



AMERICAN ASSOCIATION FOR RESPIRATORY CARE
9425 North MacArthur Blvd., Suite 100, Irving, TX 75063, (972) 243-2272, Fax (972) 484-2720
<http://www.aarc.org>, E-mail: info@aarc.org

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Administrator Seema Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1734-P – CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, etc.

As President of the American Association for Respiratory Care (AARC), I am pleased to submit comments regarding proposed updates to the calendar year (CY) 2021 physician fee schedule (PFS). The AARC is a national professional organization with membership of over 45,000 respiratory therapists and whose organizational activities impact over 150,000 practicing respiratory therapists across the country. Respiratory therapists specialize in providing pulmonary diagnostics and care and are experts in treating patients who suffer from respiratory conditions like Chronic Obstructive Pulmonary Disease (COPD), asthma, pneumonia, lung trauma and other respiratory-related diagnoses.

Telehealth

We appreciate CMS' confirmation in its June 19, 2020 update to the list of COVID-19 Frequently Asked Questions (FAQs) that auxiliary staff, such as respiratory therapists, can furnish telehealth services under Medicare's Part B "incident to" benefit category with the physician or other qualified non-physician practitioner billing Medicare. We are also supportive of CMS' decision to allow hospitals to bill for outpatient hospital services provided by auxiliary staff using telehealth and thank CMS for its example of respiratory therapists as staff who meet the criteria.

While we recognize these policies are in place only during the public health emergency (PHE), we are encouraged by the statement in the proposed CY 2021 update to the PFS that says: "We note that there are no Medicare regulations that explicitly prohibit eligible distant site practitioners from billing for telehealth services provided incident to their services." We interpret this to mean that telehealth services that remain on the list beyond the PHE or the end of CY 2021, whichever is later, could be provided by auxiliary staff incident to the practitioner's professional's service assuming relevant criteria are met and the physician or

other qualified non-physician practitioner bills Medicare. We request that CMS clarify this issue in the final rule as it pertains to services that remain on the permanent telehealth list.

List of Telehealth Services – Add CPT 94644 as a Category 3 Service

The PFS rule discusses proposed additions to the telehealth services list for CY 2021 in addition to those services to be added on a temporary basis under a new Category 3. This new Category was developed during the PHE to allow CMS to place services on the telehealth list temporarily that it believes would provide a clinical benefit but for which data are insufficient to consider whether they currently meet the requirements to be added permanently. CMS invites comment on the consideration of other services not included on the list of Category 3 proposed additions.

On April 30, 2020, CMS added CPT Code 94664, *Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device* as a temporary telehealth service during the PHE. The AARC feels strongly that this code should be added to the temporary list under Category 3 for the following reasons:

- The ability to deliver proper evaluation and demonstration of inhaler techniques in a patient’s home via telehealth addresses a real need to ensure those with chronic respiratory conditions maintain the intended clinical benefit from their inhaled medications in order to reduce acute exacerbations that could lead to costly acute care interventions.
- It allows for the collection of claims data that can show improved patient outcomes through a reduction in emergency and hospital admissions and physician visits.
- It avoids the need to put patients with underlying respiratory conditions at risk by teaching proper medication adherence that can lessen their exposure to COVID-19 without the need for an in-person physician visit.
- It is safe and ensures that high quality care can be maintained.

Medication non-adherence is costly to the health care system: The economic impact of medication non-adherence places a significant burden on the health care system. In 2016, the estimated annual cost of prescription-drug related morbidity and mortality resulting from nonoptimized medication therapy was \$528.4 billion, equivalent to 16 percent of total US health care expenditures, with a plausible range of costs between \$495.3 billion to \$672.7 billion.¹

Studies show improper inhaler techniques have important consequences: Proper device selection together with patient training and education on proper inhaler technique can improve medication adherence and is critical to optimizing patient outcomes among those with chronic respiratory disease. There are three basic types of delivery systems which include nebulizers, metered-dose inhalers, and dry-powder inhalers. All three have their own specific

¹ Watanabe JH, McInnis T, Hirsch JD. Cost of Prescription Drug-Related Morbidity and Mortality. *Ann Pharmacother.* 2018 Sep;52(9):829-837. doi: 10.1177/1060028018765159. Epub 2018 Mar 26. PMID: 29577766. Accessed September 19, 2020.

characteristics and delivery capabilities. Poor inhaler technique is common, especially among individuals with COPD. It is essential that educational interventions such as use of CPT Code 94644 via telehealth be allowed to continue not only during the pandemic but on a permanent basis to ensure Medicare beneficiaries, especially those living in rural areas, get the overall benefit of the aerosol medications they are prescribed.

