June 29, 2020

National Home Infusion Association

SUMMARY OF HOME INFUSION THERAPY SERVICE REQUIREMENTS IN CMS CY 2021 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE PROPOSED RULE

On June 25, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule: " Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements" (Proposed Rule). The Proposed Rule will be published in the Federal Register on June 30 and comments are due to CMS by 5:00 p.m. on August 29.

Regarding home infusion therapy services, the proposed rule summarizes the home infusion therapy policies finalized in the calendar year (CY 2020) Home Health Prospective Payment System final rule with comment period. CMS did not make any policy changes to those announced in last year's final rule. In addition, the Proposed Rule includes changes to the home health regulations to ensure it is clear that home infusion therapy is excluded from coverage under the Medicare home health benefit. The Proposed Rule also describes the Medicare provider enrollment policies for qualified home infusion therapy suppliers.

Summary of Home Infusion Therapy Services for CY 2021 and Subsequent Years

CMS reiterates that "home infusion drugs" are drugs and biologicals administered through a pump that is covered under the Medicare Part B durable medical equipment (DME) benefit and that beneficiaries must be under a "plan of care." CMS states that a qualified home infusion therapy supplier is responsible for reasonable and necessary services related to administering a home infusion drug in an individual's home and that those services may necessitate care coordination or monitoring outside of an infusion drug administration calendar day. CMS notes that those services are built into the bundled payment paid on days when a skilled professional is in the patient's home. CMS explains that it is necessary for the qualified home infusion therapy supplier to be in the patient's home when the drug is being administered in order to give an accurate assessment to the physician responsible for ordering the home infusion drug and services. Services would include patient evaluation and assessment; training and education of patients and their caretakers; assessment of vascular access sites and taking any necessary bloodwork; and evaluation of medication administration. Visits made solely for the purposes of venipuncture when there is no administration of the infusion drug would not be separately payable, since that would be part of the bundled payment for an infusion drug administration calendar day.

CMS reminds stakeholders that professional services covered under the DME benefit are not covered under the home infusion benefit, noting that the two benefits "exist in tandem" and are billed and paid for under distinct payment systems.

Physician Notification

Last year, CMS solicited comments on the statutory requirement that, prior to the furnishing of home infusion therapy services to an individual, a physician who establishes the plan of care provide

notification of the options available for the furnishing of infusion therapy. CMS states that for home infusion therapy services beginning in CY 2021, physicians are required to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating such discussions in the patient's medical record prior to establishing a plan of care for home infusion therapy. CMS believes the current notification to patients is appropriate and is not proposing to create a mandatory form or to require a specific manner or frequency of notification of available options. The agency noted, however, that if current practices are later found to be insufficient, CMS may consider future rulemaking to add requirements regarding this notification.

Payment for Home Infusion Therapy Services for CY 2021

CMS stated that the best way to establish a single payment amount that varies by utilization of nursing services and reflects the acuity of patients and complexity of drug administration is to group home infusion drugs by J-code. Last year, CMS finalized its proposal to maintain the three payment categories used under the temporary transitional home infusion therapy services benefit. CMS notes that there are some drugs that are paid for under the transitional benefit but would not be defined as home infusion drugs under the permanent benefit. For example, Hizentra is listed on a self-administered drug (SAD) exclusion list by the MACs, so services related to the administration of Hizentra will not be covered under the home infusion therapy services benefit beginning in 2021. Home infusion therapy services also will not be paid for related to the administration of Ziconotide, Floxuridine, as well as Morphine administered via intrathecal.

CMS reminds stakeholders that it finalized its proposal to increase the payment amounts for all three payment categories for the first home infusion therapy visit in the patient's, which results in a small decrease to the payment amounts for the second and subsequent visits, due to budget neutrality. For CY 2021 physician fee schedule rates, there was a 60 percent increase in the first visit payment amount and a 3.72 percent decrease in subsequent visit amounts.

CMS notes that it had not outlined in regulation a detailed list of services covered under the home infusion therapy services benefit but has outlined the scope of covered services in sub-regulatory guidance. The sub-regulatory guidance states that the home infusion therapy services benefit is intended to be a separate payment that covers professional services; training and education that are not covered under the DME benefit; and monitoring and remote monitoring services for providing home infusion drugs. These services are excluded from coverage under the home health benefit.

Proposed Enrollment Standards for Qualified Home Infusion Therapy Suppliers

CMS believes that the provider enrollment process is critical in its role to protect the Medicare program from fraud, waste and abuse. CMS proposes a new regulatory section for the home infusion therapy enrollment provisions. CMS proposes that a home infusion therapy supplier must complete and submit the CMS Form 885-B ("Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers.") In addition, home infusion therapy suppliers would be required to pay an application fee. A home infusion therapy supplier also must be "currently and validly accredited" by a CMS-recognized home infusion therapy supplier accreditation organization.

CMS proposes to designate home infusion therapy suppliers as "limited risk" for fraud, waste and abuse. This means the Medicare Administrative Contractor (MAC) will perform more limited screening

functions in the enrollment application review process. CMS states that it has “no recent evidence to suggest that home infusion therapy suppliers (as a supplier type) pose an enhanced threat of fraud, waste and abuse that would warrant their placement in the moderate or high screening level.” CMS is proposing that a home infusion therapy supplier may appeal the denial of its enrollment application.