



June 22, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
Committee on Finance
U.S. Senate
131 Russell Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
Committee on Finance
U.S. Senate
475 Russell Senate Office Building
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

The Council for Quality Respiratory Care (CQRC) appreciates the opportunity to provide recommendations to the Senate Finance Committee to develop solutions to help improve health outcomes for Medicare patients with chronic conditions. Specifically, the CQRC recommends:

- Establishing policies that mirror the best practices for home respiratory therapy of the most efficient and effective Medicare Advantage plans, such as implementing a timely prior authorization process;
- Allowing home respiratory therapy suppliers to participate in Medicare alternative payment programs;
- Providing stable payment rates related to the cost of providing services for home respiratory therapy services and rewarding home respiratory therapy suppliers that reduce COPD hospital admissions; and
- Permitting the use of telehealth services to fulfill face-to-face visit requirements.

The CQRC is a coalition of the nation's seven leading home oxygen and sleep therapy provider and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare beneficiaries with Obstructive Sleep Apnea (OSA).

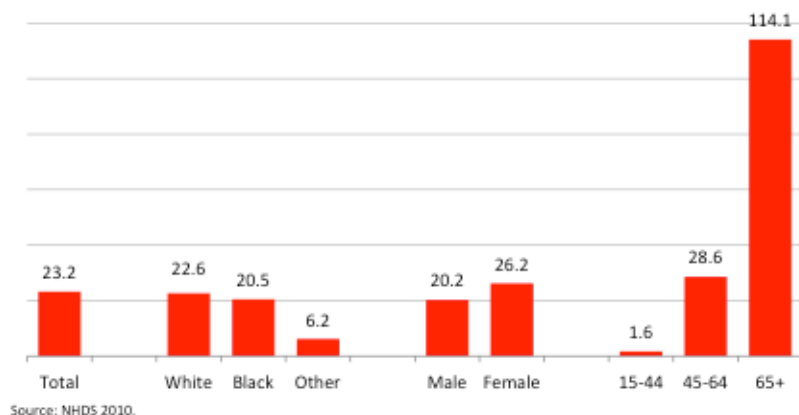
I. The Critical Role of Home Respiratory Therapy in Improving Outcomes for Patients with COPD.

The area of home oxygen therapy provides a clear example of the benefit to patients and cost-savings to Medicare. Chronic Obstructive Pulmonary Disease (COPD) affects more than 24 million Americans.¹ CMS estimates that 12 percent of Medicare fee for service beneficiaries are living with COPD, making it one of the top 10 chronic conditions among Medicare beneficiaries.² Dual-eligible beneficiaries are 1.7 times more likely to have COPD than non-dual eligible beneficiaries.³ COPD is the third leading cause of death in America, claiming the lives of 134,676 Americans in 2010.⁴

The costs associated with COPD extend well beyond the cost of home respiratory therapy services. If not managed appropriately, COPD leads to emergency room visits and hospitalizations.

COPD is an important cause of hospitalization in our aged population. Approximately 65% of discharges were in the 65 years and older population in 2010. As seen in Figure 9, the discharge rate for the population over age 65 (114.1 per 10,000 persons) was over four times higher than that in the 45-64 age group (28.6 per 10,000 persons).⁵

Figure 9: COPD – First-Listed Hospital Discharge Rates per 10,000, 2010



¹COPD Foundation, "COPD Statistics Across America," <http://www.copdfoundation.org/What-is-COPD/COPD-Facts/Statistics.aspx>

²CMS, "Chronic Conditions among Medicare Beneficiaries: Chartbook" 6 (2012).

³*Id.* at 9.

⁴Centers for Disease Control and Prevention. National Center for Health Statistics. National Vital Statistics Report. *Deaths: Final Data for 2010*. May 2013; 61(04).

⁵American Lung Association, "Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality" 20 (March 2013).

