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Request for Information
Centers for Medicare & Medicaid Services: Innovation Center New Direction

On behalf of the American Association for Respiratory Care (AARC), we appreciate the opportunity to provide comments on CMS' request for information regarding the new direction of its Innovation Center in promoting patient-centered care and testing reforms that can lead to increased choices, competition, reduced costs and improved outcomes. The AARC is a national professional organization with a membership of over 47,000 respiratory therapists who treat patients with chronic respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and whose organizational activities impact over 170,000 practicing respiratory therapists across the country.

Our comments involve the Physician Specialty Model and the Medicare Advantage Innovation Model with a focus on improving awareness of the devastating effects of COPD and engaging the expertise and skills of respiratory therapists in treating individuals diagnosed with this deadly disease which can lead to improved health status and fewer acute care interventions.

Background

The Centers for Disease Control and Prevention lists COPD as the third leading cause of death in the United States. In addition, according to data posted on CDC's website[1], national medical treatment costs for adults with COPD are projected to increase from an overall $59.3 billion in 2010 to $90.6 billion by 2020, which includes costs of treatment for injuries and other conditions such as heart disease, pneumonia, diabetes, asthma and depression which are common among people with COPD. For example, CMS' chronic conditions dashboard shows almost 57% of Medicare beneficiaries have 5 plus

[1] https://www.cdc.gov/features/ds-copd-costs/index.html. Data accessed November 12, 2017.

other conditions.[2] With non-COPD medical treatments removed from the equation, CDC website data[1] indicate costs attributable to individuals with COPD were $32.1 billion in 2010 with a projected increase to $49.0 billion by 2020. Medicare and Medicaid have paid for most of the national health care costs related to COPD, with 51% paid by Medicare and 25% paid by Medicaid in 2010. Private insurers paid 18% of COPD costs that year. State medical costs attributable to COPD ranged from $42.5 million in Alaska to 2.5 billion in Florida in 2010.

COPD is costly on many fronts, especially due to the number of hospitalizations and readmissions that occur during the patient's lifetime. Although CMS recognized 30-day hospital readmissions post-discharge of Medicare beneficiaries with COPD to be among the most costly by adding it to the list of conditions subject to penalties under the Hospital Readmissions Reduction Program, we do not believe the agency has gone far enough to raise awareness of this life-threatening disease. The time has come to improve the quality of care for these very sick patients by giving physicians more flexibility to maximize the expertise respiratory therapists can bring to their practice.

When the Medicare program was first created, its primary focus was on inpatient acute care. While the science and practice of respiratory therapy has advanced exponentially since the inception of the Medicare program, Medicare's coverage of respiratory therapy services and respiratory therapists has virtually remained as it was in 1965. It is important to note that respiratory therapists comprise the only allied health profession that receives comprehensive formal education in all aspects of pulmonary medicine. These licensed professionals undergo rigorous validated competency testing over the full scope of practice which includes diagnosis, treatment, and management of all respiratory diseases and conditions; however, access to their services outside of the acute care setting is very limited.

The Innovation Center can address this problem as part of its initiative to move in new directions with the health care delivery system by testing models that provide an opportunity to demonstrate the value respiratory therapists provide to individuals with COPD through improved outcomes and to the Medicare program through reduced utilization and lower costs.

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/chronic-conditions-region/cc_region_dashboard.html. Data accessed November 12, 2017.

Physician Specialty Model

As part of its request for information, CMS has indicated an interest in increasing the availability of specialty physician models. One option is to include "specialty physician management of a defined population of beneficiaries with complex or chronic conditions, including multiple chronic conditions."

Recommendation

We recommend CMS establish a voluntary Physician Specialty Model that 1) pays separately for a comprehensive chronic disease management program focusing on self-management education and training furnished to COPD patients by respiratory therapists, and 2) includes an incentive to the physician practice if emergency department visits and hospital readmissions are reduced and patient outcomes are improved as a result of the respiratory therapist's expertise.

Chronic disease management services should include:

- Patient education on self-management of their pulmonary disease.
- Direct observation and assessment of the patient's ability to self-administer aerosol medications.
- Training and education on the proper inhaler technique for use of aerosol medications with nebulizers, metered-dose inhalers, and dry-powdered inhalers.
- Smoking cessation counseling.
- With respect to individuals with COPD on long-term oxygen therapy, education and training on the appropriate dose of oxygen depending on the activity of the patient in order to self-manage the drug.
- Educating the patient on an action plan that enables him or her to recognize the appropriate response to self-managing their disease according to their symptoms.
- Monitoring the disease management treatment plan to ensure patient compliance.

