

§489.13

disclosures to patients in accordance with § 489.20(u); or

(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 agree-

42 CFR Ch. IV (10-1-20 Edition)

ment or approval is effective on the date the State agency, CMS, or the CMS contractor survey (including the Life Safety Code survey, if applicable) is completed, or on the effective date of the accreditation decision, as applicable, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following the expiration of the current agreement or approval.) However, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met. Federal requirements include, but are not limited to—

(1) Enrollment requirements established in part 424, subpart P, of this chapter. CMS determines, based upon its review and verification of the prospective provider's or supplier's enrollment application, the date on which enrollment requirements have been met;

(2) The requirements identified in §§ 489.10 and 489.12; and

(3) The applicable Medicare health and safety standards, such as the applicable conditions of participation, the requirements for participation, the conditions for coverage, or the conditions for certification.

(c) *All health and safety standards are not met on the date of survey.* If, on the date the survey is completed, the provider or supplier has failed to meet any one of the applicable health and safety standards, the following rules apply for determining the effective date of the provider agreement or supplier approval, assuming that no other Federal requirements remain to be satisfied. However, if other Federal requirements remain to be satisfied, notwithstanding the provisions of paragraphs (c)(1) through (c)(3) of this section, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met.

(1) For an agreement with an SNF, the effective date is the date on which—

(i) The SNF is in substantial compliance (as defined in § 488.301 of this chapter) with the requirements for participation; and

(ii) CMS or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all applicable conditions of participation, conditions for coverage, or conditions for certification; or, if applicable, the date of a CMS-approved accreditation organization program's positive accreditation decision, issued after the accreditation organization has determined that the provider or supplier meets all applicable conditions.

(ii) The date on which a provider or supplier is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies, and—

(A) CMS or the State survey agency receives an acceptable plan of correction for the lower-level deficiencies (the date of receipt is the effective date regardless of when the plan of correction is approved); or, if applicable, a CMS-approved accreditation organization program issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies; or

(B) CMS receives an approvable waiver request (the date of receipt is the effective date regardless of when CMS approves the waiver request).

(3) For an agreement with any other provider or an approval of any other supplier (except those specified in paragraph (a)(2) of this section) that is found to meet all conditions of participation, conditions for coverage, or conditions for certification, but has lower-level deficiencies and has submitted both an approvable plan of correction/positive accreditation decision and an approvable waiver request, the effective date is the later of the dates that result when calculated in accordance

with paragraph (c)(2)(ii)(A) or (c)(2)(ii)(B) of this section.

[75 FR 50418, Aug. 16, 2010, as amended at 84 FR 63204, Nov. 15, 2019]

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) *What constitutes change of ownership*—(1) *Partnership*. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) *Unincorporated sole proprietorship*. Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation*. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) *Leasing*. The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) *Notice to CMS*. A provider who is contemplating or negotiating a change of ownership must notify CMS.

(c) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) *Conditions that apply to assigned agreements*. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Compliance with applicable health and safety standards.

(3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.

(4) Compliance with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.