Hospitalization and readmissions are the primary drivers of the cost of caring for COPD patients. The National Heart Lung and Blood Institute estimated that the national projected annual cost for COPD in 2010 was \$49.9 billion, including \$29.5 billion in direct health care expenditures, \$8.0 billion in indirect morbidity costs and \$12.4 billion in indirect mortality costs.⁶ According to the COPD Foundation, the total costs incurred by COPD patients are approximately \$6000 higher than those incurred by non-COPD patients. Approximately, 13-14 percent of COPD patients had a hospital readmission, while 41-49 percent had a readmission within 60 days after discharge.⁷

The majority of these costs can be avoided with proper disease management. Effective management of COPD means reducing the frequency and severity of exacerbations, as well as controlling baseline symptoms. The primary maintenance therapy for managing severe COPD is home oxygen therapy.⁸ Without such therapy, severe exacerbations can occur and require hospitalization.⁹ In 2009, the mean-adjusted standard hospital admissions cost for a COPD patient in Medicare was more than \$14,000.¹⁰ "Treatments that reduce the frequency of COPD-related hospitalizations or exacerbations are also associated with lower COPD-related medical costs, and in some cases lower total COPD-related costs."¹¹ In fact, the COPD Foundation estimates that 40 percent of COPD costs could be avoided by preventing complications and hospitalizations.¹² The reduction in hospitalizations results in a substantial reduction in overall Medicare savings.

Similarly, positive pressure therapies, such as CPAP and BiPAP, have been shown to be effective for treating COPD and obstructive sleep apnea (OSA). Studies have shown that providing these types of therapies in the home reduces hospital admissions and minimizes overall costs.¹³ One recent study found that patients with OSA who receive positive airway pressure therapy (PAP) have lower overall medical costs (\$645.66 per patient per month) and better health outcomes than those who

⁶National Heart Lung and Blood Institute. Morbidity and Mortality: 2009 Chart Book on Cardiovascular, Lung and Blood Diseases.

⁷COPD Foundation, "Impact of COPD on Health Care Costs" available at <http://www.copdfoundation.org/pdfs/Impact%20on%20Costs.pdf>.

⁸A. 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).

⁹*Id.*

¹⁰*Id.*; see Figure 3.

¹¹ *Id.*

¹²COPD Foundation, *supra* note 7.

¹³J 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).

did not (\$846.58 per patient per month).¹⁴ Patients using PAP also have fewer hospitalizations than those who do not.¹⁵ OSA is an independent risk factor associated with cardiac readmissions. Controlling the disease through the use of home sleep therapy has been found to reduce hospital readmissions.¹⁶ Just as importantly, home sleep therapy improves patients' quality of life.¹⁷

As the research shows, the cost of providing home respiratory therapy is not the driver of the high costs for these beneficiaries. In fact, home respiratory services lower Medicare costs by providing a critical alternative to hospitalizations. CQRC members help patients manage their diseases and distinguish themselves among suppliers by providing subclinical services to patients to ensure that they remain compliant with their prescribed therapy and medications. These suppliers demonstrate that providing high quality care can lead to lower overall Medicare expenditures.

More work should be done to leverage the potential for home respiratory therapy to reduce hospitalization and maximize health outcomes for Medicare beneficiaries with COPD. The CQRC is committed to working with the Congress and CMS to develop the appropriate tools to promote this goal.

II. CQRC Responses to Chronic Care Working Group Questions

The CQRC appreciates the opportunity to provide responses on the questions outlined by the Senate Finance Committee Chronic Care Working Group. We would welcome the chance to provide additional information or answer any questions that might arise from our responses.

1. Improvements to Medicare Advantage for patients living with multiple chronic conditions

For home respiratory therapy, Medicare Advantage (MA) plans provide beneficiaries with COPD with the most effective way to obtain the services they need to manage their multiple chronic conditions. As noted above, managing COPD

¹⁴ Kevin J. Potts, Dell T. Butterfield, Penny Sims, RN, Micah Henderson, BS, Cary B. Shames, "Cost Savings Associated with an Education Campaign on the Diagnosis and Management of Sleep-Disordered Breathing: A Retrospective, Claims-Based US Study" 16 *Popul Health Manag.* 7-13 (2013).

¹⁵ Cai Q, Tan H, Singer J., Impact of Positive Airway Pressure among Obstructive Sleep Apnea Patients 1 *Am J Manag Care.* 18 (2012).

¹⁶ Khayat R, Abraham W, Patt B, Brinkman V, Wannemacher J, Porter K, Jarjoura D., "Central Sleep Apnea Is a Predictor of Cardiac Readmission in Hospitalized Patients with Systolic Heart Failure 18 *J Card Fail.* 534-40 (2012).

