APPROVAL AND OVERSIGHT OF HOME INFUSION THERAPY SUPPLIER ACCREDITING ORGANIZATIONS

488.1010 Application and reapplication procedures for national home infusion therapy accrediting organizations.
488.1015 Resubmitting a request for reapproval.
488.1020 Public notice and comment.
488.1025 Release and use of home infusion therapy accreditation surveys.
488.1030 Ongoing review of home infusion therapy accrediting organizations.
488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accreditation organization.
488.1040 Onsite observations of home infusion therapy accrediting organization operations.
488.1045 Voluntary and involuntary termination.
488.1050 Reconsideration.

AUTHORITY: 42 U.S.C 1302 and 1395hh.

SOURCE: 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 488.1 Definitions.

As used in this part—

Act means the Social Security Act.

Certification means a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements.

Conditions for certification means the health and safety standards RHCs must meet to participate in the Medicare program.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Deemed status means that CMS has certified a provider or supplier for Medicare participation, based on all of the following criteria having been met: The provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization under the applicable Medicare accreditation program; the accrediting organization has recommended the provider or supplier to CMS for Medicare participation; CMS has accepted the accrediting organization's recommendation; and CMS finds that all other participation requirements have been met.

Full review means a survey of a provider or supplier for compliance with all of the Medicare conditions or requirements applicable to that provider or supplier type.

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

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

National accrediting organization means an organization that accredits provider entities, as that term is defined in section 1865(a)(4) of the Act, under a specific program and whose accredited provider entities under each program are widely located geographically across the United States.

Provider of services or provider refers to a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The

State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accrediting organization has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions provided for in sections 1864, 1819(g), and 1919(g) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that would, if found to be present, adversely affect the health and safety of patients or residents and raises doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements.

Supplier means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006; 80 FR 29834, May 22, 2015]

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.
1128A—Civil money penalties.
1138(b)—Requirements for organ procurement organizations and organ procurement agencies.
1814—Conditions for, and limitations on, payment for Part A services.
1819—Requirements for SNFs.
1820—Requirements for CAHs.
1832(a)(2)(C)—Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.
1832(a)(2)(F)—Requirements for ASCs.
1832(a)(2)(J)—Requirements for partial hospitalization services provided by CMHCs.
1861(e)—Requirements for hospitals.
1861(f)—Requirements for psychiatric hospitals.
1861(m)—Requirements for Home Health Services
1861(o)—Requirements for Home Health Agencies
1861(p)(4)—Requirements for rehabilitation agencies.
1861(z)—Institutional planning standards that hospitals and SNFs must meet.
1861(aa)—Requirements for RHCs and FQHCs.
1861(cc)(2)—Requirements for CORFs.
1861(dd)—Requirements for hospices.
1861(ee)—Discharge planning guidelines for hospitals.
1861(ff)(3)(A)—Requirements for CMHCs.
1861(ss)(2)—Accreditation of religious nonmedical health care institutions.
1863—Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.
1864—Use of State survey agencies.
1865—Effect of accreditation.
1875(b)—Requirements for performance review of CMS-approved accreditation programs.
1880—Requirements for hospitals and SNFs of the Indian Health Service.
1881—Requirements for ESRD facilities.
1883—Requirements for hospitals that furnish extended care services.
1891—Conditions of participation for home health agencies; home health quality.
1902—Requirements for participation in the Medicaid program.
1913—Medicaid requirements for hospitals that provide NF care.
1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999; 77 FR 67164, Nov. 8, 2012; 80 FR 29834, May 22, 2015]