Act Now to Protect Medicare Respiratory Patients:
Pass S. 2736/H.R. 5210 "The PADME Act"

COPD is a costly and deadly disease that is on the rise

Chronic Obstructive Pulmonary Disease (COPD) is the **third leading cause of death in the U.S.**[1] COPD encompasses **a number of lung diseases** that result in patients not getting enough oxygen into their blood and/or not being able to get rid of enough carbon dioxide. Over time, the patient's body becomes stressed and unhealthy. Without sufficient oxygen, the rest of the organs cannot work properly. **Emphysema and chronic bronchitis** are the most common conditions in the COPD group of diseases.[2] Causes of COPD include exposure to tobacco smoke, air pollution, infectious diseases, and genetic conditions.

12 percent of Medicare fee for service beneficiaries live with COPD,[3] which is more than those fighting Alzheimer's Disease (11%), artial fibrillation (8%), cancer (8%), osteoporosis (7%), asthma (5%), and stroke (4%). **Dually eligible beneficiaries are 1.7 times more likely to have COPD** than non-dually eligible beneficiaries.[4] COPD patients often have **5 or more comordities** in addition to their respiratory disease.[5] There is evidence of a **gender disparity in COPD**: women are surpassing men in terms of morbidity and mortality. **Women are twice as likely to be diagnosed with COPD**.[6]

Beneficiaries with stroke and COPD, which is one of the 5 most costly combinations of comorbidities, have per **capita costs that are 5 times higher** than average spending for Medicare fee for service beneficiaries.[7] **20 percent** of patients hospitalized with COPD exacerbations are **readmitted within 30 days**. These exacerbation **costs account for nearly 70 percent of the estimated $50 billion in annual COPD expenditures**, with **readmission-related expenses ranking third highest among Medicare beneficiaries**.[8] **Deaths from COPD are increasing annually.**[9]

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[1]Centers for Disease Control and Prevention
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm?s_cid=mm6146a2_w
[2] American Lung Association *Trends in COPD: Morbidity and Mortality* (2013)
http://www.lung.org/assets/documents/research/copd-trend-report.pdf
[3]Centers for Medicare & Medicaid Services https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf
[4]*Id.*
[5]*Id.*
[6] ALA supra note 2
[7]CMS supra note 3.
[8] COPD Foundation at http://www.copdfoundation.org/About-Us/Press-Room/Press-Releases/ID/223/COPD-Foundations-COPD-Readmissions-Summit-Identifies-Strategies-for-Reducing-Hospital-Readmissions-Develops-Compendium-of-Best-Practices.aspx
[9]ALA supra note 2.

COPD can be effectively managed, improving patient quality of life and reducing overall Medicare expenditures.

Yet, the disease **can be managed** with the proper use of home respiratory therapies, including **oxygen therapy and sleep therapy**.[10] Supplemental oxygen increases the amount of pure oxygen a patient breathes in. The supplemental oxygen provides the lungs with more oxygen to absorb and distribute to the rest of the body. By getting the most oxygen possible, breathing is easier and patients are able to do more activities without becoming short of breath.

The proper management of COPD in the home is critical to reducing emergency room (ER) visits and hospital readmissions. **Medical research finds that long-term oxygen therapy provides evidence to reduce readmissions**.[11]

While CMS has initiated several programs to reduce ER visits and readmissions for COPD patients, each of these programs has expressly excluded home respiratory therapy suppliers. **It is little wonder that for COPD patients the rates for ER visits are on the rise[12] and readmissions have dropped only slightly, falling far short of the reductions achieved for other disease states.** The CQRC believes that this difference stems from the fact that **CMS has ignored a critical care partner in managing COPD by excluding home respiratory therapy suppliers and simultaneously has created disincentives to provide care management and coordination services by implementing draconian rate cuts**.

As the data show, the prevalence of COPD is on the rise[13] and the costs of treating complications of the disease are increasing.[14] It seems shortsighted to try to cut home respiratory therapy services to the bone and disincentivize the provision of services that can lower overall Medicare spending; but that is precisely what CMS has done. Thus, as more patients with COPD age into Medicare, there will be fewer services to help them manage their disease and stay out of the hospital.

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[10]A. Dalal, F. Liu, & A. Riedel, "Cost trends among commercially insured and Medicare Advantage-insured patients with chronic obstructive pulmonary disease: 2006 through 2009," Int J Chron Obstruct Pulmon Dis. 2011; 6: 533–542 (Oct. 2011); J M Tuggey, P K Plant, M W Elliott , "Domiciliary non-invasive ventilation for recurrent acidotic exacerbations of COPD: an economic analysis" 58 Thorax 867–871 (2003).