¹⁷ Tsolaki V, Pastaka C, Karetsi E, Zygoulis P, Koutsokera A, Gourgoulisanis KI, Kostikas K, "One-year non-invasive ventilation in chronic hypercapnic COPD: effect on quality of life" 102 *Respir Med* 904-911 (2008).

appropriately at home can result in improved patient outcomes. MA plans have implemented efficient and effective mechanisms to ensure medical necessity while reducing administrative burden. Specifically, many MA plans have implemented prior authorization processes for home respiratory therapy equipment and services. These programs rely upon templates that prompt physicians to provide the required information to establish medical necessity. There is no guessing as to what information is needed.

Under this program, suppliers know before providing services whether they will be reimbursed. With this stability, suppliers are able to develop and implement programs to help ensure beneficiary compliance with these therapies and develop innovative ways to assist patients in managing their comorbidities. For example, one CQRC member provides in-home monitoring by using respiratory therapists and other personnel to help patients with COPD and congestive heart failure (CHF) comply with their home oxygen therapy, as well as manage their weight and other health conditions to reduce the likelihood of a hospital admission for CHF. Through this program, hospital admissions for these patients have been substantially reduced.

As described in detail above, prior authorization and reduced administrative burden allow suppliers to focus on coordinating care and improving patient outcomes, rather than chasing documents and waiting for years to make it through the appeals process only to be paid after the long delay. Applying this best practice from MA plans to Medicare fee-for-service would be an important step toward improving outcomes for beneficiaries.

2. Transformative policies that improve outcomes for patients living with chronic diseases either through modifications to the current Medicare Shared Savings ACO Program, piloted alternate payment models (APMs) currently underway at CMS, or by proposing new APM structures

As Section I of this letter describes, home respiratory therapy can play an important role in helping patients with COPD and other chronic conditions manage their diseases and improve their health outcomes. CQRC members have worked with individual hospitals on an ad hoc basis to help demonstrate the value of these home services, but have been prohibited from participating in Accountable Care Organizations (ACOs) and other alternative payment models.

Thus, the CQRC strongly encourages the Committee to consider expanding the ACOs and other alternative payment models to permit home respiratory therapy suppliers to participate in these shared savings and innovative payment system programs. More importantly, we believe that there may be additional models that could leverage these therapies. We would like to have the opportunity to work with

the Committee and CMS to develop new models.

3. Reforms to Medicare's current fee-for-service program that incentivize providers to coordinate care for patients living with chronic conditions

The Medicare fee-for-service program should be modified to remove unnecessary barriers to providing high quality care, as well as incentivize care coordination for patients living with chronic conditions.

First, it is important that Medicare establish adequate payment rates for these items and services necessary to managing chronic conditions. We agree that payment amounts should be related to the cost of providing items and services, but also believe that payments for chronic care services should not be viewed in isolation. Payment policy should also recognize the importance of services, such as home respiratory therapy services, in reducing Medicare payments overall. Ensuring stable reimbursement rates allows providers and suppliers to invest in the infrastructure necessary to improve care coordination and the management of chronic diseases.

Second, it is important that fee-for-service audit and appeals policies allow for predictable and stable payments. For home respiratory therapy suppliers, current policies have resulted in an enormous backlog of claims waiting for hearings with Administrative Law Judges. This backlog is due to the exponential rise in appeal requests and a lack of consistency or accuracy in the review of claims by DMEMACs. Rather than being able to focus resources on care coordination and managing COPD or other chronic conditions, most home respiratory therapy suppliers must concentrate on chasing physician notes and defending claims that have been inappropriately denied. As we have discussed in Question 1, implementing prior authorization for home respiratory therapy would address this problem. With streamlined, predictable documentation requirements inherent in a prior authorization program and the timely payment for claims that would result, home respiratory therapy suppliers could redirect their efforts to care coordination and improve beneficiary outcomes, while reducing Medicare Part A costs.

Third, the CQRC supports rewarding home respiratory therapy suppliers for improving patient outcomes and care coordination. We would welcome the opportunity to work with the Committee and CMS to develop a value-based pilot program that could reward suppliers who reduce admissions/readmissions of COPD beneficiaries. Measures already exist, but so far, home respiratory therapy suppliers have been excluded from participating in such programs.