Data from a controlled randomized trial on the use and inhalation technique of inhaled medication in patients with asthma and COPD² showed that COPD patients had a significantly better mean FEV₁% predicted at baseline when they used their devices correctly compared to those with incorrect techniques who were more likely to suffer from cough or breathlessness while walking uphill or a flight of stairs. There was no significance found in asthma patients. The study concluded that “correct inhalation of prescribed medication is associated with improved health status and lung function” and encouraged healthcare professionals to provide instructions on correct inhalation technique and to regularly re-evaluate the patients’ inhalation technique. Proper inhaler technique and medication adherence are especially important given that 56 percent of Medicare beneficiaries with COPD have 5 or more other conditions and 49 percent of those with asthma have 5 or more other conditions.³

Upfront investment of personnel to train patients in proper inhaler technique can save time and resources by preventing uncontrolled exacerbations because of poor technique, and respiratory therapists working “incident to” the physician’s professional service are best positioned to improve patient outcomes. A study designed to look at the effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD⁴ found “...between 4 percent and 94 percent of patients, depending on the type of inhaler and method of assessment, do not use their inhalers correctly.” The study cited the most common errors as “failure to exhale before actuation, failure to breath-hold after inhalation, incorrect positioning of the inhaler, incorrect rotation sequence, and failure to execute a forceful and deep inhalation” leading to insufficient drug delivery and hence to insufficient lung deposition and noted that as many as 25 percent of patients have never received verbal inhaler technique instruction, and for those that do, the quality and duration of instruction is not adequate and not reinforced by follow-up checks.”

A study to evaluate teaching inhaler techniques in COPD patients⁵ found that incorrect use of inhalers is very common in these individuals. Some of the consequences of poor inhaler technique listed in the study include “reduced therapeutic dosing, medication adherence, and disease stability, which can lead to increased morbidity, decreased quality of life, and a high

² Gregoriano C, Dieterle T, et al. Use and inhalation technique of inhaled medication in patients with asthma and COPD: data from a randomized controlled trial. *Respiratory Research* (2018) 19:237 <https://doi.org/10.1186/s12931-018-0936-3>. Accessed September 15, 2020.

³ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CCDashboard>. Accessed September 26, 2020.

⁴ Lavorini F, Magnan A, et al. Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. *Respir Med*. 2008 Apr;102(4):593-604. doi: 10.1016/j.rmed.2007.11.003. Epub 2007 Dec 20. PMID: 18083019. Accessed September 24, 2020.

⁵ Lareau S, Hodder R. Teaching inhaler use in chronic obstructive pulmonary disease patients. *J Am Acad Nurse Pract*. 2012 Feb;24(2):113-20. Doi: 10.1111/j.1745-7599.2011.00681.x. Epub 2011 Dec 19.

burden on the healthcare system.” The study concluded that “knowledgeable evaluation and frequent reassessment of inhaler use coupled with education of patients, caregivers, and healthcare professionals can significantly improve the benefits COPD patients derive from inhaled therapy.”

Respiratory therapists are experts in demonstrating and evaluating proper inhaler technique:

Aerosol therapy is considered one of the cornerstones in the management and treatment of chronic respiratory disease and exemplifies the nuances of both the art and science of 21st century medicine. As chronic respiratory disease continues to grow in prevalence and consume a large portion of healthcare dollars, an explicit understanding of the science of aerosol therapy, the nuances of the different delivery devices, and the ability to provide accurate and reliable education to patients has become increasingly important.

A multicentric study to evaluate correct inhalation techniques in a nationwide sample of patients and medical personnel to define targeted educational goals⁶ found that only 9 percent of patients, 15 percent of nurses, and 28 percent of physicians showed a correct inhalation technique. Respiratory therapists are experts when it comes to the delivery of aerosol therapy and should be the primary health care professionals to teach Medicare beneficiaries with chronic respiratory conditions how to correctly use their inhalers. In the hospital setting, instructions of patients by respiratory therapists on metered-dose inhaler use led to a decrease in patient errors with the baseline error rate of 6.72 (out of 15 possible) errors per patient to 2.43 errors per patient after RT-provided instructions.⁷ Tailored educational interventions to teach inhaler technique should be part of the process of initiating and monitoring inhaled therapies.⁸ We believe demonstration and evaluation of inhaler techniques can easily be transferred to a telehealth platform with comparable results.

Due to the complexities of inhaler devices and variations among products, respiratory therapists’ expertise can help bridge the gap between pulmonary patients’ needs and their ability to minimize unnecessary, ineffective, or wasteful interventions. AARC recognizes that with a renewed focus on wellness and prevention within the US health care system and a determined focus to minimize cost and waste, the choice of appropriate respiratory medications and delivery devices makes selection of both the drug and optimum delivery device even more critical. Adequate patient education and self-management, in addition to matching the correct device to the patient via telehealth, will increase patients’ chances for better adherence to therapy and outcomes over the long term and respiratory therapists can help achieve those goals via telehealth.

