National Home Infusion Association

Home Infusion Transitional and Permanent Reimbursement Rule
Professional Services

The Issue

On July 2, 2018 the Centers for Medicare and Medicaid Services' (CMS') released the proposed rule entitled *"Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations"* (CMS-1689-P). Comments on the proposed rule are due on August 31, 2018.

NHIA has a number of concerns with the proposed rule, the foremost being it incorrectly requires a skilled professional to be physically present in the home for infusion when the very purpose of home infusion is to avoid that requirement when medically appropriate and does not adequately define professional services home infusion suppliers utilize to provide home infusion to Medicare beneficiaries. By requiring higher levels of care than are medically appropriate or used today, and without a proper definition of professional services, home infusion reimbursement in the Medicare program will remain broken and the extensive work that Congress invested in enacting two separate bills to create the benefit will be undone.

The term professional services in statute serves two purposes. The first reason the term is used is to define what services home infusion suppliers will be reimbursed for. The second reason is as part of the transitional reimbursement in the *Bipartisan Budget Act of 2018* the furnishing of professional services defines a calendar day of administration. It is vitally important that CMS appropriately define professional services to ensure home infusion suppliers are adequately reimbursed after CY 2021 and that they are reimbursed for a day of administration starting in 2019. And it is just as important that CMS not add requirements that Congress did not require to ensure the benefit is appropriately launched during the transition period.

CMS states in the rule:

> *"As section 1861(iii)(2)(A) of the Act refers to the **professional services**, including nursing services, we believe this to mean **skilled services** as set out at 42 CFR 409.32." (emphasis added)*

CMS then goes on to require such professional services to be performed by a professional *physically in the home on the day of drug administration* to be eligible for reimbursement. Referencing a section of the Code of Federal Regulations (CFR) that has no bearing on home infusion professional services is inappropriate and requiring that someone provide those services physically in the home is a misread of the law. CMS' contention that professional services mean skilled services in a Skilled Nursing Facility (SNF) an inappropriate assumption unsupported by legislative text, legislative history, or actual practice. Instead of misusing an inappropriate requirement that is not relevant to beneficiaries who are able to be treated at home, a new home infusion specific definition of professional services is necessary. At a minimum, however, to initiate the *Bipartisan*

Budget Act of 2018, the requirement that a nurse (or other skilled professional) must be physically in the beneficiary's home for the infusion to be eligible for reimbursement must be removed.

The law states that the services to be covered include "professional services, including nursing services." By virtue of this statutory text there are professional services in addition to nursing that are within the scope of what Congress intended be provided and covered. In fact, for an infusion administration to occur, a considerable amount of professional services are "furnished to administer such drugs to such individual." These services include: drug preparation by a licensed pharmacist; medication profile review; potential drug interaction review; clinical care coordination between physicians, nurses, pharmacist and patients; lab result interpretation; and other various other services. Without these services home infusion drug administration will never happen, therefor they are services provided to the patient when a drug administration occurs. While a home infusion provider may not be in the home at the time of the administration, the home infusion supplier's professional services are delivered to the patient by virtue of the administration of the drug.

The Solution

CMS in the final rule needs to withdraw the requirement that a nurse or other professional be physically present in the home for reimbursement to occur. CMS needs to appropriately define professional services to include the full range of professional services associated with the delivery of home infusion. These services should be considered "furnished to administer such drugs to such individual" as the statute states.

Further Policy Discussion

CMS made a set of highly concerning statements, assumptions, and omissions in the rule.

1. CMS throughout the rule omits reference to pharmacy and pharmacy services as a component of home infusion care and professional services. The only way a home infusion supplier to be eligible for the transitional reimbursement is to be a licensed pharmacy and enrolled in the Durable Medical Equipment (DME) program as a pharmacy provider. The eligibility requirement clearly indicates that pharmacy services are vitally important to the delivery of home infusion and should be considered professional services.

   Furthermore, the taxonomy code for home infusion that is approved by CMS has been in effect since 2006 states:

   > *"Home Infusion Therapy Pharmacy - Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance."*

   CMS by their own standards has stressed the importance of pharmacy services as part of the fabric of home infusion professional services.

   The inclusion of pharmacy services in the definition of professional services is vitally important to ensure that the drugs being provided to patients are safe and effective. Not only does the rule leave pharmacy out of the definition of professional services for the virtue of a calendar day of administration, pharmacy services are not included as a demanded element of accreditation of home infusion suppliers. Home infusion suppliers should be held to a high standard for drug preparation. Most, if not all, drugs prepared for home infusion are compounded for the individual patient pursuant to an individual prescription. Home infusion pharmacy services operate as 503(A) pharmacies and should be regulated as such. If there is no reference to pharmacy services to receive payment or accreditation edibility for this benefit could become a loophole for unscrupulous individuals.

2. CMS in certain sections of the rule truncated their statutory responsibilities. By not including a full reflection of statute, CMS has in essence avoided certain duties that are essential to carrying out the implementation of the home infusion transitional reimbursement and the permanent reimbursement starting in CY2021.

   When defining the qualification for a home infusion supplier the rule states:

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 Standards for Home Infusion Therapy.

However, the CMS definition is patently inconsistent with statute. When defining the qualifications for a home infusion supplier the law states:

``(D)(i) The term `qualified home infusion therapy supplier' means ***a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or [typo in statute] services or supplier furnishes items or services*** *and that--*

``(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
``(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;
``(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and
``(IV) 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.*** *(emphasis added)*

NHIA believes these important references point toward the need for pharmacy services to be considered professional services. CMS' review of Medicare Advantage plans' and private sectors' requirements will make it be abundantly clear that pharmacy services are a core component of professional services home infusion suppliers furnish.