National Home Infusion Association

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May 8, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1744-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC)

Dear Administrator Verma:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the interim final rule with comment period: *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (the "Interim Final Rule") published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on April 6, 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 the changes CMS is making to respond to the COVID-19 public health emergency (PHE). In general, NHIA appreciates the spirit with which the Interim Final Rule was written, putting patients over paperwork and reducing regulatory red tape that together make critical health care services and innovations, like telehealth technologies, available safely to the public, in the home, during the pandemic.

For more than 40 years, home infusion pharmacies have safely and effectively coordinated services associated with administering intravenous and subcutaneous medications to patients in their homes, where they are less exposed to the risk of secondary infections. The option to receive these treatments at home has never been more important than now, during the COVID-19 pandemic.

[1] 85 Fed. Reg. 19,230 (April 6, 2020).

Home infusion is a safe and effective alternative to institutional care for treatment of many disease states.[2] Offering patients the option to receive home infusion treatments for infection, congestive heart failure, immune diseases, cancer, and a variety of other conditions frees up capacity, allowing 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 PHE, 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. CMS recognizes this priority in some areas of the Interim Final Rule, including policies related to telehealth and laboratory testing. In the context of laboratory testing, CMS notes, "[W]ith patients confined to their homes for their own safety or the safety of others, there is an additional need to have patients tested in their homes and minimize exposure to others." **Despite these observations, CMS does not make significant policy changes in the Interim Final Rule that promote access to home infusion therapy for patients who rely on infused medications to manage their clinical conditions**.

NHIA appreciates the extraordinary efforts CMS has made to respond to the needs of providers to help them safely treat Medicare beneficiaries during this unprecedented public health emergency. While NHIA is encouraged that CMS has acknowledged the need for broader access to infused drugs that are currently delivered across various settings, we do not believe the changes in the Interim Final Rule alone will generate significant improvements in access to home infusion for Medicare beneficiaries who need protection from the spread of COVID-19. NHIA believes that CMS's Interim Final Rule misses a critical opportunity to provide flexibility for vulnerable Medicare beneficiaries to access home infusion. NHIA believes access to home infusion services will only be accomplished when the home infusion provider is reimbursed directly for the time spent coordinating care and providing the necessary professional services (i.e., assessments, therapy design, drug preparation and delivery, monitoring, education, and 24/7 availability). A summary of our recommendations is provided here and articulated in greater detail below.

1) CMS should utilize 1135 waiver authority to allow accredited home infusion providers enrolled in the Part B DMEPOS program to bill services codes G0068, G0069, and G0070 for each day equipment, supplies, and professional pharmacy and/or nursing services are provided for infusion drugs and biologicals billed to Medicare Part D.
2) 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.[3]
3) Allow home infusion providers to bill for professional pharmacist services provided remotely when patients are receiving home health nursing services, which will ensure patients receive the full benefit of both services while maximizing nursing resources.

[2] Polinski, J. M., Kowal, M. K., Gagnon, M., Brennan, T. A., & Shrank, W. H. (2017). Home infusion: Safe, clinically effective, patient preferred, and cost saving. Healthcare, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004

[3] In a subsequent COVID-19 IFR issued on April 30, CMS clarified that pharmacists are included within the regulatory definition of "auxiliary personnel." *See* 85 Fed. Reg. 27,550 (May 8, 2020).

4) For drugs covered under the Medicare Part B DMEPOS benefit, CMS should use existing authority to issue guidance revising the definition of "infusion drug calendar day" to remove the in-person requirement and permit payment for each day services are provided remotely by pharmacists and nurses as outlined in the plan of care authorized by the physician.
5) NHIA does not recommend CMS expand home infusion access to additional drugs and biologicals through the External Infusion Pump local coverage determination (LCD) because of risks for shortages of durable medical equipment (DME) for certain therapies, and increased exposure to contaminated equipment being returned to the pharmacy.

The Use of Interactive Telecommunications Technology to Expand Home Infusion Access for Drugs not Covered under the Medicare Part B DMEPOS Benefit

NHIA supports the use of telehealth visits as an alternative for physician office or home health visits to assess a patient's progress toward therapy goals. The use of real-time, interactive audio and video technology when indicated to reduce the risk of exposure to coronavirus for the beneficiary or health care provider is a positive step forward to supporting remote services to patients at risk of severe complications from COVID-19. Despite these enhancements, significant challenges remain when providing physician incident-to infused drugs to beneficiaries at home. Home infusion requires additional services that go beyond the usual physician practice capabilities. Many physicians do not have the operational capacity to conduct assessments of home environment safety; develop protocols and procedures to facilitate home administration; arrange delivery of the drug, equipment, and supplies to the patient's home; provide 24/7 support for patients receiving infusions over extended timeframes; and coordinate nursing services. Additionally, while subcontracting for the nursing-related services to a home health agency or home infusion therapy services provider is an option, most physicians do not have the relationships or administrative capacity to enter into workable arrangements.

