(3) OTPs may enter into provider agreements only to furnish opioid use disorder treatment services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986; 58 FR 30676, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 62 FR 46037, Aug. 29, 1997; 68 FR 66720, Nov. 28, 2003; 84 FR 63204, Nov. 15, 2019; 87 FR 72309, Nov. 23, 20221

§ 489.3 Definitions.

For purposes of this part—

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

Physician-owned hospital means any participating hospital (as defined in § 489.24) in which a physician, or an immediate family member of a physician (as defined in §411.351 of this chapter), has an ownership or investment interest in the hospital. The ownership or investment interest may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in the hospital. This definition does not include a hospital with physician ownership or investment interests that satisfy the requirements §411.356(a) or (b) of this chapter.

Provider agreement means an agreement between CMS and one of the providers specified in §489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986; 54 FR 5373, Feb. 2, 1989; 59 FR 56250, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995; 72 FR 47412, Aug. 22, 2007; 73 FR 48757, Aug. 19, 2008; 80 FR 29840, May 22, 2015]

§ 489.10 Basic requirements.

(a) Any of the providers specified in §489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions

for participation and the requirements set forth in this section and elsewhere in this chapter. The OTPs must meet the requirements set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the applicable civil rights requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601):

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

- (3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and beneficiaries of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and
- (4) Other pertinent requirements of the Office of Civil Rights of HHS.
- (c) In order for a hospital, SNF, HHA, hospice, or RNHCI to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.
- (d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to CMS.
- (e) In order for a home health agency to be accepted, it must also meet the surety bond requirements specified in subpart F of this part.
- (f) In order for a home health agency to be accepted as a new provider, it