



AMERICAN ASSOCIATION FOR RESPIRATORY CARE
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June 27, 2016

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-5517-P: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Mr. Slavitt:

The American Association for Respiratory Care (AARC) appreciates the opportunity to comment on the proposed rule. The AARC is a national professional organization with a membership of 50,000 respiratory therapists who treat patients with chronic respiratory diseases such as asthma and Chronic Obstructive Pulmonary Disease (COPD) and whose organizational activities impact over 170,000 practicing respiratory therapists across the country.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the sustainable growth rate formula used to determine physician payments and replaced it with a new Merit-based Incentive Program (MIPS), or “Quality Payment Program” as referred to by CMS in the proposed rule. The new payment system becomes effective January 1, 2019; however, the baseline year for establishing performance begins January 1, 2017.

A key element of the new program is the provision of the law that streamlines the current incentive payment reporting programs, (e.g., Physician Quality Reporting Program (PQRS), Value-Based Payment Modifier (VM) and the Medicare Electronic Health Records (EHR) Incentive Program) into one reporting system that includes four performance categories: Quality, Resource Use, Clinical Practice Improvement Activities, and Advancing Care Information. Although there are numerous measures to choose from, MIPS offers eligible clinicians the flexibility to choose those measures and reporting mechanisms they feel can best demonstrate performance relative to their practice.

As CMS moves to a value-based quality payment system as envisioned by MACRA, we strongly support the inclusion of any measures that will improve the quality of life and health outcomes from Medicare beneficiaries who suffer from debilitating chronic lung disease.

Quality Performance Category

Individual Measures – Spirometry Testing

As part of the Quality Performance Category, eligible MIPS clinicians can choose from a list of individual quality measures that count toward their performance score. These measures are incorporated in Table A in the proposed rule and were finalized in previous rulemaking.

Of particular note is measure **#0091 Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation** which has been part of the Physician Quality Reporting System (PQRS) since 2007. Developed by the American Thoracic Society (ATS) and endorsed by the National Quality Forum (NQF), the descriptor for this measure under the proposed Effective Clinical Care Domain reads: *“Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.”*

In addition to measure #0091, the National Committee for Quality Assurance (NCQA) has developed measure **#0577 Use of Spirometry Testing in the Assessment and Diagnosis of COPD**, which is also endorsed by the NQF but is not included in CMS’ proposed individual quality measures list. The descriptor for that measure is *“Percentage of patients 40 years of age and older with a new diagnosis of COPD (emphasis added) or newly active COPD who received appropriate spirometry testing to confirm the diagnosis.”*

RECOMMENDATION: The AARC strongly recommends CMS consider adding measure #0577 to the MIPS reporting system based on the discussion below. Any and all measures that improve the diagnosis of COPD are critical to improving patient outcomes and reducing costly hospital readmissions and acute exacerbations. Spirometry is the standard of care when it comes to measuring airflow obstruction for the diagnosis and management of COPD.

As early as 2004 the American Thoracic Society (ATS) and European Respiratory Society (ERS) produced a report on “Standards for the Diagnosis and Management of Patients with COPD”.¹ The ATS and ERS committee members included clinicians, nurses, respiratory therapists and educators interested in the field of COPD as well as input from patients suffering from the disease. Key points in the section on Definitions, diagnosis and staging included the following:

¹ Standards for the Diagnosis and Management of Patients with COPD. American Thoracic Society, European Respiratory Society. Copyrighted 2004. <http://www.thoracic.org/copd-guidelines/resources/copddoc.pdf>. (Accessed June 20, 2016).

- COPD is characterized by airflow limitation
- **The diagnosis is confirmed with spirometry**
- Assessment of COPD is performed using spirometry, dyspnea and body mass index (BMI).