By contrast, the private sector model for providing home infusion therapy leverages capabilities of pharmacists and nurses working at the top of their licenses to coordinate and facilitate the administration of home infusion therapies. NHIA recommends that CMS allow physicians to delegate the coordination of home infusion therapy to home infusion pharmacists and nurses specially trained to manage these services in the home setting, just as they do today for patients with commercial insurance and under the Medicare Part B home infusion benefit. To support this recommendation, which is consistent with how home infusion services are delivered in the private sector, CMS should provide direct reimbursement to the home infusion provider.

The majority of home infused drugs (e.g., antibiotics, hydration with electrolytes, biologics) do not require the use of a mechanical pump and are readily accessible to patients with commercial insurance. While infusion drugs administered at home using non-mechanical devices are billed to Medicare Part D, there is no coverage for the supplies and professional services, which severely limits access to home infusion for millions of Medicare beneficiaries. This gap in the Medicare program results in beneficiaries having to either pay out-of-pocket, defy stay-at-home recommendations, or skip needed medical treatments. Home infusion providers are already able

to acquire the majority of infused drugs through the Medicare Part D program, and Part D plan administrators have existing networks of credentialed home infusion pharmacies capable of procuring and billing for infused drugs administered in the home setting. Building on this existing infrastructure will prevent delays in program implementation by eliminating the need to enroll providers into A/B MACs, ensuring home infusion providers are not burdened with developing billing software programs in order to access Part B drug reimbursement, and ensuring that CMS and the A/B MACs are not burdened with developing and implementing a new enrollment process to accommodate home infusion providers. To expeditiously create home infusion access for all Medicare beneficiaries who need it due to the risk of serious complications from COVID-19 during the PHE, NHIA believes CMS should use 1135 waiver authority to close the supplies and professional service coverage gap that exists today for infused drugs and biologicals billed to Medicare Part D.

NHIA Recommendation:

> **CMS should utilize 1135 waiver authority to allow accredited home infusion providers enrolled in the Part B DMEPOS program to bill services codes G0068, G0069, and G0070 for each day supplies and professional pharmacy and/or nursing services are provided for infusion drugs and biologicals billed to Medicare Part D.**

Billing for Professional Services Provided Remotely

In order to initiate home infusion services, the physician must identify an eligible patient, order the infusion drug, and sign a plan of care outlining the specific elements and frequency of the services to be delivered. The home infusion therapy plan of care, in conjunction with visits performed by the physician either in the office or through newly created telehealth programs allow physicians to maintain oversight of the home infusion treatment. The sub-contracting arrangements proposed in the IFR offer an unnecessarily arduous solution for both the physician and the home infusion therapy provider. No precedent exists for this type of arrangement for home infusion service provided in the private sector today.

CMS has set a helpful precedent in the IFR by extending physician supervision to auxiliary personnel, including pharmacists to "…leverage additional staff and technology necessary to provide care that would ordinarily be provided incident to a physicians' service (including services that are allowed to be performed via telehealth)."[4] In the subsequent IFR regarding flexibilities for providers to respond to the COVID-19 public health emergency that was released on March 30, CMS clarified that pharmacists fall within the regulatory definition of "auxiliary personnel" and may provide the services incident to and under the appropriate level of supervision of the billing physician or non-physician practitioner (NPP) if payment for the services is not made under Medicare Part D. CMS stated its belief that this clarification may encourage pharmacists to work with physicians and NPPs in additional ways to expand the

[4] 85 Fed. Reg. 19,230 at 19,246

availability of health care services during the public health emergency.[5] Consistent with that goal, NHIA believes a pharmacist or nurse, working under the physician home infusion plan of care should be able to bill for services through the home infusion therapy services benefit. Therefore, NHIA recommends CMS allow home infusion providers to bill for infusion-related services (i.e. assessments, education, and monitoring) provided remotely by pharmacists and nurses for home infusion patients.

