October 4, 2021

The Honorable Chiquita Brooks La-Sure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

As leaders in the home respiratory community, we thank you for the support that the Centers for Medicare & Medicaid Services (CMS) has provided to providers and suppliers during the COVID-19 pandemic. As we have shared in other comments, expanding access to home oxygen therapy to certain acute beneficiaries, as well as reducing the documentation burden for chronic beneficiaries, has been instrumental in combating the pandemic. We applaud CMS for not only recognizing the importance of this access during the pandemic, but also for opening the National Coverage Determination (NCD) to provide that coverage permanently.

Yet, to protect this access, it is equally important that current barriers within the documentation and audit requirements are removed so that beneficiaries receive the right equipment at the right place and at the right time. Based on the collective experience of our organizations, we ask that CMS eliminate medical record review and accept the clinician prescription/Standard Written Order as the required documentation for establishing medical necessity, as it does for other prescription medications. Alternatively, along with the prescription, CMS could require clinicians to complete the existing supplemental home oxygen templates that would constitute the sole documentation to establish medical need and be sufficient for medical necessity review.

To achieve CMS's goals of providing beneficiaries with access to supplemental oxygen within in their homes and communities, it is necessary that suppliers be allowed to fill clinician's prescriptions with the assurance that they will be reimbursed, just as pharmacists are when they fill drug prescriptions. Given the complexities of the medical record and differing clinician documentation preferences, medical record review is not optimal and should be avoided. Using the Standard Written Order and CMS's existing templates would provide uniformity and certainty, while eliminating inconsistencies, in the review of individual claims.

During the pandemic, CMS provided flexibilities that removed the requirement for a clinician's medical record notes to be used to document medical necessity in order to pay

the supplier's claim. Instead, medical necessity documentation has been based on the clinician's prescription and the Standard Written Order. This documentation has worked, and there have been no systemic fraud or abuse.

This experience is not surprising given CMS's own data. The publicly available CERT auditor reports demonstrate the problem with using the medical record notes. The CERT reports from the past 10 years show that there is no evidence of fraud or abuse in terms of beneficiaries receiving home oxygen who do not medically require the equipment, supplies, and services. Instead, the basis for denials sits with how contractors interpret clinicians' medical record notes. Less than one percent of the claims denied since 2016 have been because a patient did not medically need the therapy. During the same period, 80-90 percent of home oxygen claims were denied because of a problem the contractor found with the way the clinician documented the patient's condition in the medical record. There is little benefit in this process to the federal government, clinicians, suppliers, and certainly not for beneficiaries.

Eliminating medical record review and contractor discretion in favor of Standardized Written Orders and templates to document medical necessity would protect against fraud and abuse, reduce the burden on clinicians and suppliers, and protect access for beneficiaries. The goal of medical necessity review is to protect the federal government and beneficiaries from fraud. Yet, this well-intentioned program has morphed into an assessment of clinician charting that does not identify fraud or abuse. Without clear, objective standards for review, it will become difficult for suppliers to continue filling clinician prescriptions for beneficiaries. It is time to fix this broken system and make sure that beneficiaries maintain access to these important home oxygen therapies.

Thus, we ask that CMS in connection with the oxygen NCD, as well as through contractor, supplier, and provider guidance, eliminate medical record review and accept the clinician prescription/Standard Written Order as the required documentation for establishing medical necessity.

Sincerely,

AAHomecare
Allergy & Asthma Network
Alpha 1 Foundation
American Association for Respiratory Care
American Lung Association
American Thoracic Society
CHEST/American College of Chest Physicians
COPD Foundation
Council for Quality Respiratory Care
Dorney-Koppel Foundation
Pulmonary Fibrosis Foundation
Respiratory Health Association
U.S. COPD Coalition
VGM & Associates