December 29, 2019

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comment on CMS-2019-0100-0562 ("Medicare and Medicaid Programs: CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements.")

Dear Administrator Verma,

On behalf of the 25 to 30 million Americans with one of the over 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments on the final rule titled, "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."

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. Since 1983, we have been committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

NORD believes that all rare disease patients should have access to quality, affordable health care that is best suited to their medical needs. NORD aims to ensure that the perspective of the rare disease patient is considered each time a decision by the federal government can impact access to care.

Obtaining appropriate care can be particularly challenging for rare disease patients. It can often take years for a rare disease patient to acquire a diagnosis. Further, once a patient secures a diagnosis, it is unlikely that there will be a treatment that has been approved by the Food and Drug Administration (FDA) to treat his or her rare disease, given that over 90 percent of the 7,000 rare diseases are still without an approved therapy.

Fortunately, science is advancing rapidly and patients who were once without any hope of receiving targeted treatments for their condition may soon have access to an approved therapy. It is a significant landmark when FDA approves a therapy for a patient's rare disease. Once a drug is approved by FDA, though, patients quickly face challenges associated with obtaining coverage of the therapy. Congress has sought to address some of these challenges. Specifically for patients requiring infusions of therapies in the home, Congress aimed to ease some of the barriers to care by enacting specific

provisions in the 21st Century Cures Act of 2016 and the Bipartisan Budget Act of 2018.[1,2] As CMS itself recognized, these provisions, which established the home infusion benefit, "give patients the freedom to safely access critical treatments, such as chemotherapy, at home instead of traveling to the hospital or doctor's office, improving their quality of life."[3] This is only the case, however, if CMS properly administers this benefit.

CMS has interpreted the definition of "home infusion drug" in section 1861(iii)(3)(C) of the Social Security Act to mean drugs delivered through a pump that "is an item of DME [durable medical equipment] covered under the Medicare Part B DME benefit."[4] NORD urges CMS to recognize and facilitate the clear intent of Congress to allow for expeditious access to new therapies coming to market by updating those drugs covered under the DME Local Coverage Determination (LCD) for External Infusion Pumps or by issuing subregulatory guidance that lists new drugs as home infusion drugs as allowed under section 1834(u)(7)(C) of the Social Security Act. The existing process for coverage under the Medicare Part B DME benefit, without intervention, is insufficient to meet the expectations of patients and Congress alike.

As CMS frequently points out in this final rule, the home infusion benefit applies to "a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of DME as defined under section 1861(n) of the Act… [not including] insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list."[5] Despite this definition, MACs have repeatedly denied coverage for non-self-administered therapies, according to numerous reports from rare disease stakeholders.

CMS should promptly ensure that innovative therapies that clearly ought to be meeting the standard for the home infusion benefit are covered so that patients can access these benefits in their homes. Table 30 within the final rule suggests that CMS has made no additional effort following the passage of the Bipartisan Budget Act of 2018 to update the number of drugs eligible for the home infusion benefit, despite the fact that additional drugs have come to market.[6] For the sake of rare disease patients who depend on new infusion therapies, this list must be updated.

CMS should work to quickly identify new and innovative therapies that qualify for the home infusion benefit and ensure they are considered home infusion drugs either through the LCD reconsideration process or subregulatory guidance. As in other coverage determinations, in developing criteria for extending coverage under the DME benefit, CMS should consider the current standard of care and the potential benefit of home infusion to the patient, such as whether it is medically appropriate, whether the patient will be spared potential infection by remaining in the home and avoiding hospitals, and whether it is difficult for the patient to travel. Further, as is clearly stated in statute, CMS should ensure that therapies that are not self-administered are included.[7]

[1] Pub.L.114-255
[2] Pub.L.115-123
[3] "Trump Administration Announces Steps to Strengthen Medicare with New Home Infusion Therapy Benefit and New Regulations That Put Patients Over Paperwork." *Centers for Medicare & Medicaid Services*, July 11, 2019. https://www.cms.gov/newsroom/press-releases/trump-administration-announces-steps-strengthen-medicare-new-home-infusion-therapy-benefit-and-new.
[4] 84 FR 60478 (pg.60617)
[5] 84 FR 60478 (pg.60613)
[6] 84 FR 60478 (pg.60626)
[7] Section 1861(iii)(3)(C) of the Social Security Act

CMS has a key role to play in ensuring coverage. Patients cannot wait any longer to access these critical therapies in the environment that is safest for them, which is often in the home pursuant to their provider's orders. NORD urges CMS to help advance patient access to innovative therapies by working proactively to incorporate therapies that could be eligible for the home infusion benefit onto DME LCDs or into subregulatory guidance as home infusion drugs.

NORD thanks CMS for the opportunity to comment. We look forward to working with CMS to ensure that rare disease patients have access to needed therapies in the home. For questions regarding NORD or these comments, please contact me at rsher@rarediseases.org, or 202-588-5700.

Sincerely,

Rachel Sher
Vice President, Policy and Regulatory Affairs