



**Congress of the United States**  
**House of Representatives**

April 25, 2017

The Honorable Thomas E. Price, M.D.  
Secretary  
United States Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Price:

I am contacting you on behalf of all the national pulmonary medicine societies and related patient groups (American College of Chest Physicians, American Thoracic Society, National Association for Medical Direction of Respiratory Care, American Association for Respiratory Care, the American Lung Association, the COPD Foundation, the ALS Foundation, the Post Polio Network, the Cystic Fibrosis Foundation, the Pulmonary Fibrosis Foundation and the United Spinal Association) to request your assistance on a lingering and problematic policy at the Centers for Medicare and Medicaid Services (CMS).

In March of 2014, at the request of the Durable Medical Equipment Medicare Administrative Contractors (DME MAC) medical directors, the pulmonary medicine societies undertook a major effort to create a "white paper" addressing appropriate use of a range of ventilators to treat various chronic pulmonary related diseases in the home. That lengthy document has not resulted in any formal response other than acknowledgement of receipt of the white paper.

In the spring/summer of 2015, because of the lack of response, their focus shifted to CMS central office to address several key issues impacting severely ill patients at home who require mechanical ventilation:

1. CMS does not accept Food and Drug Administration (FDA) classifications of certain devices as "ventilators," instead referring to them as "respiratory assist devices." This term that does not appear in the clinical literature and continues to confuse the broad medical community because of inconsistent decisions by CMS in application of existing rules and regulations.
2. CMS rules and regulations continue to create an environment where the most expensive home ventilators are relatively easy to access and more appropriate, less expensive ventilators have notable clinical requirements for access that challenge even the most respected pulmonary physicians.
3. After meetings, conversations, and e-mail exchanges, CMS recommended that the societies submit a formal request for a National Coverage Determination (NCD) re-consideration to address their concerns, pointing out that other regulatory options were not available.
4. That formal request was submitted early in 2016, and existing rules clearly state that a response is generally provided within 60 days. After 180 days the societies received a letter from CMS indicating that the issue is complicated and has local and national considerations, and therefore they will not act on the request.

The impact of this lack of direction from CMS has been highlighted by the Office of Inspector General (OIG), clearly documenting what the pulmonary physician community and others have been telling the Agency for years: Devices are being used inappropriately at great cost to the taxpayer.

In the view of the pulmonary medicine societies, the only avenue left open prior to a legislative fix would be action by the Coverage & Analysis Group to act on the societies' formal request that would recognize FDA classifications of mechanical ventilators, require CMS to create categories for appropriate usage of home mechanical ventilators (continuous, nocturnal, and intermittent), and several other actions to improve access to home mechanical ventilators and reduce costs to the program. Importantly, the clinical and patient communities are not making any recommendations regarding payment amounts for these devices.

As a medical professional, you know the importance of working with the clinical and patient communities to address issues such as these. I respectfully request that the Department work with these medical societies to resolve this problem. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Collins". The signature is fluid and cursive, with the first name "Chris" and last name "Collins" clearly distinguishable.

CHRIS COLLINS  
Member of Congress