

424.68 Enrollment requirements for home infusion therapy suppliers.

(a) Definition. For purposes of this section, a home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following requirements:

- (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) Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of this section and subpart P of this part.

(b) General requirement. For a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must qualify as a home infusion therapy supplier (as defined in this section) and be in compliance with all applicable provisions of this section and of subpart P of this part.

(c) Specific requirements for enrollment. To enroll in the Medicare program as a home infusion therapy supplier, a home infusion therapy supplier must meet all of the following requirements:

- (1)(i) Fully complete and submit the Form CMS-855B application (or its electronic or successor application) to its applicable Medicare contractor.
- (ii) Certify via the Form CMS-855B that the home infusion therapy supplier meets and will continue to meet the specific requirements and standards for enrollment described in this section and in subpart P of this part.
- (2) Comply with the application fee requirements in § 424.514.
- (3) Be currently and validly accredited as a home infusion therapy supplier by a CMS-recognized home infusion therapy supplier accreditation organization.
- (4) Comply with § 414.1515 of this chapter and all provisions of part 486, subpart I of this chapter.
- (5) Successfully complete the limited categorical risk level of screening under § 424.518.

(d) Denial of enrollment. (1) Enrollment denial by CMS. CMS may deny a supplier's enrollment application as a home infusion therapy supplier on either of the following grounds:

(i) The supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in subpart P of this part.

(ii) Any of the applicable denial reasons in § 424.530.

(2) Appeal of an enrollment denial. A supplier may appeal the denial of its enrollment application as a home infusion therapy supplier under part 498 of this chapter.

(e) Continued compliance, standards, and reasons for revocation. (1) Upon and after enrollment, a home infusion therapy supplier -

(i) Must remain currently and validly accredited as described in paragraph (c)(3) of this section.

(ii) Remains subject to, and must remain in full compliance with, all of the provisions of -

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter.

(2) CMS may revoke a home infusion therapy supplier's enrollment on any of the following grounds:

(i) The supplier does not meet the accreditation requirements as described in paragraph (c)(3) of this section.

(ii) The supplier does not comply with all of the provisions of -

(A) This section;

(B) Subpart P of this part;

(C) Section 414.1515 of this chapter; and

(D) Part 486, subpart I of this chapter; or

(iii) Any of the revocation reasons in § 424.535 applies.

(3) A home infusion therapy supplier may appeal the revocation of its enrollment under part 498 of this chapter.