In 2011, the American College of Physicians (ACP), American College of Chest Physicians (ACCP), American Thoracic Society (ATS) and the European Respiratory Society (ERS) updated their 2007 Clinical Practice Guidelines² on the diagnosis and management of stable COPD intended for clinicians who manage patients with COPD. With respect to spirometry, the recommendation reads as follows:

“Recommendation 1: ACP, ACCP, ATS and ERS recommend that spirometry should be obtained to diagnose airflow obstruction in patients with respiratory symptoms (Grade: strong recommendation, moderate-quality evidence.). Spirometry should not be used to screen for airflow obstruction in individuals without respiratory symptoms (Grade: strong recommendation, moderate-quality evidence).”

In 2016, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) updated its Global Strategy for the Diagnosis, Management and Prevention of COPD³ by stating the following: “Assessment of COPD is based on the patient’s level of symptoms, future risk of exacerbations, the severity of the spirometric abnormality, and the identification of comorbidities. **Whereas spirometry was previously used to support a diagnosis of COPD, spirometry is now required to make a confident diagnosis of COPD.**”

Last, according to a recent study,⁴ females with COPD exacerbations now account for one-half of all hospital admissions for that condition and the rates have been increasing over the last few decades. The study concluded that there are gender differences in some of the clinical features of COPD, reiterating the “absolute importance of spirometry in the diagnosis of COPD.”

We recognize that the two spirometry measures #0091 and #0577 may compete with each other but one thing is clear from the evidence – spirometry is required in diagnosing COPD. In the NQF’s draft report on Pulmonary and Critical Care 2015-2016⁵, the Committee noted that

² ACP Clinical Practice Guidelines. Qaseem A, Wilt TJ, Weinberger, SE, Hanania NA, et al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191. Downloaded from <http://annals.org> on June 7, 2016.

³ Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2016. Available from <http://goldcopd.org/>. (Accessed June 14, 2016).

⁴ Roberts NJ, Patel IS, Partridge MR. The diagnosis of COPD in primary care; gender differences and the role of spirometry. *Respir Med* 2016 Feb;111:60-3. doi: 10.1016/j.rmed.2015.12.008. Epub 2015 Dec 19.

⁵ Pulmonary and Critical Care 2015-2016. Draft Report for Comment April 21, 2016. National Quality Forum http://www.qualityforum.org/Pulmonary_and_Critical_Care_Project.aspx. (Accessed June 16, 2016).

the measures were related and recommended that they be harmonized with respect to the age limit and timeframe since the measures have similar goals. For example, the ATS measure addresses patients 18 and over while the NCQA measure focuses on patients over age 40. This apparently is not the first time harmonization has been suggested, but for now, both measures are viable and used in various reporting scenarios.

Although there are similarities, there are arguments to consider both measures. In updating its submission for the NQF's 2015-2016⁶ measures maintenance report noted earlier, the ATS maintains its measure is more consistent with the GOLD guidelines and that "spirometry should be used to assess all adults with COPD, not just adults with a new diagnosis of COPD, which is the cornerstone of measure #0577." Further, the ATS believes its measure allows more flexibility because the spirometry evaluation can take place at any time during the measurement period as opposed to the NCQA's requirement that spirometry be performed within 6 months of a new diagnosis of COPD. Notwithstanding those comments, the NCQA's rationale for their quality measure is to "ensure that patients receive spirometry testing to confirm a COPD diagnosis and determine the severity of the disease, its impact on the patient's health status and the risk of future events (such as exacerbations, hospital admissions or death), in order to guide therapy."⁷ For these reasons, we believe both quality measures should be available for reporting as part of the MIPS payment system.

According to the National Heart, Lung and Blood Institute (NHLBI), data indicate that 14.8 million U.S. adults have been diagnosed with COPD but the actual number of those adults who go undiagnosed is estimated to be 12 million, which represents a significant under-diagnosis of this life-threatening disease.⁸ Moreover, current estimates suggest that COPD costs the nation almost \$50 billion annually in both direct and indirect health expenditures.⁹

With COPD on CMS' list of conditions subject to the Hospital Readmissions Reduction Program and the third leading cause of death as reported by the Centers for Disease Control and Prevention, the AARC believes it is vitally important that the new physician payment reporting system support measures that reflect the standard of care and are consistent with national guidelines that require spirometry to diagnose and assess COPD. Therefore, we encourage the use of both measures as CMS moves forward with implementation of the new Quality Payment Program.

