§ 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—

(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.

[85 FR 70355, Nov. 4, 2020]

Subpart F—Limitations on Assignment and Reassignment of Claims

§ 424.70 Basis and scope.

(a) *Statutory basis.* This subpart implements sections 1815(c) and 1842(b)(6) of the Act, which establish limitations on who may receive payments due a provider or supplier of services or a beneficiary.

(b) *Scope.* This subpart—

(1) Prohibits the assignment, reassignment, or other transfer of the right to Medicare payments except under specified conditions;

(2) Sets forth the sanctions that CMS may impose on a provider or supplier that violates this prohibition, or on a supplier that violates the conditions to which it agreed in accepting assignment from the individual; and

(3) Specifies the conditions for payment under court-ordered assignments or reassignments.

§ 424.71 Definitions.

As used in this subpart, unless the context indicates otherwise—

Court of competent jurisdiction means a court that has jurisdiction over the subject matter and the parties before it.