NHIA Recommendation:

> **Allow home infusion providers to bill services codes G0068, G0069, and G0070 for pharmacy and nursing professional services provided remotely in accordance with the plan of care authorized by the physician.**

Intersection of Home Infusion Therapy and Home Health

NHIA fully supports the expansion of home health through CMS's efforts to expand the definition of "homebound" to include a beneficiary who "has a condition that may make him or her more susceptible to contracting COVID-19," however this may have the unintended effect of limiting the use of home infusion. Given that the Centers for Disease Control and Prevention (CDC) has identified "older adults" as being at-risk for COVID-19, virtually all Medicare beneficiaries could be considered "homebound" and eligible for the home health benefit, rather than the home infusion therapy services benefit. Currently, home infusion therapy suppliers are precluded from billing Medicare for professional services when a patient is receiving home health services under Medicare Part A. NHIA suggests this can be corrected by allowing the home infusion therapy provider to bill for professional services in situations when a home health agency is providing home infusion nursing services.

> **Allow home infusion therapy providers to bill for professional pharmacist services provided remotely when patients are receiving home health nursing services, which will ensure patients receive the full benefit of both services and to leverage nursing efficiencies.**

Infusion Drug Administration Calendar Day and Physical Presence Requirement for Part B Covered Therapies

Since the beginning of implementation of the Medicare Part B home infusion therapy services benefit, CMS has promulgated policy that reimburses home infusion professional services only on days when a skilled professional is present in the patient's home despite the fact that many patients who receive home infusion today learn to independently administer their medication. In light of the PHE due to the COVID-19 pandemic, this requirement could interfere with the delivery of home infusion services that could otherwise be provided remotely by nurses and

[5] 85 Fed. Reg. 27,550 (May 8, 2020)

pharmacists. Within the context of the temporary transitional payment for home infusion services established by the Bipartisan Budget Act of 2017, CMS defined "infusion drug administration calendar day" as "the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration." NHIA has long contended that CMS's policy is inconsistent with the statute that created the benefit and with Medicare Advantage, TRICARE, and commercial insurance plans, which reimburse for each day a patient receives treatment, regardless of whether a skilled professional is present. Indeed, Members of Congress have sent numerous letters to CMS consistent with this position. Moreover, this physical presence requirement is inconsistent with the statute and unnecessarily requires healthcare personnel to make in-home visits when existing standards of care allow for certain services to be provided remotely.

NHIA Recommendation:

> **For drugs covered under the Medicare Part B DMEPOS benefit, CMS should use existing authority to issue guidance revising the definition of "infusion drug calendar day" to remove the in-person requirement and permit payment for each day services are provided remotely by pharmacists and nurses as outlined in the plan of care authorized by the physician.**

Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic

In the Interim Final Rule, CMS relaxes the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump national coverage determinations (NCDs) and local coverage determinations (LCDs) during the public health emergency. NHIA supports CMS not enforcing these clinical indications during the public health emergency. Relaxing the clinical indications for the drugs covered under the Medicare Part B durable medical equipment (DME) benefit may reduce delays in accessing the few drugs covered, but could go further to expand access to all patients who receive Part B-covered infused therapies. NHIA recommends expanding the non-enforcement of clinical indications for parenteral nutrition and enteral nutrition policies so facilities are able to rapidly transition patients to the home environment. NHIA also requests CMS confirm that home infusion services can continue for beneficiaries accepted during the public health emergency when policy reverts back to enforcement of clinical indications.

Most drugs and biologics administered at home do not require the use of DME (infusion pumps). While pumps are unavoidable in cases where the drug requires continuous or very frequent dosing (i.e. every 4 to 6 hours), their use should be minimized to such cases during this PHE. Infusion pumps introduce complexity which often extends the time nurses must spend in the home for teaching. NHIA also has concerns for impeding access to certain home infusion therapies (i.e. parenteral nutrition, pain management, immune globulin) as a result of requiring pumps be used for an expanded number of drugs that do not routinely use them today. Additionally, this approach to expanding home infusion therapy may have other unintended consequences such as increasing compounding time and increasing exposure of nursing and

pharmacy staff to coronavirus and other infectious pathogens during return delivery, cleaning, and testing procedures associated with DME.

NHIA Recommendation:

> **NHIA does not recommend CMS expand home infusion access to additional drugs and biologicals through the External Infusion Pump LCD.**

In conclusion, NHIA asks CMS to adopt policies that leverage the home site of care whenever possible to free up limited capacity in institutional settings. This would allow acute care professionals to care for those most affected by the virus as well as limit exposure for our vulnerable Medicare population. If CMS adopts the recommendations NHIA has outlined, which have demonstrated high rates of success and satisfaction in the commercial sector, home infusion can be an immediate and powerful tool in the fight against COVID-19.

NHIA appreciates the opportunity to provide comments on these important issues and we welcome the opportunity to serve Medicare beneficiaries in offering expanded home infusion options during the COVID-19 pandemic. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

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