⁶ Ibid.

⁷ Ibid.

⁸ National Heart, Lung, and Blood Institute. 2012. "Morbidity and Mortality: 2012 Chart Book on Cardiovascular, Lung, and Blood Diseases." http://www.nhlbi.nih.gov/files/docs/research/2012_ChartBook_508.pdf. (Accessed June 20, 2016).

⁹ Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality. American Lung Association Epidemiology and Statistics Unit, Research and Health Education Division. March 2013

Sleep Apnea Measures

CMS proposes to revise the reporting mechanism for several sleep apnea measures that include assessment of sleep symptoms, positive airway pressure (PAP) therapy prescribed, and assessment of adherence of PAP therapy. These measures are not new and were previously reported as part of the PQRS but were included in a Measures Group which is no longer a mechanism for data submission under MIPS. We agree with CMS that these measures address a clinical performance gap and should be continued and support CMS' proposal to change the status to an individual measure in order to allow continued data submission.

Other Noteworthy Measures

Specialty Measure Sets

CMS proposes to establish specific "MIPS Specialty Measure Sets" that include several measures aimed at addressing the following respiratory-related topics:

- flu immunization
- pneumococcal vaccination
- optimal asthma control measure
- medication management for people with asthma (a new measure to specifically address pulmonary care within primary care)
- avoidance of inappropriate use regarding antibiotic treatment for adults with acute bronchitis
- appropriate treatment for children with upper respiratory infection

The AARC concurs with the inclusion of these measures in the proposed specialty sets as well as the high priority designation where noted.

Episode-Based Measures

CMS has proposed episode-based measures for inclusion in the MIPS Resource Use Performance Category for a variety of conditions that are considered to be high cost, have high variability in resource use, or are for high impact outcomes. Six of the episode-based measures relate to respiratory conditions, two of which (e.g., Asthma/COPD, Acute Exacerbation and Inpatient-Based Community Acquired Pneumonia) were included in the 2014 Quality and Resource Reports. The new measures address Chronic Asthma/COPD triggered by an inpatient hospital claim with a principal diagnosis of any COPD Chronic trigger codes, Outpatient-Based Community Acquired Pneumonia, Acute Pulmonary Embolism, and Acute Upper Respiratory Infection, Simple.

The AARC supports the inclusion of these proposed episode-based measures in the Resource Use Performance Category, especially given that pneumonia and COPD are on the readmissions penalties list.

Additional Measures for Consideration

CMS has stated in the proposed rule that it plans to increase the requirements for reporting outcome measures over the next several years as additional measures become available, since these types of measures are deemed to be more instrumental in determining quality of care than process measures.

RECOMMENDATION: The AARC recommends CMS add outcome measures in future rulemaking that address improvements in quality of life scores and functional capacity for those COPD patients who are enrolled in pulmonary rehabilitation programs.

Pulmonary rehabilitation is a life-saving program for those Medicare beneficiaries who have been diagnosed with moderate, severe, and very severe COPD. It is generally recognized as a cornerstone in the comprehensive management of patients with COPD. According to ATS,¹⁰ evidence for improvement in exercise endurance, dyspnea, functional capacity, and quality of life is stronger for rehabilitation than for almost any other therapy in COPD which can lead to favorable outcomes. Therefore, we believe it is important for CMS to recognize the importance of this program under the new MIPS payment system.

Currently, there are two outcome measures that have been developed with respect to pulmonary rehabilitation programs. These were developed by the American Association for Cardiovascular and Pulmonary Rehabilitation (AACVPR) and were included in the NQF's 2015-2016 draft pulmonary report¹¹ noted earlier; however, they were not reviewed as part of its update. At the time NQF was considering these measures, the AARC sent comments in support of their inclusion in the NQF's *National Voluntary Consensus Standards for Patient Outcomes Phase I and II*. CMS should consider these in future rulemaking.