⁶ Plaza V, Sanchis J. Medical Personnel and Patient Skill in the Use of Metered Dose Inhalers: A Multicentric Study. *Respiration* 1998;65:195–198. <https://doi.org/10.1159/00029259>. Accessed September 18, 2020.

⁷ 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* 2005 Aug;50(8):1040-5.

⁸ Melzer AC, Ghassemieh BJ, et al. Patient characteristics associated with poor inhaler technique among a cohort of patients with COPD. *Respiratory Medicine* 123 (2017) 124-130 <http://dx.doi.org/10.1016/j.rmed.2016.12.011>. Accessed September 19, 2020.

Direct Supervision

Recognizing that direct supervision can be an issue under the incident to rule, CMS has allowed the eligible distant site physician or non-physician practitioner to meet the direct supervision requirement through a virtual presence that includes two-way, audio-video communications technology for the duration of the PHE. Under the CY 2021 PFS update, CMS is now proposing to expand this policy to make the virtual physician supervision requirement available through the later of the end of the calendar year in which the PHE ends or December 31, 2021. The AARC supports the proposal.

Considering whether virtual direct supervision should remain beyond the extended time noted above, CMS asks whether there are any “guardrails” that should be put in place to ensure patient safety and clinical appropriateness beyond clinical standards or whether restrictions should be put in place to prevent possible fraud or inappropriate use. Because there are relatively few telehealth services on CMS’ list outside of the usual office visits and consultations, except for smoking cessation counseling, that would be used for beneficiaries with chronic respiratory conditions, we believe the physician’s clinical judgment consistent with accepted guidelines and knowledge of the individual beneficiary and treatment plan is sufficient to ensure whether telehealth is safe and effective and appropriate in a given situation.

Remote Physiological Monitoring (RPM)

The AARC appreciates CMS clarifying CPT codes 99453, 99454, 99091 and 99457 (and the add-on code, CPT 99458) that describe various components of remote physiological monitoring (RPM) of a patient’s health. We support and are encouraged that 99453 and 99454 are valued to include clinical staff time (e.g., auxiliary personnel) under the physician’s general supervision, particularly with respect to instructing a patient and/or caregiver about using one or more medical devices. When collecting data on pulse oximetry and respiratory flow rates, for example, this clarification ensures that respiratory therapists can be directly involved in the set-up and educational process of RPM devices for those beneficiaries with chronic respiratory disease.

Although we recognize that the code descriptors for CPT 99457 and 99458 include a “live, interactive communication” with the patient/caregiver, we disagree with CMS’ interpretation of what that involves. The actual descriptor of the code is the following:

CPT 99457: Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes

The code descriptor implies the live, interactive communication with the patient is part of the 20-minute minimum which also allows time for the physician or other qualified practitioner to review or analyze the data as part of “monitoring” the treatment plan. There is nothing to suggest, as CMS proposes, that a full 20 minutes of interactive communication must be met. CMS also proposes that “interactive communication” involves real-time audio interaction that is capable of being enhanced with video. The discussion suggests that this type of communication

is like G2012, which consists of a “virtual e-visit” in which the physician spends 5-10 minutes of medical discussion. We disagree with both analogies and feel that the ability of patients to receive these important services will be dramatically impacted if CMS finalizes this proposal. CMS has emphasized that RPM is separate from telehealth and not subject to its restrictions which require a synchronous two-way audio/visual communication. The interpretation that the interactive communication must be capable of being enhanced with video runs counter to the way RPM services are furnished.

We recommend CMS revise its description of “live, interactive communication” in the final rule to clarify that this type of communication can be provided by two-way audio interaction and that the 20 minutes includes both monitoring and communication.

Transitional Care Management Services (TCM)

Transitional Care Management (TCM) involves moderate or high-complexity decision making services for patients that are transitioning from a hospital or other facility, such as skilled nursing or inpatient rehabilitation, and are designed to prevent hospital readmissions within 30 days of discharge. Non-face-to-face services can be provided by clinical staff under the general supervision of the physician or other qualified health care professional. Early on, CMS determined that TCM services and chronic care management (CCM) services could not be billed concurrently due to the potential for duplication. But beginning in CY 2020, CMS changed its policy due to low utilization and allowed certain TCM services to be furnished concurrent with CCM. In the CY 2021 update, CMS is proposing to add an additional 15 codes that could be billed concurrently with TCM, one of which includes G2058, Chronic care management services, each additional 20 minutes of clinical staff time under the general supervision of the physician or other qualified health care professional. The AARC supports the inclusion of this code.

We commend CMS for the many waivers and lifting of restrictions during the public health emergency that have allowed increased access to telehealth and other important services. We are especially appreciative of flexibilities CMS has made that improve access to respiratory care services.

Sincerely,



Karen S. Schell, DHSc, RRT, RRT-NPS, RRT-SDS, RPFT, RPSGT, AE-C, CTTS
President