(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64040, Sept. 16, 2016, as amended at 84 FR 51830, Sept. 30, 2019]

Subpart H—[Reserved]

Subpart I—Requirements for Home Infusion Therapy Suppliers

SOURCE: 83 FR 56630, Nov. 13, 2018, unless otherwise noted.

GENERAL PROVISIONS

§ 486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§ 486.505 Definitions.

As used in §§ 486.520 and 486.525:

Applicable provider means a physician, a nurse practitioner, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

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.

[83 FR 56630, Nov. 13, 2018, as amended at 84 FR 60646, Nov. 8, 2019]

STANDARDS FOR HOME INFUSION THERAPY

§ 486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§ 486.525 Required services.

(a) The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(1) Professional services, including nursing services.

(2) Patient training and education not otherwise paid for as durable medical equipment as described in §424.57(c)(12) of this chapter.

(3) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

(b) All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

[83 FR 56630, Nov. 13, 2018, as amended at 86 FR 61625, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Subpart A—General Provisions

Subpart B—Special Requirements

Subpart C—Survey Forms and Procedures

Subpart D—Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

Subpart E—Survey and Certification of Long-Term Care Facilities