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August 17, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1730-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements (CMS-1730-P)

Dear Administrator Verma:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the 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* (the “Proposed Rule”) issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on June 30, 2020.¹ NHIA is a trade association that represents home infusion therapy providers, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback on proposed home infusion therapy services requirements. A summary of our recommendations is provided here and articulated in greater detail below. NHIA requests that CMS:

- 1) Continue to allow home infusion therapy services providers to bill for infusion services that were provided within 30 days of an applicable DME infused drug.
- 2) Revise the existing definition of infusion drug administration calendar day to allow for reimbursement of home infusion professional services each day that an infusion drug physically enters the patient’s body, irrespective of whether a skilled professional is in the individual’s home.

¹ 85 Fed. Reg. 39408 (June 30, 2020).

- 3) Add home infusion therapy services supplier to the list of provider types that may utilize telehealth when providing remote monitoring and other professional services in accordance with the plan of care authorized by the physician.
- 4) Update the list of category two eligible drugs to include Xembify® and Cutaquig®.
- 5) Permit home infusion pharmacies, enrolled with the Medicare Part B Durable Medical Equipment program to provide external infusion pump items, to utilize their existing NPI number to enroll with the A/B MACs to provide HIT Services.

Home Infusion Therapy Services Billing

NHIA is concerned about the apparent narrowing of the situations in which home infusion therapy services may be billed. In the Proposed Rule, CMS states that payment to a qualified home infusion therapy supplier may occur “only for the date on which professional services were furnished to “administer” infusion drugs to an individual and that “it is necessary for the qualified home infusion therapy supplier to be in the patient’s home on occasions when the drug is being administered.”² NHIA is concerned that CMS is restricting access to home infusion therapy services without justification. Under the temporary transitional benefit, home infusion therapy services providers were permitted to bill if the appropriate drug associated with the visit was billed within 30-days of the visit. CMS provides no justification for the much more restrictive billing rule under the permanent benefit and NHIA is concerned that this change will reduce access to home infusion therapy for vulnerable Medicare beneficiaries.

Furthermore, this more restrictive language would prohibit a home infusion therapy services supplier from billing for essential services provided in accordance with the plan that do not occur on days when an infusion drug is being administered. For example, home infusion nurses often respond to calls from patients after hours to perform unplanned visits to assess an IV catheter that has become occluded or dislodged. Under this draft rule, a visit performed to assess the catheter and report to the physician would not be billable.

Providers should also not be precluded from performing education and training that facilitates the transition of care between the hospital and the home, as is often done when patients are discharged in the evening, but the next dose of medication does not occur until the following day. By designing a benefit that only values the physical act of drug administration, CMS misses the point of home infusion all together, which is to provide patients with multi-disciplinary, all-embracing clinical support for patients to self-administer medications and avoid unnecessary emergency department visits and hospitalizations. These goals and benefits are only realized when the full range of pharmacist and nursing services are recognized and valued as part of the reimbursement methodology.

NHIA Recommendation:

NHIA requests that CMS continue to allow home infusion therapy services providers to bill for visits that are provided within 30 days of an applicable infusion drug, and not limit billing to

² *Id.* at 39434.

instances where a drug is being actively infused. If CMS wishes to change this rule, NHIA asks that CMS provide its rationale and justification for such a change, and allow opportunity for public comment.

Access to Home Infusion Therapy Services

NHIA is troubled by the Medicare home infusion therapy services data that it has reviewed from 2019. Data obtained by NHIA via a Freedom of Information Act (FOIA) request, shows that Medicare payment for home infusion therapy services under the transitional benefit for the first quarter of 2019 was less than \$1 million. In addition, claims data obtained through a third party shows that Medicare paid less than \$4 million for home infusion therapy services for all of calendar year 2019. This amount is a tiny fraction of the \$60 million that was projected as an annual amount for home infusion therapy services and confirms NHIA's fears that CMS's faulty policies are restricting access to the full range of services to ensure quality and optimal outcomes.

NHIA is particularly concerned about the drop in utilization of the Medicare Part B home infusion benefit for Category 1 drugs. The generic drugs in this category are used especially by patients with serious infections, cardiac and pulmonary conditions, and cancer-related pain to avoid extended hospitalization and nursing facility stays. Suppliers and users of Category 1 drugs in the first quarter of 2019 have each dropped by 7% over the same period in 2018. This fact, coupled with the low utilization in service payments for Category 1 drugs in 2019, suggests patients are not accessing home infusion for these conditions as frequently due to the lack of adequate reimbursement to support the high-touch services required to manage acute conditions in the home setting.

NHIA has long expressed concern that CMS's definition of "infusion drug administration calendar day" would have the effect of reducing access to home infusion therapy services for vulnerable Medicare beneficiaries. NHIA believes that the data bears this out and again asks CMS to revisit its flawed definition. At a time when commercial payers are incentivizing the home site of care for infused drugs, Medicare policy remains fractured, with large coverage gaps that disincentivize the home site of care by limiting the range of services by under-paying suppliers. This is particularly troubling during the current COVID-19 pandemic, when it is more critical than ever that vulnerable Medicare beneficiaries have access to safe at-home treatments and allow hospitals to focus on serving COVID-19 patients. Increasing access to home infusion also provides seniors at higher risk of contracting COVID-19 an alternative to visiting the hospital or clinic to receive infusions necessary for managing chronic conditions. During this public health emergency, it is critical that CMS promote programs that encourage vulnerable Medicare beneficiaries to receive care in their homes and reduce their potential exposure to COVID-19.

