achieve specific outcomes within specific timeframes.

(c) *Duration and effect of sanction.* If the HHA fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, CMS:

(1) May impose one or more other sanctions set forth in § 488.820; or

(2) Terminates the provider agreement.

§ 488.855 Directed in-service training.

(a) *Application.* CMS may require the staff of an HHA to attend in-service training program(s) if CMS determines that—

(1) The HHA has deficiencies that indicate noncompliance;

(2) Education is likely to correct the deficiencies; and

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare Home Health Providers, or as deemed acceptable by CMS and/or the State (by review of a copy of curriculum vitas and/or resumes/references to determine the educator's qualifications).

(b) *Procedures*—(1) *Action following training.* After the HHA staff has received in-service training, if the HHA has not achieved compliance, CMS may impose one or more other sanctions specified in § 488.820.

(2) *Payment.* The HHA pays for the directed in-service training for its staff.

§ 488.860 Continuation of payments to an HHA with deficiencies.

(a) *Continued payments.* CMS may continue payments to an HHA with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) *Criteria.* CMS may continue payments to an HHA not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) The HHA has been imposed an alternative sanction or sanctions and termination has not been imposed.

(ii) The HHA has submitted a plan of correction approved by CMS.

(iii) The HHA agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS may terminate the HHA's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments for new admissions.* If termination is imposed, either on its own or in addition to an alternative sanction or sanctions, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the HHA will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) *Failure to achieve compliance with the conditions of participation.* If the HHA does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS will terminate the provider agreement of the HHA in accordance with § 488.865.

§ 488.865 Termination of provider agreement.

(a) *Effect of termination by CMS.* Termination of the provider agreement ends—

(1) Payment to the HHA; and

(2) Any alternative sanction(s).

(b) *Basis for termination.* CMS terminates an HHA's provider agreement under any one of the following conditions—

(1) The HHA is not in compliance with the conditions of participation.

(2) The HHA fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The HHA fails to relinquish control to the temporary manager, if that sanction is imposed by CMS.

(4) The HHA fails to meet the eligibility criteria for continuation of payment as set forth in § 488.860(a)(1).

(c) *Notice.* CMS notifies the HHA and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) *Procedures for termination.* CMS terminates the provider agreement in

accordance with procedures set forth in § 489.53 of this chapter.

(e) *Appeal.* An HHA may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

Subpart K—[Reserved]

Subpart L—Accreditation of Home Infusion Therapy Suppliers

SOURCE: 83 FR 56631, Nov. 13, 2018, unless otherwise noted.

GENERAL PROVISIONS

§ 488.1000 Basis and scope.

(a) *Regulatory basis for home infusion therapy services.* The home infusion therapy health and safety regulations are codified at part 486, subpart I, of this chapter.

(b) *Statutory basis for the accreditation of home infusion therapy suppliers.* (1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) *Scope.* This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§ 488.1005 Definitions.

As used in this subpart—

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

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

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

Rural area as defined at section 1886(d)(2)(D) 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 the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a qualified home infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.