



February 23, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra,

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. With the recent announcement that the COVID-19 Public Health Emergency (PHE) will end on May 11, we request that the Centers for Medicare & Medicaid Services (CMS) provide a clear transition policy for Medicare beneficiaries who rely upon supplemental oxygen and respiratory therapies, including sleep therapies (*e.g.*, Positive Airway Pressure devices), and non-invasive ventilation (*e.g.*, Respiratory Assist Devices) to remain in their homes and their communities. We also strongly urge CMS to adopt the clinical data element (CDE) oxygen template as the required documentation for establishing medical necessity for beneficiaries receiving supplemental oxygen. We are deeply concerned that if CMS does not take these two steps and does not provide stakeholder notice of these actions well before the PHE's end, we will see beneficiaries lose access to supplemental oxygen and respiratory therapy and end up in acute crises that require more expensive hospitalization or even long-term care.

To protect access to home respiratory therapy, especially in underserved populations, it is imperative that physicians, health care professionals, and suppliers have a clear understanding of how CMS will transition those patients who began oxygen or other home respiratory therapies during the pandemic to post-pandemic documentation requirements.

The larger national suppliers estimate that physicians have prescribed supplemental oxygen to more than one million beneficiaries during the PHE and who will require oxygen, sleep therapy, and non-invasive ventilation after May 11. Under the relaxed documentation standards, the records created for the vast majority of these patients will not meet the pre-pandemic requirements. It is not logistically possible given the current stresses in the health care system to expect all of these beneficiaries to visit their physicians and to be tested again by May 11. In addition, it would not make sense to

ask suppliers to obtain documentation from physicians for beneficiaries prescribed oxygen, sleep therapy, and non-invasive ventilation during the pandemic who no longer require it.

As a community, we ask that CMS adopt a balanced approach that protects Medicare against fraud and recognizes the flexibilities that were in place during the pandemic. Specifically, for patients receiving home oxygen, sleep therapy, or non-invasive ventilation equipment, we ask that CMS grandfather these patients in terms of the qualification requirements that were in place during the pandemic. We believe this policy is consistent with the guidance CMS provided as part of the PHE flexibilities, but needs to be affirmatively stated. For the purposes of audit review process, we request that CMS indicate that:

- Any patient set up during the PHE who ended service (equipment picked up) during PHE would not have his/her claims subject to a medical necessity audit.
- Any patient set up during the PHE who ended service (equipment picked up) within one year of the PHE ending would not have his/her claims subject to a medical necessity audit.
- Any patient set up or that required recertification for oxygen or showing continuing need during the PHE, could be subject to a medical necessity audit. The supplier would have to provide only a standard written order (SWO) to establish the documentation to support any claim that were audited, which would include establishing continued need post-PHE. The SWO would need to be obtained within one year after the PHE ends.
- For other home respiratory therapy equipment, any patient set up that required a showing of continued need, could be subject to a medical necessity audit. The supplier would have to provide only a standard written order (SWO) to establish the documentation to support any claims that were audited. The SWO would need to be obtained within one year after the PHE ends.

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. Prior to the pandemic, it was clear that the medical record review created problems, but at least during appeals suppliers could turn to the Certificate of Medical Necessity (CMN) to show objective support that the physician properly prescribed supplemental oxygen. Under the new NCD and LCDs, however, the CMN has been eliminated and the only documentation Medicare contractors will accept is the patient's medical record.

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. CMS should require clinicians to complete the supplemental home oxygen templates it has already created that would constitute the sole documentation to establish medical need and be sufficient for medical necessity review.

Publicly available CERT auditor reports demonstrate the problem with using the medical record notes alone. 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. Since 2016, the CERT has reported that less than one percent of the improper payment rate was due to patients not meeting Medicare's medically necessity requirements.¹ During the same period, the CERT has also reported that 72 to 99 percent of the oxygen improper payment rate was due to problems with the ordering clinicians' documentation.²

Eliminating medical record review and contractor discretion in favor of Standardized Written Orders and a CDE 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. With the end of the PHE in sight, it is necessary to make sure that beneficiaries maintain access to these important home oxygen therapies.

CMS has created a set of CDE templates that could quickly be updated to address the new policies under the revised oxygen NCD. Requiring Medicare contractors to recognize this document as the basis for medical necessity is long overdue. Using it will allow physicians and other prescribers to know what information is required to establish medical necessity and end the game of "gotcha" that has surrounded the reliance on medical records for too long.

¹Centers for Medicare and Medicaid Services. Comprehensive Error Rate Testing (CERT), *2017-2021 Medicare-for-Service Supplemental Improper Payment Data. Tables D2 and J2*. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports>

²*Id.*; Centers for Medicare and Medicaid Services. Comprehensive Error Rate Testing (CERT), *Medicare Fee-for-Service 2016 Improper Payment Rate Report*. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports>.

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As the country transitions out of the COVID-19 PHE, we want to make sure that beneficiaries who rely upon supplemental oxygen, sleep therapies, and non-invasive therapies continue to be able to access it. We look forward to working with your teams to make sure the transition is successful.

Sincerely,

AAHomecare

American Association for Respiratory Care

American Lung Association

American Thoracic Society

Council for Quality Respiratory Care

Pulmonary Fibrosis Foundation

VGM & Associates