NHIA Recommendation:

NHIA again requests that CMS revise the existing definition of "infusion drug administration calendar day" to allow for reimbursement of home infusion professional services each day that

an infusion drug physically enters the patient's body, irrespective of whether a skilled professional is in the individual's home. Revising this unsound definition will help ensure that Medicare beneficiaries that rely on Category 1 drugs have adequate access to the clinical support required to prevent hospitalizations, emergency department use, and skilled facility admission.

Remote Monitoring

As discussed above, CMS has interpreted the HIT service benefit to also include a physical presence requirement in order for billing to occur. Allowing home infusion providers to bill for services that occur remotely would ensure patients are receiving necessary infusions to ensure they avoid unnecessary hospitalizations or trips to the emergency room. While not all in-person home infusion services can be eliminated, the ability to use telehealth when appropriate would put patients at ease during the public health emergency by reducing the frequency of visits by a healthcare professional and extend capacity for home infusion providers whose services are in high demand due to the pandemic.

Section 1861(iii)(2) of the Social Security Act includes remote monitoring among the items and services that are included in the definition of "home infusion therapy." Despite this clear intent of Congress to provide for payment of remote monitoring services, CMS has said virtually nothing about remote monitoring. This is particularly problematic in the context of the current public health emergency, during which CMS has provided for payment of telehealth services for many other services including mental health services, physician services, end-stage renal disease (ESRD) and home health services. Indeed, in the proposed rule, CMS provides detailed examples of other categories of services including training and education, patient assessment and evaluation, and medication and disease management and education, but is silent on any details related to remote monitoring. NHIA is astonished that CMS would not take advantage of the opportunity to protect vulnerable Medicare beneficiaries from the risks of COVID-19 when it has specific legislative authority to do so. As discussed above, the current policy that requires a nurse or other skilled professional to be face-to-face in order for the services to be reimbursed puts these patients and their caregivers in jeopardy despite the fact that much of the support and monitoring for these patients could be achieved through remote communications.

NHIA Recommendation:

NHIA requests that CMS provide immediate relief through interpretive guidance or amendment of 42 CFR 486.505 to allow home infusion providers to bill services codes G0068, G0069, and G0070 for pharmacist and nursing professional services provided remotely in accordance with the plan of care authorized by the physician.

Payment Categories for Xembify® and Cutaquig®

Section 1834(u)(7)(C) of the Social Security Act states that the Secretary of the Department of Health and Human Services (HHS) is required to assign the appropriate payment category

(payment category one (1), two (2) or three (3)) to drugs that are covered under the Durable Medical Equipment (DME) local coverage determination (LCD) for external infusion pumps and billed under HCPCS codes J7799 and J7999. In the Proposed Rule, CMS states that subsequent drugs added to the DME LCD for external infusion pumps under HCPCS codes J7799 and J7999 would be grouped into the appropriate payment category by the DME Medicare Administrative Carriers (MACs). CMS notes that payment category 1 would include any subsequent additions to intravenous infusion drugs, payment category 2 would include any subsequent additions to subcutaneous infusion drugs, and payment category 3 would include any subsequent additions to intravenous chemotherapy or other highly complex drug or biologic infusions.³

NHIA notes that Xembify® J1558 (INJECTION, IMMUNE GLOBULIN (XEMBIFY), 100 MG) was added to the External Infusion Pump LCD effective May 31, 2020 and should be reflected as a category 2 drug in Table 12 of the Proposed Rule. In addition, on July 23, 2020, the DME MACs released the final External Infusion Pump LCD, which adds coverage of Cutaquig® effective September 6, 2020. Cutaquig® also should be listed as a category 2 drug in future rule making.

NHIA Recommendation:

NHIA requests that CMS include Xembify® and Cutaquig® in payment category 2 in the final rule.

Enrollment Issues

CMS proposes to require that home infusion therapy suppliers complete and submit the form CMS-855B Medicare enrollment form. In addition, CMS previously has stated that home infusion therapy suppliers will be required to enroll in each of 12 Medicare A/B MACs in order to bill for home infusion therapy services in those areas, which may require obtaining MAC specific NPI numbers. NHIA continues to have concerns that this enrollment requirement is unduly burdensome. In addition, home infusion therapy professional services are primarily pharmacy-based and currently do not require the provider to be in the same physical state as the patient. NHIA is concerned that some A/B MACs will require providers to have a physical presence in their jurisdiction or state, which would cause an unnecessary burden and dramatically reduce the number of providers available to provide services to Medicare beneficiaries, especially in rural areas

NHIA Recommendation:

NHIA requests that CMS allow home infusion pharmacies enrolled with the Medicare Part B Durable Medical Equipment program to provide external infusion pump items to utilize their existing NPI number when enrolling with the A/B MACs to provide home infusion therapy services. NHIA also requests that CMS ensure home infusion therapy service suppliers are not required to have a physical presence in the state or jurisdiction to provide and bill for services.

³ *Id.* at 39437.

NHIA appreciates the opportunity to provide comments on these important issues and we welcome the opportunity to continue working with CMS to improve the Medicare home infusion therapy benefit for Medicare beneficiaries. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan".

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer