
This content is from the eCFR and is authoritative but unofficial.

Title 42 – Public Health

Chapter IV – Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter G – Standards and Certification

Part 489 – Provider Agreements and Supplier Approval

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

Source: 45 FR 22937, Apr. 4, 1980, unless otherwise noted.

Subpart A General Provisions

- § 489.1 Statutory basis.
- § 489.2 Scope of part.
- § 489.3 Definitions.
- § 489.10 Basic requirements.
- § 489.11 Acceptance of a provider as a participant.
- § 489.12 Decision to deny an agreement.
- § 489.13 Effective date of agreement or approval.
- § 489.18 Change of ownership or leasing: Effect on provider agreement.

Subpart A—General Provisions

§ 489.1 Statutory basis.

- (a) This part implements section 1866 of the Social Security Act (the Act). Section 1866 of the Act specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under 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 and intensive outpatient 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, 2022; 88 FR 82184, Nov. 22, 2023]

§ 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 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
- (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 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.

(e) **Effect of leasing.** The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994]