

§ 489.11

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