4. *The effective use, coordination, and cost of prescription drugs*

The CQRC does not have any recommendations for this question.

5. *Ideas to effectively use or improve the use of telehealth and remote monitoring technology*

Under current regulatory requirements, beneficiaries receiving home respiratory therapy must visit their physicians multiple times to maintain access to home respiratory therapy. These in-person visits must occur whether or not the physician believes they are medically necessary. As a result, beneficiaries who have difficulty getting to their physicians may lose access to their home respiratory therapy. Without these therapies, patients end up in the hospital or forced to seek long-term institutionalized care.

The CQRC supports the expansion of telehealth to allow beneficiaries to rely upon this technology to meet the regulatory visit requirements. Rather than having regulators making the decision, this policy would allow physicians and their patients to make the determination when a visit must be made in person and when a telehealth visit would be more appropriate.

One situation in which use of telehealth could be appropriate even for an “initial” Medicare face-to-face physician’s evaluation visit is when a patient who has received home respiratory therapy under his/her commercial or employer plan ages into Medicare. In such instances, the only reason for the visit is to satisfy the Medicare requirements, despite the fact that the new beneficiary has already received the necessary testing and diagnosis. Providing more flexibility in cases such as these would make it easier for patients to engage with their physicians, while still protecting the integrity of the Medicare program.

6. *Strategies to increase chronic care coordination in rural and frontier areas*

As noted in Questions 3 and 5, it is important to ensure adequate reimbursement rates for providers and suppliers in rural and frontier areas, as well as to provide beneficiaries with flexible option, such as telehealth services, for engaging with their physicians. It is also important to incentivize the behaviors that lead to better coordination.

Home respiratory therapy suppliers are in a unique and important position to help patients with COPD and other comorbid chronic conditions in rural and frontier areas. Because managing patients with COPD requires the engagement of the patient on a regular basis, home respiratory therapy suppliers can make adjustments in their delivery models that can result in significant improvements in

health outcomes and savings for the Medicare program. They are the eyes and ears of patients' physicians who cannot be in the home or see the patient as regularly.

One strategy to help drive these types of care coordinating services in the context of COPD and home respiratory therapy is to allow for telehealth services as described in Question 5. Another strategy would be to reward those suppliers that show improvement and/or attainment of certain quality measures for the patients for whom they care, which requires coordinating care among different providers. While COPD hospital readmissions measures already exist, there may be other metrics that could be developed to address CHF or similar comorbid conditions patients with COPD face as well.

The current barrier to establishing and implementing the infrastructure necessary to allow all home respiratory therapy suppliers to engage in health outcome-based strategies and improved care coordination is the lack of adequate reimbursement. Home respiratory therapy suppliers experience higher costs in rural and frontier areas. For example, CQRC surveyed its members in 2014 to determine the cost of providing services. When the CQRC compared the cost of providing services in ZIP codes in Competitive Bidding Areas (CBAs) with ZIP codes in other parts of the country, we found that the cost of providing services in non-CBAs is approximately 11 percent higher than the cost of providing the same services in CBAs. The cost of providing services in areas among the lowest quartile of all rural counties by population density is approximately 17 percent higher than the cost of providing the same services in CBAs. Yet, the current policy set to take effect January 1, 2016 would reduce rates to a level below the cost of providing services in these areas.

There are several reasons for the cost differential. The cost of providing home respiratory therapy items and services varies significantly based upon the geographic area in which they are furnished. Fuel costs related to the greater distances traveled to beneficiaries' homes, as well as the lower population density, drive higher costs in rural areas. The most recent data available from the Bureau of Labor Statistics (2011) show that household expenditures for fuel costs and health care costs are higher in rural areas.¹⁸ For example, rural households spent \$3,115 on gasoline and motor oil, compared with the \$2,613 spent by urban households,¹⁹ making fuel costs about 84 percent higher in rural areas.

