PUBLICATION

CMS Issues Proposed Enrollment Standards for Home Infusion Therapy Suppliers

Authors: Kathleen Rose Salsbury
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On June 30, 2020, Centers for Medicare and Medicaid Services (CMS) published a proposed rule that includes new provisions implementing the home infusion therapy (HIT) benefit category and outlines enrollment standards for HIT suppliers who wish to bill Medicare for HIT services. The new provisions appear with the proposed rule updating the home health prospective payment system (HH PPS) for CY 2021 and addressing other home health related provisions. Comments are due no later than August 31, 2020.

The HIT benefit category is relatively new; temporary transitional payments for HIT services to certain Medicare-enrolled pharmacies began on January 1, 2019 and the benefit is set to be fully implemented on January 1, 2021, in accordance with section 5012 of the 21st Century Cures Act.

To support the full implementation of this benefit category, CMS seeks to amend 42 C.F.R. § 409.49 to exclude services covered under the HIT benefit from the home health benefit. CMS further proposes to maintain the three payment categories previously established for the temporary transitional payments and outlined intended payment rate adjustments for CY 2021.

Under the new HIT benefit, HIT services must be furnished by a "qualified home infusion therapy supplier," which is defined by statute to mean "a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that:

- furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
- ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;
- is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and
- meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector."

To implement these requirements, CMS proposes enrollment standards for HIT suppliers who wish to be eligible to receive payment for HIT services in new 42 C.F.R. § 424.68. Many of these standards mirror general Medicare enrollment requirements, while some create new obligations applicable specifically to HIT suppliers.

A summary of the proposed enrollment standards is outlined below:

- **CMS-855B**: CMS proposes that HIT suppliers be required to complete and submit the Form CMS – 855B application, currently used for clinics, group practices and other supplier types that are not individual physicians or practitioners. HIT suppliers would be required to certify that they meet and will

continue to meet enrollment requirements and standards enumerated in proposed 42 C.F.R. § 424.68 and part 424, subpart P.

- **Application Fee**: Based on its conclusion that a HIT supplier meets the definition of an "institutional provider" as that term is defined under CMS's enrollment regulations, CMS proposes that HIT suppliers be required to pay an application fee consistent with 42 C.F.R. § 424.514.
- **Accreditation**: In accordance with statutory requirements, CMS proposes that a HIT supplier must be currently and validly accredited by a CMS-recognized HIT supplier accreditation organization in order to enroll and remain enrolled in Medicare.
- **Compliance with Existing Quality and Payment Standards**: In new § 424.68(c)(4), CMS proposes to explicitly require HIT suppliers to comply with all payment requirements in § 414.1505 and all provisions of part 486, subpart I in order to enroll and maintain enrollment. These include requirements that beneficiaries be under a physician's plan of care and that the HIT supplier provide services in accordance with nationally recognized standards of practice. The standards incorporated also require that the HIT supplier make patient training, remote monitoring and professional services available 24 hours a day, 7 days a week. CMS also proposes that HIT suppliers must meet all general enrollment requirements established in 42 C.F.R. part 424, subpart P.
- **Screening Level**: For enrollment screening purposes, CMS proposes to assign HIT suppliers to the lowest category: limited risk.
- **Denial of Enrollment and Appeal Rights**: CMS proposes new provisions that would permit denial of a HIT supplier's enrollment application if it does not meet all requirements in § 424.38 and part 424, subpart P, or for any of the denial reasons permitted under CMS's existing enrollment regulations at 42 C.F.R. § 424.530. CMS's proposed regulations would permit HIT suppliers that are denied enrollment to appeal the determination under the existing Medicare enrollment appeal provisions in part 498.
- **Revocation**: The Proposed Rule would permit revocation of a HIT supplier's billing privileges for failure to meet accreditation requirements, failure to comply with applicable regulations, or for any revocation reason found in existing 42 C.F.R. § 424.535. Under the proposed provisions, revocation would be appealable under the existing appeals regulations at part 498.
- **Effective Date**: CMS proposes to make the effective date of HIT supplier billing privileges the later of 1) the date of filing of a Medicare enrollment application that was subsequently approved; or 2) the date the supplier first began furnishing services at a new practice location. Under the proposed provisions, retrospective billing would be permitted for up to 30 days prior to the effective date if circumstances precluded enrollment in advance of providing services, or 90 days prior to the effective date if a Presidentially declared disaster under the Stafford Act precluded enrollment in advance of providing services.

Comments on provisions of the Proposed Rule must be submitted no later than 5 p.m. Eastern on August 31, 2020 in order to be considered.

For more information or any question regarding these issues, please contact Katie Salsbury or any member of Baker Donelson's Reimbursement team.