October 10, 2023

Ms. Connie Leonard
Division of Recovery Audit Operations
Provider Compliance Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Connie,

We are writing today to express our concern about the direction of what we understand to be an eClinical oxygen template pilot program based on recent discussions our members have had with the Centers for Medicare & Medicaid Services (CMS) and its contractor Mettle Solutions. We appreciate the ongoing dialogue you have had with the supplemental oxygen prescribers, suppliers, and manufacturers during the last decade. While we were hopeful that the pilot would be the next step in achieving the goal of replacing medical record review with a set of standardized clinical data elements that would clearly indicate what information prescribers need to provide when ordering supplemental oxygen for their patients, it appears that the pilot is focusing on the electronic interface instead of the clinical data elements in the template and complicating what should be a straight-forward process. To that end, we recommend CMS simply require the DME MACs and other contractors to use the existing CMS template (modified consistent with the community's recommendations) so that as audits resume, beneficiaries, prescribers, and suppliers will not be overburdened with audits.

While we very much appreciated the time that the CMS staff and contractor took to learn more about the supplier and prescriber perspective, we found that their questions were not related to the supplemental oxygen template at all. Rather, the presentation focused on a prior authorization electronic submission process. The contractor reported that they did not even know that there was a supplemental oxygen template with standardized clinical data elements under consideration. We shared that the primary pain point in the process is the decision of CMS and the audit contractors to rely solely on prescribers' notes when assessing medical necessity rather than on the actual data elements required to establish medical necessity. Because physicians write their notes to support patient care and not the Medicare audit process, the notes often do not meet the contractor's desired wording. Despite efforts during the last several years to educate prescribers, the problems inherent in this process remain unresolved, as the CERT data have consistently demonstrated. The industry does not

need to test how to exchange information electronically. There are already several ePrescribing platforms and electronic medical record (EMR) systems that can address the goals of the pilot. The only pieces missing are the agreed upon clinical data elements and a requirement that the DME MACs and other contractors accept these data elements in lieu of medical records when reviewing audited claims.

The problem that the community would like CMS to address is the Medicare program's reliance on medical record notes. This concern stems from the fact that the contractor has not focused on the actual data elements, but rather on how to establish a prior authorization electronic interface, which is not the intent of the clinical template as we understand it. With the ending of the pandemic, the elimination of the Certificate of Medical Necessity, and the initiation of audits, not addressing this central problem will create a costly and unnecessary burden that without having any objective documentation for the appeals process could impact beneficiaries directly.

We agree that the entire process could and should be electronic, but the most important aspect is to have CMS establish the clinical data elements. The work of the pilot would be more impactful if it were based on the already completed oxygen clinical data elements. The first step of the program should be for CMS to agree on the clinical data elements that would be part of a supplemental oxygen template. In light of the changes in the oxygen National Coverage Determination (NCD), the community joined together and offered in April 2023 a set of recommended changes to address the new coverage requirements. We attach these recommendations again to this letter. Once CMS requires DME MACs and other contractors to accept these data elements (*e.g.,* the clinical template) in lieu of medical records, existing private sector tools can be used to achieve the goals of creating an electronic transmission of the data elements more quickly than would building a new system from the bottom up as the pilot seeks to do.

As always, we truly appreciate your engagement with the community. The issue of requiring audit contractors to use standardized clinical data elements in a template – whether on paper or incorporated into ePrescribing and/or EMRs – has been lingering for more than a decade. It is time to take the final step to protect beneficiaries, prescribers, suppliers, and the Medicare program. Once again, you have the commitment of our organizations to support such a step. However, testing the electronic transmissions for a specific contractor is not the same as mandating the supplemental oxygen template. We welcome the chance to talk through the next steps so that the template could be implemented by January 1, 2024.

Sincerely,

AAHomecare
American Association for Respiratory Care
American Thoracic Society
CHEST/American College of Chest Physicians
Council for Quality Respiratory Care
The VGM Group