In addition, the distance between beneficiary homes is also significantly greater in rural areas when compared to urban areas. Greater distances not only require home respiratory therapy suppliers to use more fuel, but they also require these suppliers to employ additional personnel, including when appropriate, health

¹⁸<http://www.bls.gov/opub/btn/volume-2/expenditures-of-urban-and-rural-households-in-2011.htm>

¹⁹ *Id.*

care professionals such as respiratory therapists, who provide services in these areas. The locations in rural markets typically have at least one customer service employee, one driver or service provider, one clinician, and one person to provide required minimum levels of service to patients that include maintaining a minimum of 30 office hours as required by CMS. Medicare's quality standards also require certain professionals to be on-call for beneficiaries 24/7. In some areas where the distances are great, an additional service provider, driver, or clinician is required to ensure that beneficiaries have access to these services when needed. With fewer patients per employee in rural areas, higher revenues per beneficiary are needed to cover the cost of providing services.

In addition to the higher fuel costs, the distances between the supplier's location and the beneficiaries' homes are greater in low population density areas. For example, one CQRC member company operating in Georgia provides services to beneficiaries in a rural area that extends 98 miles from the supplier's location. It can take the employees one-and-a-half hours to visit the various beneficiaries in this area, resulting in travel that averages approximately 250-300 miles a day. Montana is another example of where an average in-home delivery may be located 110 miles away from the supplier's location. As noted in the previous section, these greater distances also mean that supplier must hire more staff to ensure that beneficiaries have access to the required services in a timely manner.

Additionally, the lower population density substantially reduces the ability to develop efficiencies and economies of scale. Supplier locations in the lowest population density areas serve fewer beneficiaries due to lower populations. However, the centers' fixed costs, such as rent, utilities, licensing, information technology infrastructure, financial/accounting, compliance, and employee wages, are almost identical to the locations in more densely populated markets with higher beneficiary counts and more total revenues that come from serving more beneficiaries. Thus, urban centers can cover their fixed costs with a lower per beneficiary rate than a center in a low population area can.

In order to achieve the goals of coordinating care, improving patient outcomes, and reducing overall Medicare costs, home respiratory therapy suppliers must have stable and adequate funding to be able to invest in the labor-intensive strategies and infrastructure to better manage and coordinate care.

7. Options for empowering Medicare patients to play a greater role in managing their health and meaningfully engaging with their health care providers

To some degree, the home respiratory therapy benefit already empowers Medicare patients to manage their care by allowing them to remain in their homes and communities. However, more can be done. Allowing these suppliers to participate in alternative payment models, as well as incentivizing them to support such programs, is an important option for empowering Medicare patients.

Home respiratory therapy suppliers do more than simply provide equipment. Suppliers work with beneficiaries in their homes to help them understand their disease and how to manage it. Some suppliers currently work with hospitals to engage patients in ways to manage their behaviors and living conditions to reduce the frequency and severity of exacerbations, as well as controlling baseline symptoms. Incentivizing these types of services would provide Medicare patients living with COPD with the help they need to play a greater role in managing their health.

8. Ways to more effectively utilize primary care providers and care coordination teams in order to meet the goal of maximizing health care outcomes for Medicare patients living with chronic conditions

As noted in Section 1, home respiratory therapy suppliers provide in-home care and can serve as the eyes and ears for physicians managing patients with COPD and other comorbid chronic conditions. They are an integral part of keeping these patients out of hospitals and other institutional care settings. Yet, they have been expressly prohibited from participating in alternative payment models and value-based purchasing programs. Even so, they have shown in work with commercial insurers the value they can bring by substantially reducing hospital admissions and readmissions. Unfortunately at the same time, traditional Medicare fee-for-service policies have sought to reduce these services to a commodity and subjected them to unreasonable audit practices and delayed payments. Changing current policies and incentivizing home respiratory therapy suppliers to improve patient outcomes through bonus payments would allow them to become more integrated with other providers in the continuum of care.

III. Conclusion

The CQRC appreciates the opportunity to provide comments to the Committee and Working Group. We strongly believe that home respiratory therapy has been forgotten and underutilized in efforts to improve the management of patients with chronic conditions. Therefore, we encourage you to incorporate these

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important home-based services in your efforts to improve the Medicare benefit. We would like to meet with your team to further discuss the potential opportunities new policies could create. Please do not hesitate to contact me at (202) 534-1773 or klester@lesterhealthlaw.com if you would like to discuss these comments in more detail.

Sincerely,

A handwritten signature in cursive script that reads "Kathy Lester".

Kathy Lester
Executive Director
Council for Quality Respiratory Care