Measure #	Steward	Description
0770	AACVPR	Percentage of patients with COPD enrolled in pulmonary rehabilitation (PR) who are found to increase their health-related quality of life score (HRQL).
0701	AACVPR	Percentage of patients with COPD who are enrolled in pulmonary rehabilitation (PR) who are found to increase their functional capacity by at least 25 meters (82 feet), as measured by a standardized 6 minute walk test (6MWT).

¹⁰ American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. *Am J Respir Crit Care Med* Vol 173 pp 1390-1413, 2006. DOI: 10.11164/rccm.200508-1211ST. <https://www.thoracic.org/statements/resources/copd/atserspr0606.pdf>

¹¹ Pulmonary and Critical Care 2015-2016. Draft Report for Comment April 21, 2016. National Quality Forum. http://www.qualityforum.org/Pulmonary_and_Critical_Care_Project.aspx. (Accessed June 16, 2016).

Clinical Practice Improvement Activities (CPIA) Performance Category

The CPIA Performance Category focuses on several MIPS goals that include a patient-centered approach to program development leading to “better, smarter, and healthier care” and incentives that can reform current health care delivery principles. In establishing the new MIPS payment system, the law set forth certain subcategories that address beneficiary engagement, care coordination, patient safety and population management, among others. Among the 90+ activities from which eligible clinicians can choose, those categorized as “high” or “medium” earn 20 or 10 points each, respectively, in calculating the performance score. CMS hopes to “raise the bar” over time as improvement rises.

RECOMMENDATION: As the CPIA Performance Category evolves, the AARC recommends that CMS add an additional Population Management activity that addresses accurate assessment and delivery of supplemental oxygen in accordance with evidence-based guidelines for patients with chronic lung disease in need of long-term oxygen therapy (LTOT).

Home oxygen is critical to approximately one million Medicare beneficiaries who suffer from respiratory illnesses such as COPD. Disease progression in COPD often leads to the development of stable but chronic hypoxemia, which is commonly treated with long-term oxygen therapy (LTOT) as these beneficiaries require oxygen therapy for their long-term survival and well-being. For over 30 years, LTOT in the home has been a standard and accepted treatment for patients with severe chronic obstructive pulmonary disease (COPD) demonstrating stable, chronic hypoxemia. Moreover, oxygen and pulmonary rehabilitation are the only non-invasive therapies shown to prolong the life of COPD patients with severe hypoxemia.

As with any chronic progressive disease, effective treatment is an on-going process requiring consistent re-assessment, monitoring/trending, and changes in modalities and/or prescriptions to meet changes and aging that naturally occur. One of issues that patients on LTOT face is knowing whether the equipment they have been prescribed is adequate and appropriate for their needs in order to maintain adequate oxygen saturation rates, especially as their condition may change over time. Since the majority of patients are first prescribed oxygen in the inpatient hospital setting, it is critical that follow-up care in the physician practice in assessing and managing supplemental oxygen needs be evidence-based.

Studies have shown that proper management of LTOT can improve the delivery of health care and result in significant savings. For example, a study¹² that involved assessment of users of LTOT by respiratory therapists as part of an oxygen therapy clinic found that utilization differed significantly over time.

¹² Chaney JC, Jones K, Grathwohl R, Olivier KN. Implementation of an Oxygen Therapy Clinic to Manage Users of Long-term Oxygen Therapy. *Chest* 2002; 122:1661-1776.

- Of 97 patients with a new oxygen prescription during hospitalization, 50.5% no longer met CMS guidelines for oxygen (order discontinued) and 27.9% required significant changes in their oxygen orders.
- Of 95 outpatients with existing orders for oxygen contacted for recertification, 31.6% met Medicare criteria for oxygen, (order discontinued) and 26% required significant change to their oxygen prescription.
- Of 91 home oxygen patients referred from other outpatient clinics, 22% discontinued use of oxygen and 29.7% required significant changes to their oxygen prescription.