Over a decade ago, Congress enacted a law that provided separate payment for self-management training for diabetes patients which has proven successful in improving patient outcomes. Unfortunately, the current Medicare fee-for-service payment structure only covers self-management services when bundled with other services, even though separate codes exist to identify the services. Recent coverage of transitional care and chronic care management services are designed to improve health and keep patients out of the hospital, but they do not go far enough because a patient's self-

management of their disease is expected to be carried out non-face-to-face and bundled with a variety of other services that comprise these benefits. Moreover, primary care physicians are more likely than not to refer their COPD patients to a pulmonologist who specializes in such conditions offering little incentive to use respiratory therapists over their nursing staff. By incorporating preventive measures and improved health outcomes as part of their treatment practices, respiratory therapists can help pulmonologists reduce the economic burden of COPD.

Self-management Education and Training Can Lower Costs and Improve Health Outcomes

Recently, the National Heart, Lung and Blood Institute finalized the first ever COPD National Action Plan. Among the goals of the action plan is "helping people with COPD, including their families and caregivers, recognize the disease through risk and symptom awareness, early detection, and diagnosis" while empowering them to self-manage their disease. The plan also aims to improve access to care for those individuals with COPD who reside in hard-to-reach areas. Incorporating respiratory therapists' expertise into a Physician Specialty Model can go a long way in carrying out the goals of the plan.

There is sufficient evidence to support separate payment for self-management education and training. A meta-analysis of 22 studies[3] involving 3,854 COPD patients who either received COPD self-management interventions that included action plans for acute exacerbations of COPD or usual care found that self-management interventions with action plans generally improved outcomes in health-related quality of life as measured by the St. George's Respiratory Questionnaire and lower probability of respiratory-related hospital admissions.

Another study[4] involving education and training by a respiratory therapist COPD Case Management Team under the supervision of a pulmonologist resulted in decreased healthcare utilization and improved patient outcomes. The program was designed to accomplish the following:

- Simplify patient education;
- Promote awareness of COPD;

[3] Lenferink A, Brusse-Keizer M, et al. Self-management interventions including action plans for exacerbations versus usual care in patients with chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2017. Aug:4;8:DC011682. Doi: 10.1002/14651858.CD011682.pub2.

[4] Young, MS, Craddock, KM, et al. Chronic Obstructive Pulmonary Disease Education and Training by Respiratory Care Practitioners Decreases Healthcare Utilization and Improves Patient Outcomes. University of California Davis Health System (UCDHS), Sacramento, CA.

- Assist in the proper diagnosis, staging, and treatment in accordance with the Global Initiative of Chronic Obstructive Lung Disease (GOLD) Guidelines;
- Support COPD patients and their family through the continuum of their disease; and,
- Provide a written action plan regarding discharge respiratory medications, rescue action plan and follow-up instructions.

Sixty patients were treated. Thirty-eight percent of patients in the study had very severe COPD, 43% had severe COPD and 17% had moderate COPD. Only 2% were assessed as having mild COPD. The average length of stay for an acute exacerbation of COPD was reduced by 28.7%; the rate at which patients were readmitted was reduced to 5%.

Further evidence of the impact respiratory therapists have on outcomes is evidenced by a one-year study[5] conducted at five VA medical centers to determine whether a simplified disease management program reduces hospital admissions and emergency department (ED) visits due to COPD. Patients assigned to usual care received a one-page handout containing a summary of the principles of COPD care and the telephone number for the 24-hour VA nursing helpline, a service available to all VA patients. Patients assigned to the disease management arm attended a single 1 to 1-1/2 hour group education session conducted by a respiratory therapist case manager. After one year, COPD-related hospitalizations and emergency department visits were reduced by 41%.

Proper Education and Training Can Improve Medication Adherence

Medication non-adherence has been estimated to cost the US health care system between $100 billion and $289 billion in direct costs according to an Evidence Report/Technology Assessment[6] conducted by the Agency for Healthcare Research and Quality. The report cites studies that provide strong evidence suggesting "benefits attributable to improved self-management of chronic diseases could result in a cost-to-savings ratio of approximately 1:10."