[11]*See, e.g.,* Stoller, James K., et al., *Oxygen Therapy for Patients with COPD, Current Evidence and the Long-Term Oxygen Treatment Trial,* Chest, Vol. 138(1), July 2010; O'Reilly, Philip and William Bailey, *Long-term Continuous Oxygen Treatment in Chronic Obstructive Pulmonary Disease: Proper Use, Benefits and Unresolved Issues,* Pulmonary Medicine, Vol. 13(2), 2007; and Prior, Thomas Skovhus and Thomas Troelsen, Ole Hilberg, *Driving Performance in Patients with Chronic Obstructive Lung Disease, Interstitial Lung Disease and Health Controls,* BMJ Open Respiratory Research, Vol. 2(1), 2015; Panettieri, Reynold A., *Reducing Readmission in COPD,* Emergency Medicine, Published online October 8, 2013.

[12]*See,* State Level Chronic Conditions Tables, Prevalence, Medicare Utilization and Spending, 2007-2014.

[13] Readmission Rates for COPD from State Level Chronic Conditions, Prevalence, Medicare Utilization and Spending, 2007-2014; Rates for all Medicare are from Brennan, National Medicare Readmission Findings: Recent Data and Trends, Office of Information Products and Data Analysis CMS.

[14]COPD Foundation, *supra* note 8.

Applying urban competitive bid rates to the rest of the country may result in Medicare Part B savings, but will increase Medicare Part A expenditures.

While the morbidity, mortality, and costs related to COPD are increasing, CMS has cut rates for home respiratory therapies by applying competitive bid rates to parts of the country excluded from the competitive bidding program.

It is inappropriate to apply competitive bid rates to the rest of the country without further study primarily for three reasons. First, the rates were established using bids from suppliers that included the ability to increase the number of patients they serve in a relatively homogeneous urban area**. The assumptions that applied to these bids are not true in the rural, non-competitive bid areas**.

Second, hundreds of experts have questioned the appropriateness of competitive bid rates. When the program launched, **more than 244 auction experts** wrote to President Obama requesting significant changes in the structure and raising concerns about the lack of transparency. They stated: **"The use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids—submitting bids dramatically below actual cost.**"[15] The prediction appears to have been fulfilled given the rates have fallen more than 50 percent.

Third, the Office of the Inspector General (OIG) reported that CMS has not followed its own rules for qualifying bidders. **Nearly 50 percent of winning bidders who promised to provide services were not licensed in the States in which they won bids.** Including bids from these unqualified bidders into the process for selecting the competitive bid rate essentially results in lower rates. That is because CMS uses a median to set the bid. **If these bidders had been eliminated at the time the rates were set, then the process would have included bidders with higher bids that would have raised the median**, resulting in higher rates. More troubling is that while CMS recognizes the problem and ended the contracts with these suppliers, it has not adjusted the rates. Thus, CMS has also not followed the process it set forth in regulation for setting the rates.

Now CMS wants to apply the results of this flawed system to areas the Congress expressly stated it should not be applied. The competitive bid program currently applies in only 100 areas throughout the United States. Suppliers in these areas have been able to continue providing services because of economies of scale and other methods of reducing costs. These same methods cannot be applied in rural areas. While the CQRC predicts that many suppliers will go out of business and others will not have the resources to take their place, especially in rural areas, more time is needed to evaluate the impact of the cut before it is fully implemented.

[15]Letter from 244 Concerned Auction Experts on Medicare Competitive Bidding Program to President Barak Obama (2011).

Conclusion: Congress needs to act now!

The CQRC remains deeply concerned that if the competitive bid rates are fully applied to noncompetitive bid areas, beneficiaries will experience a substantial reduction in services. Instead of being a partner in managing COPD with physicians and hospitals and serving as the eyes and ears on the ground, suppliers will be forced to reduce contact with patients making them more likely to require ER visits or experience readmissions.

The Congress should quickly to enact The PADME Act and extend the phase-in of the full application of competitive bid rates to noncompetitive bid areas. With the additional time, home respiratory suppliers can work with the Administration to lower the cost of providing care to beneficiaries in ways that do not impact the services provided. For example, reducing the audit burden and providing prompt payment for services provided through a prior authorization program would significantly reduce costs of serving beneficiaries, as evidenced in managed care and Medicaid programs, while not impacting the actual services provided to beneficiaries. Additionally, we could work with CMS to address the flaws in the current competitive bid process that would allow the program to work as the Congress intended. Most importantly, extending the phase-in period will provide the Administration and the Congress with the information it needs to understand whether it is actually appropriate to apply these flawed rates to the rest of the country.