As part of the Clinical Practice Improvement Activity, we recommend physicians use the AARC’s Clinical Practice Guideline (CPG) “Oxygen Therapy in the Home or Alternative Site Health Care Facility” as it provides a full description of the types of oxygen systems necessary to establish adequacy of a patient’s response to therapy. This guideline must also be followed by Durable Medical Equipment suppliers as part of their quality standards, but parts of the CPG address clinical care and fall to the attending physician. Further, with the variety of portable oxygen concentrators on the market today, it is imperative to know the variations in settings among manufactures as they differ significantly. To that end, the AARC has developed a “*Guide to Portable Concentrators*”. Both the CPG and Guide are available at www.aarc.org.

We suggest CMS consider adding the following CPIA as part of its Population Management subcategory:

Subcategory	Activity	Weighting
Population Management	Proactively manage patients with chronic lung disease in need of long-term oxygen therapy that include one of the following: Use of evidence-based guidelines such as the American Association for Respiratory Care’s “Oxygen Therapy in the Home or Alternative Site Health Care Facility” Clinical Practice Guideline Integration of respiratory therapists as part of the care team to improve oxygen utilization and medication adherence and to conduct self-management education and training.	Medium

Telehealth and Remote Patient Monitoring

The CPIA Performance Category also expands opportunities under the Care Coordination, Expanded Practice Access, and Population Management subcategories to improve health outcomes through the use of telehealth and remote patient monitoring (RPM). The AARC is one of numerous stakeholders that comprise a multi-stakeholder coalition of healthcare and technology communities that promote the expansion of telehealth and remote patient monitoring (RPM).

RECOMMENDATION: We recommend that CMS waive in its entirety the telehealth restrictions in §1834 (m) of the Social Security Act, especially for those participating in the new MIPS payment system as Alternative Payment Models. In doing so, AARC strongly supports including respiratory therapists as telehealth/RPM providers for those beneficiaries with specific at-risk chronic conditions, such as COPD.

In the past, little emphasis has been placed on the skills of respiratory therapists and the value they can bring to the numerous innovative payment models CMS has been testing since passage of the Affordable Care Act. Therefore, with the incentives offered to those who participate in APMs under the new Quality Payment System, it is important to waive current restrictions to permit enhanced use of telehealth and RPM and to include respiratory therapists as telehealth providers.

Respiratory therapists as telehealth providers can meet respiratory patients' unmet needs, improve access to care, improve health outcomes and reduce hospital readmissions through a comprehensive telehealth disease management program that includes:

- Education on self-management of the patient's disease;
- Education and training in the use of prescribed self-monitoring devices such as peak flow measurement and pulse oximetry;
- Education and training on the proper inhaler technique for use of aerosol medications with nebulizers, metered-dose inhalers, and dry-powdered inhalers;
- Direct observation and assessment of the patient's ability to self-administer aerosol medications;
- Smoking cessation counseling;
- Education and training on compliance with medications and respiratory devices such as oxygen equipment and nebulizers; and,
- Development of an action plan that enables patients to recognize the appropriate response to self-managing their chronic disease according to their symptoms.

Respiratory therapists can also be valuable assets in assisting the primary care physician or specialist in the APM in managing and evaluating their patients with chronic lung disease via RPM. There are numerous studies related to respiratory care and training to teach patients how to manage their chronic lung disease via telehealth and RPM that show these types of services are beneficial in lowering costs and improving quality of life. A few of these are discussed below.