As part of a respiratory therapist-led comprehensive chronic disease management Physician Specialty Model, patient education and proper device selection for inhalers is

[5] KL Rice, et al. Disease Management Program for Chronic Obstructive Pulmonary Disease: A Randomized Controlled Trial. *Am J Resp CC Medicine* Feb 2010 [online]

[6] Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment Number 208.4; Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science. Executive Summary. AHRQ Pub. No. 12-E010. Sept. 2012.

critical for optimal clinical outcomes and cost effectiveness for patients with COPD. The time respiratory therapists spend with the patient to assist the physician can be invaluable. Due to the complexities of inhaler devices, respiratory therapists' expertise can aid in minimizing unnecessary, ineffective or wasteful interventions. Several studies support the need for proper inhaler education and training. They include the following:

- Only 1 out of 10 patients with a metered-dose inhaler performs all essential steps correctly. Strong education initiatives enable patients to respond effectively to prescribed therapeutic regimens.[7]

- Instruction of hospitalized patients with obstructive lung disease by a respiratory therapist improves their correct use of metered-dose inhalers (MDIs).[8]

- Evidence suggests that multiple inhaler types cause confusion among patients and increase errors in patient use, especially among the elderly. Short of a simple universal inhaler, patient and caregiver education remains the best solution to correct patient errors.[9]

Medicare Advantage Innovation Models

In its request for information, CMS indicates an interest in a Medicare Advantage (MA) demonstration that incentivizes MA plans to compete for beneficiaries, including those beneficiaries in fee-for-service based on quality and cost. We believe much of what we've outlined regarding a comprehensive chronic disease management plan furnished by respiratory therapists to COPD patients under the Physician Specialty model could be translated into a voluntary supplemental benefit under the Medicare Advantage Innovation Model.

Recommendation

We recommend certain telehealth waivers be granted to Medicare Advantage plans to permit respiratory therapists to furnish telehealth chronic disease management services to beneficiaries with COPD in their home as a way to encourage competition and innovation among plans and to reach those in low-income or rural areas who would otherwise not have access to the expertise of a respiratory therapist.

[7] Restrepo RD, Alvarez MT, et al. Medication adherence issues in patients treated for COPD. *Int J Chron Obstruct Pulmon Dis.* 2008;3(3):371-384.

[8] Song, WS, Mullon J, Regan NA, Roth BJ. Instruction of hospitalized patients by respiratory therapists on metered-dose inhaler use leads to decrease in patient errors.
Respiratory Care 2006 Feb;51(2):158-72.

[9] Rau Joseph L. Practical problems with aerosol therapy in COPD. *Respiratory Care* 2006 Feb;51(2):158-72.

As part its new direction, CMS sought comment as to whether there are any payment waivers it should consider as necessary to help providers advance innovative care delivery. We recommend CMS consider waiving sections 1834(m)(D) and (E) of the Social Security Act to lift the restrictions on who is eligible to furnish telehealth services and allow respiratory therapists to furnish chronic disease management services via telehealth to Medicare beneficiaries with COPD under a MA Innovation Model. An additional waiver to section 1834(m)(C)(ii) should be granted to add an individual's home as a telehealth site.

These changes would go a long way to encouraging beneficiaries with chronic respiratory disease to consider switching from the fee-for-service benefit to Medicare Advantage. From the perspective of wanting to attract participants in the MA program, being able to offer less restricted telehealth can be a reward and a competitive advantage. Further, this approach would allow these MA plans to take the lead in demonstrating the value of connected health technologies in innovating care delivery and improving access and efficient delivery of care, in both rural and urban settings.

Summary

Medicare patients with COPD are costly and prevalent. Given increased access to respiratory therapists in a pulmonary specialty practice and via telehealth can improve the health outcomes of those who suffer from COPD while reducing hospital readmissions and lowering costs.

Respiratory therapists have expertise in all facets of pulmonary medicine. The lack of recognition of their skills in the Medicare statute limits their exposure outside the hospital setting and is a major drawback in the ability of Medicare patients with COPD to access their services post-discharge.

Numerous studies show that patient self-management education and training through a comprehensive chronic disease management program can improve health outcomes and quality of life and is cost effective. Because coverage of self-management is reimbursed by and large as part of other bundled services, it does not address the needs of COPD patients who often rely on complex devices to keep them alive and who often misuse or do not adhere to their treatment regimen through lack of understanding. Current transitional care management services and chronic care management services do not go far enough to address these problems but new directions in the Innovation Center can address these problems.

The AARC appreciates the opportunity as an interested stakeholder to provide input that will be useful to the Innovation Center as it moves to new directions in the delivery and payment of health care services.

Sincerely,

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