[DATE]

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 [ORGANIZATION NAME] 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.[[1]](#footnote-1) [INTRODUCTION TO COMPANY AND WHAT COMPANY DOES IN RELATION TO HOME INFUSION]

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. [ORGANIZATION NAME] does not support expanded coverage for additional drugs eligible for home infusion therapy as it is currently defined by CMS in the Final Rule. We respectfully provide our reasoning here.

Eligible Drugs

[ORGANIZATION NAME] 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. The publicly available data shows a sharp decline in the number of Medicare beneficiaries utilizing DME infused drugs from CY2016 to CY2017, when the reduction CURES Act drug reimbursement reduction went into effect.

[STATEMENT OF HOW THE EXISTING TEMPORARY RULE AND/OR THE PROPOSED RULE FOR 2021 IS/WILL IMPACT YOUR PATIENTS AND BUSINESS]

Enrollment

[ORGANIZATION NAME] 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. [INSERT CONCERNS RELATED TO ENROLLMENT IN A/B MAC.] Note: A/B MACs do not have a clearing house for enrollment, requiring the HIT supplier to enroll with each of the 12 A/B MACs that it plans to provide service and which is based on where the beneficiary resides. A/B MAC policies are largely based on bricks and mortar physical locations, while home infusion services are coordinated/dispatched from a central location to a wide geographic area, often over state lines and across Jurisdictions.

Accreditation

[ORGANIZATION NAME] is also concerned with the timing of CMS identifying deemed Accreditation Organizations (AO) being such that it may not allow time for those that wish to continue providing the full range of home infusion services (including nursing). [INSERT CONCERNS RELATED TO ACCREDITATION] Note: my organization has been accredited with (INSERT AO) for X years. This accreditation is accepted by commercial payers as evidence that we meet high standards in the provision of and coordination of care.]

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. [ORGANIZATION NAME] 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.

[EXAMPLE OF HOW RULE WOULD IMPACT YOUR PATIENTS AND BUSINESS]

Conclusion

[ORGANIZATION NAME] 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 [CONTACT INFO].

Sincerely,

[NAME AND TITLE]

1. 84 Fed. Reg. 60478 [↑](#footnote-ref-1)