



December 9, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1711-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Dear Administrator Verma:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the Final Rule with comment period entitled “Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements,” (hereinafter “Final Rule”) published in the Federal Register on November 8, 2019.<sup>1</sup> NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion industry, we write to share our feedback on the questions CMS posed regarding options to improve future policies regarding coverage of eligible drugs for home infusion therapy.

In the Final Rule, CMS solicited comments on the criteria it should consider to allow coverage of additional drugs under the durable medical equipment (DME) benefit. In addition, CMS asked for suggestions on options to enhance future policies related to coverage of eligible drugs for home infusion therapy. NHIA does not support expanded coverage for additional drugs eligible for home infusion therapy as it is defined by CMS in the Final Rule. We respectfully provide our reasoning here.

### Eligible Drugs

NHIA does not support any expansion of coverage of additional drugs eligible for home infusion therapy, as this would increase the number of drugs that are subject to CMS’s seriously flawed implementation of the home infusion therapy services benefit. Unless CMS corrects the many defects in its implementation of the home infusion therapy benefit, including its incorrect interpretation of “infusion drug administration calendar day,” CMS should not expand the number of drugs eligible for coverage under the benefit as access to these drugs could be negatively impacted. Expansion of the list of drugs eligible for home infusion therapy would further exacerbate the decreases in access that NHIA already is hearing about from its members. For example, we are aware that some home infusion therapy providers are no longer accepting new patients under the Medicare Part B benefit. The publicly available DME Utilization

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<sup>1</sup> 84 Fed. Reg. 60478



data shows that 20 percent fewer Medicare beneficiaries received DME infused drugs in 2017 compared to 2016, likely due to the drastic reduction in drug payments without an off-setting services reimbursement. NHIA again urges CMS to follow the lead of commercial payers. Commercial home infusion benefits are generally structured as a pharmacy-coordinated service through which a home infusion pharmacy assumes responsibility for case-managing the therapy and providing oversight for all of the professional services. As such, commercial payers reimburse home infusion providers for each day the drug is infused.

NHIA also notes the potential for expansion of the home infusion benefit is very limited due to CMS's requirement that Medicare Part B only cover home infusion drugs that are necessary for the effective use of an external infusion pump. This requirement is not consistent with how physicians order drugs for home infusion – home infusion drugs are ordered based on the totality of patient needs, not whether a pump is used.

#### Enrollment

NHIA is also concerned that the lack of clarity around the enrollment process for home infusion therapy (HIT) providers that currently are enrolled as DME suppliers in the A/B Medicare Administrative Contractors (MACs) could further negatively impact beneficiary access. CMS has not issued any guidance in this area and its current enrollment form does not list home infusion therapy as a supplier type. NHIA has many questions regarding this process and we welcome the opportunity to meet with CMS to try and resolve issues prior to implementation of the permanent home infusion therapy services benefit in 2021.

#### Plan of Care

CMS states that the home infusion plan of care must be established and reviewed by the physician in consultation with the DME supplier responsible for furnishing the home infusion drugs. NHIA is disappointed that CMS did not address the concerns expressed by home infusion providers in our comments to the proposed rule regarding the fragmentation of care this policy promotes. Requiring the physician (who may be separate and distinct from the physician ordering the DME) to sign the HIT plan of care and coordinate services between the HIT and DME suppliers will create an unnecessary administrative burden for physicians as well as HIT providers, and will further reduce access to HIT services for Medicare Part B beneficiaries.

NHIA thanks CMS for the opportunity to provide comments on these important issues and we welcome the opportunity to work with the organization on alternative approaches to implementation of the home infusion therapy services benefit. If CMS has questions or needs additional information, please contact me at [connie.sullivan@nhia.org](mailto: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