

(ii) A provisional certification under § 8.11(e) of this title does not meet the requirements of paragraph (b)(4)(i) of this section.

(5) Report on the Form CMS-855A or Form CMS-855B (as applicable) and/or any applicable supplement all OTP staff who meet the definition of “managing employee” in § 424.502. Such individuals include, but are not limited to, the following:

(i) Medical director (as described in § 8.2 of this title).

(ii) Program sponsor (as described in § 8.2 of this title).

(6)(i)(A) Must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a Federal or State felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries based on the same categories of detrimental felonies, as well as case by case detrimental determinations, found at § 424.535(a)(3).

(B) Paragraph (b)(6)(i)(A) of this section applies regardless of whether the individual in question is:

(1) Currently dispensing narcotics at or on behalf of the OTP; or

(2) A W-2 employee of the OTP.

(ii) Must not employ or contract with any personnel (regardless of whether the individual is a W-2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6) of this chapter.

(iii) Must not employ or contract with any personnel (regardless of whether the individual is a W-2 employee of the OTP) who has a prior adverse action by a State oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. CMS will consider the factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this paragraph.

(7)(i) Sign (and adhere to the term of) a provider agreement in accordance with the provisions of part 489 of this chapter.

(ii) An OTP’s appeals under part 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53 of this chapter) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter.

(8) Comply with all other applicable requirements for enrollment specified in this section and in subpart P of this part.

(c) *Clarification of required enrollment forms.* (1) An OTP may only be enrolled as an OTP via the Form CMS-855A or Form CMS-855B but not both.

(2) If a currently enrolled OTP is changing its OTP enrollment from a Form CMS-855B enrollment to a Form CMS-855A enrollment, or vice versa, the effective date of billing that was established for the OTP’s prior enrollment under §§ 424.520(d) and 424.521(a) is applied to the OTP’s new enrollment.

(d) *Denial of enrollment.* CMS may deny an OTP’s enrollment application on any of the following grounds:

(1)(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement in this section.

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

(2) An OTP may appeal the denial of its enrollment application under part 498 of this chapter.

(e) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, an OTP—

(i) Must remain validly certified by SAMHSA as required under § 8.11 of this title.

(ii) Remains subject to, and must remain in full compliance with, the provisions of this section and of subpart P of this part. This includes, but is not limited to, the provisions of paragraph (b)(6) of this section, the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

(iii) Upon revalidation, successfully complete the moderate categorical risk

level screening required under § 424.518(b).

(2) CMS may revoke an OTP's enrollment on any of the following grounds:

(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (e)(1) of this section.

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

(3) An OTP may appeal the revocation of its enrollment under part 498 of this title.

(f) *Claim payment.* For an OTP to receive payment for furnished drugs:

(1) The prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 of the Form CMS-1500; and

(2) All other applicable requirements of this section, this part, and part 8 of this title must be met.

(g) *Relation to part 8 of this title.* Nothing in this section shall be construed as:

(1) Supplanting any of the provisions in part 8 of this title; or

(2) Eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8 of this title.

[84 FR 63202, Nov. 15, 2019, as amended at 85 FR 85038, Dec. 28, 2020]

§ 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—