- Medicare beneficiaries in a telehealth/care management program to enhance patient education, self-management and timely access to care, were associated with 23% lower quarterly all-cause hospital admissions and 40% lower quarterly respiratory-related hospital admissions.¹³
- Home telehealth in elderly, severe COPD patients with multiple comorbidities is safe and efficacious in reducing healthcare utilization. Vital signs monitored on a daily basis for seven months showed a significant reduction in ED visits, length of stay and need for non-invasive mechanical ventilation.¹⁴
- Telehealth in chronic respiratory failure patients on oxygen or home mechanical ventilation prevents hospitalization while reducing the overall cost for each patient by 33%.¹⁵
- A retrospective cohort study of moderate to severe COPD patients enrolled in the VA's Care Coordination Home Telehealth (CCHT) program showed that 71.5% had a reduction in the number of ED visits and exacerbations requiring hospitalization after enrollment in the program.¹⁶
- Telemedicine can enable care equivalent to that provided face-to-face by a respiratory therapist for certain activities involving mechanically ventilated neonates and children in the ICU.¹⁷
- A web-based telehealth program for continuous positive airway pressure (CPAP) adherence coaching by respiratory therapists significantly reduced the number of minutes required per patient by 59% while maintaining similar adherence and effectiveness.¹⁸

¹³ Au DH, et al. Impact of a Telehealth and Care Management Program for Patients with Chronic Obstructive Pulmonary Disease. *Annals ATS*. First published online 02 Feb 2015 as doi: 10.1513/AnnalsATS.201501-042OC.

¹⁴ Segrelles Calvo, G, et al. A home telehealth program for patients with severe COPD: The PROMETE study. *Resp Med*. Volume 108, Issue 3, March 2014;pp. 453-462. doi:10.1016/J.rmed.2013.12.003.

¹⁵ Vitacca M, et al. Tele-assistance in chronic respiratory failure patients: a randomized clinical trial. *Eur Respir J*. 2009. Feb;33(2):411-418. Epub 2008 Sep 17.

¹⁶ Alrajab S, Smith TR, et al. A home telemonitoring program reduced exacerbation and healthcare utilization rates in COPD patients with frequent exacerbations. *Telemed J E Health*. 2012 Dec;18(10):772-6.

¹⁷ Bell RC, Yager PH, et al. Telemedicine Versus Face-to-Face Evaluations by Respiratory Therapists of Mechanically Ventilated Neonates and Children: A Pilot Study *Resp Care*. February 1, 2016; vol. 62. No. 2:149-154.

¹⁸ Munafo D, Heyener W, et al. A telehealth program for CPAP adherence reduced labor and yields similar adherence and efficacy when compared to standard of care. *Sleep Breath*. DOI 10.1007/s11325-015-1298-4. Published online January 2016.

MIPS Offers New Opportunities for Respiratory Therapists

Respiratory therapists can make a difference in the lives of pulmonary patients. In order to gain optimal clinical outcomes and improve cost effectiveness, patient education and proper device selection for aerosol delivery and oxygen systems are critical. Licensed respiratory therapists are experts in this field and the added time they can spend with the patient to assist physicians in the office setting can be invaluable.

Physician practices and their patients can reap the benefits of employing and utilizing the expertise of respiratory therapists -- hospital admissions, readmissions and ED visits can be reduced, acute exacerbations can be prevented, adherence through proper demonstration and training on use of respiratory devices including oxygen can be improved, and the progression of pulmonary disease can be slowed with self-management education and training.

We believe the new MIPS payment system expands opportunities for respiratory therapists to be chronic disease managers and to work outside of the acute care inpatient setting. To improve overall efficiency, care coordination and quality of care, and to strengthen efforts to reform delivery systems that serve Medicare beneficiaries as outlined in the subject proposed rule, we encourage physician practices to include respiratory therapists as part of the team, even if on a part-time basis.

With the incentives offered by the new Quality Payment System, respiratory therapists can be a valuable asset to the physician practices and Alternative Payment Models. Overall, respiratory therapists have the expertise to assist physicians to determine the clinical needs of patients with chronic lung disease and to educate patients on self-managing their disease.

We appreciate the opportunity to provide comments on this important proposed rule.

Sincere

A handwritten signature in black ink, appearing to read "Frank R. Salvatore". The signature is fluid and cursive, with the first name "Frank" being the most prominent.

Frank R. Salvatore, RRT, MBA, FAARC
President