

(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, 2022]

§ 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 at § 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

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must also meet the capitalization requirements specified in subpart B of this part.

[58 FR 61843, Nov. 23, 1993, as amended at 59 FR 6578, Feb. 11, 1994; 63 FR 312, Jan. 5, 1998; 68 FR 66720, Nov. 28, 2003; 84 FR 63204, Nov. 15, 2019]

§ 489.11 Acceptance of a provider as a participant.

(a) *Action by CMS.* If CMS determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) *Action by provider.* If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) *Notice of acceptance.* If CMS accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994; 62 FR 43937, Aug. 18, 1997]

§ 489.12 Decision to deny an agreement.

(a) *Bases for denial.* CMS may refuse to enter into an agreement for any of the following reasons:

(1) Principals of the prospective provider have been convicted of fraud (see § 420.204 of this chapter);

(2) The prospective provider has failed to disclose ownership and control interests in accordance with § 420.206 of this chapter;

(3) The prospective provider is a physician-owned hospital as defined in § 489.3 and does not have procedures in place for making physician ownership disclosures to patients in accordance with § 489.20(u); or

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(4) The prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(b) [Reserved]

(c) *Compliance with civil rights requirements.* CMS will not enter into a provider agreement if the provider fails to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90, subject to the provisions of § 489.10.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 4027, Jan. 27, 1989; 59 FR 6578, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994; 72 FR 47413, Aug. 22, 2007]

§ 489.13 Effective date of agreement or approval.

(a) *Applicability—(1) General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare are subject to a determination by CMS on the basis of—

(i) A survey conducted by the State survey agency or CMS surveyors; or

(ii) In lieu of such State survey agency or CMS conducted survey, accreditation by an accreditation organization whose program has CMS approval in accordance with section 1865 of the Act at the time of the accreditation survey and accreditation decision.

(2) *Exceptions.* (i) For an agreement with a community mental health center (CMHC) or a federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(iii) For an agreement with an opioid treatment program (OTP), the effective date is the effective date of billing as established under § 424.520(d) or § 424.521(a), as applicable.

(b) *All health and safety standards are met on the date of survey.* The agreement or approval is effective on the date the State agency, CMS, or the