



Submitted Electronically to: MEDCACpresentations@cms.hhs.gov

June 22, 2020

Medicare Evidence Development and Coverage Advisory Committee
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee – July 22, 2020

Dear MEDCAC members:

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') above captioned notice of its Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on July 22, 2020. AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members provide beneficiaries with respiratory items and services such as ventilators, respiratory assist devices (RADs), continuous positive airway pressure devices (CPAPs), and home oxygen therapy in their homes every day.

We thank MEDCAC and CMS for holding a public meeting to discuss home use of noninvasive positive pressure ventilation in patients with chronic respiratory failure (CRF) due to chronic obstructive pulmonary disease (COPD). Having a public discussion to comprehensively discuss all of the available clinical evidence is an important start in developing coverage criteria that will ultimately impact the lives of patients with CRF. We are concerned, however, that the short timeframe between the announcement of the meeting and comment due date has limited the Committee's access to all the available and relevant information. With the current COVID-19 Public Health Emergency, it is a demanding time for respiratory clinicians and the DMEPOS community, limiting the bandwidth available for stakeholders at this time. Our members and the clinical community have been overwhelmed with taking care of COVID-19 patients and navigating

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through this unpredictable environment. Recognizing the strain COVID-19 has put on the DMEPOS industry, in April, CMS removed non-invasive ventilators from Round 2021 of the Competitive Bidding Program to protect patient access.¹ We do not believe it is the time for MEDCAC to hold this meeting while the nation is in the midst of a pandemic. We recommend MEDCAC and CMS extend the comment deadline beyond June 22nd and postpone the July 22nd meeting to allow for all stakeholders to weigh in on this important discussion.

COPD is a treatable respiratory disease that is characterized as “breathlessness.” The underlying cause and response to treatment vary from patient to patient. It is important to protect access to effective therapy options and allow for clinicians to select the best equipment for their patients. Any coverage criteria Medicare develops must be clear to ensure there are no adverse effects on the documentation requirements. The 2019 CERT Supplemental Improper Payments Data states that 78.1% of the DME error rate is due to insufficient documentation by the prescriber while 5.7% is due to lack of medical necessity.² For CPAP, the CERT reported 83.5% error rate due to insufficient documentation and 1.7% due to medical necessity.³ These numbers indicate that prescriber intent and patient needs usually meet coverage criteria and the problem is CMS’ burdensome documentation requirements. We recommend MEDCAC provide clear coverage recommendations to CMS to avoid complicating documentation requirements even further.

AAHomecare is in support of the recommendations provided by the clinical community. In addition, we are in support of comments submitted by the Council for Quality Respiratory Care, ResMed, Hillrom and other AAHomecare members that have provided clinically based responses to the four discussion questions. Our DME supplier and manufacturer members work in partnership with the clinical community in providing appropriate, effective services to respiratory patients and are committed to providing innovative accessible therapies. Due to the clinical expertise and the deep understanding of the health outcomes, AAHomecare urges MEDCAC to consider all recommendations provided by the clinical community and DMEPOS industry.

In support of the clinical community, AAHomecare recommends MEDCAC to not endorse length of use as a criterion. The clinical community has contended that length of use parameters would be difficult to implement and document because it is ambiguous and subjective. To protect patient access to important life-enhancing equipment, MEDCAC should not recommend implementing a time-based criterion.

We thank MEDCAC for considering stakeholder feedback and ask that the MEDCAC consider all clinical data evidence available. It is our understanding there are conflicting studies on the

¹ *Competitive Bidding Implementation Contractor, “CMS REMOVES NON-INVASIVE VENTILATORS FROM ROUND 2021 OF THE COMPETITIVE BIDDING PROGRAM” Updated 04/09/2020:*

<https://www.dmecompetitivebid.com/cbic/cbic2021.nsf/DocsCat/News~TXYEIKZ5FH?open&navmenu=||>

² *Centers for Medicare and Medicaid Services. 2019 Medicare Fee-for-Service Supplemental Improper Payment Data.*

³ *Id.*

benefits of respiratory products and we believe it is important that all clinical studies are reviewed when determining coverage criteria. We also recommend MEDCAC and CMS continue to solicit industry input after coverage criteria is determined. We believe stakeholder involvement throughout the process is crucial in ensuring patient access.

We appreciate the opportunity to provide comments. This Committee's discussion is a meaningful step in the development of policies that will impact the quality of care for COPD patients. We reiterate that we do not believe the Committee provided an adequate notice on this opportunity and recommend extending the comment submission deadline and postpone the July 22nd meeting. Please feel free to reach out to me if there are any questions. I can be reached at (202)372-0753 and TomR@aahomecare.org. We look forward to future opportunities for collaboration.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Ryan", with a stylized, cursive script.

Tom Ryan
President & CEO
American Association for Homecare