



September 13, 2021

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, District of Columbia 20201

RE: CMS-1751-P: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

The national pulmonary organizations listed below appreciate the opportunity to comment on the proposed CY 2022 updates to the physician fee schedule (PFS). We are especially interested in CMS' proposed changes to policies impacting coverage of pulmonary rehabilitation (PR) services. These deal with the timeframe for continuing virtual direct supervision, the safety of delivering PR services virtually, expanded coverage for Medicare beneficiaries post-COVID-19 hospital discharge who meet certain criteria, the addition of two new PR CPT codes and conforming changes to PR terminology and definitions to align with cardiac and intensive cardiac rehabilitation. Our detailed comments on these issues are outlined below.

I. Virtual direct supervision for pulmonary rehabilitation

In 2020, as part of the agency's response to the COVID-19 pandemic, CMS offered the flexibility to meet direct supervision requirements for pulmonary, cardiac, and intensive cardiac rehabilitation services virtually without requiring the physician's physical presence in the location where services are provided. The rationale provided by CMS initially was to improve access for patients and reduce burden for providers during the public health emergency (PHE). Virtual presence is delivered through audio/video real-time communications technology (excluding audio-only), subject to the clinical judgment of the supervising physician.

In the CY 2021 PFS update, CMS extended continuation of the virtual direct supervision policy through the later of the end of the calendar year in which the PHE for COVID-19 ends or December 31, 2021. In the subject CY 2022 proposed rule, CMS is seeking input on the extent to which this requirement is being used and whether physicians and practitioners anticipate relying on this flexibility after the end of the PHE. Last, CMS invites comments on whether the virtual direct supervision should be made permanent or if the policy should be continued for a short additional time to facilitate a gradual sunset of the provision.

RECOMMENDATION

We strongly recommend that CMS continue to allow direct supervision to be met via virtual presence beyond the PHE and ultimately on a permanent basis.

Rationale: Some PR programs were forced to move out of the hospital to make room for COVID patients. This virtual option of direct supervision has allowed hospitals to provide PR at hospital outpatient off-campus locations where a physician is not physically and immediately available. It has particularly provided improved access to PR services in rural and critical access hospitals (CAH) through expanded hours that, under this temporary waiver, are not restricted to the provision of services only when a physician is immediately and physically available.

The safety of pulmonary rehabilitation has been well-substantiated. Rates of reported adverse events are very low at 0.4 percent.¹ Anecdotal evidence to date suggests that there have been no medical emergencies with direct supervision delivered via virtual audio-visual telecommunication technology.

Recognizing that more than 97 percent of PR programs are in the hospital outpatient setting,² it will be critical that virtual direct supervision be an option for *both* the outpatient and physician office setting on a permanent basis. This is especially important because these valuable programs have proven not only to improve health outcomes and quality of life, but a recent study shows a 37% drop in mortality in those who received pulmonary rehabilitation within three months of hospital discharge.³ Our professional societies believe it will be evident that the quality and safety of pulmonary rehabilitation services are not negatively affected and, in fact, access to these services is improved with a virtual option for direct supervision requirements.

II. Safety and continued virtual delivery of pulmonary rehabilitation sessions

COVID safety protocols have severely limited access to pulmonary rehabilitation services and continue to do so. To address the issue, CMS adopted an interim final rule at the end of March 2020 (85 FR 19245) to include the virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology, recognizing that the physical presence of the physician or practitioner might present an additional risk of infection to the patient. At the time we strongly supported this decision although we were disappointed when CMS decided not to make it permanent but to continue it with the specified deadlines discussed in Item I.

RECOMMENDATION

Current enhanced access to PR via virtual delivery should be extended into 2022 as health care in the US moves increasingly to effective telehealth models.

Rationale: In addition to CMS' analysis of PR utilization rates among Medicare beneficiaries, studies confirm that PR services are extremely underutilized.^{4,5} With waivers adopted during the pandemic, the flexibility to deliver PR sessions via virtual real-time communications technology and telehealth has benefitted PR beneficiaries throughout the U.S. Anecdotal and early research suggests beneficiaries have exhibited improved adherence due to removal of

previously identified barriers such as travel, time, restricted PR space, expenses, and other deterrents to utilization. Virtual delivery of PR sessions appears to yield similar outcomes to center-based PR, including:

- Significant reduction in 30-day readmission rates for COPD patients, including those discharged from the hospital after a COPD exacerbation,⁶
- Significantly improved exercise endurance and self-efficacy of patients and a positive trend towards improvements in health-related quality of life (HRQoL) when compared with usual medical care,^{7,8,9}
- Feasible, safe, and equivalent short-term clinical gains,¹⁰
- High degree of adherence and improved self-management abilities.¹¹

Real-time (synchronous) virtual delivery of PR requires the flexibility to meet the direct supervision requirement via virtual presence using real-time audio-visual technology. Because many PR programs have not had the bandwidth to expand to virtual delivery during the PHE, data on outcomes in comparison to center-based rehabilitation are in the early stages of assessment. Given the current rise in COVID-19 cases due to the delta variant, it is critical that the virtual delivery of pulmonary rehabilitation continue. As noted above, the safety of PR services has been validated and offers strong evidence that the virtual delivery of services is an important aspect in improving patient outcomes.

III. Expansion of Pulmonary Rehabilitation for Certain COVID-19 Beneficiaries

CMS is proposing to expand coverage of PR services to include beneficiaries who were hospitalized with a diagnosis of COVID-19 and continue to experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge. After a thorough analysis of the impact of this change, CMS concludes that as hospitalizations and COVID-19 cases decline, the annual impact on utilization will also likely decrease although the long-term impact is unknown due in part to the unpredictable nature of the public health emergency. We strongly support CMS' proposed expansion of PR services and believe its impact on utilization should be a non-starter given the fact that early research cited by CMS indicates PR will be beneficial for beneficiaries with this diagnosis.² However, we have concerns about restricting coverage for this population until 4-weeks after hospital discharge.

RECOMMENDATIONS

Although we strongly support the CMS proposal to expand PR to long-haul COVID-19 beneficiaries, we suggest removing the restriction of a 4-week delay between hospital discharge and start of PR for all eligible patients. For some beneficiaries, this is a critical time when the medical surveillance provided in PR earlier than one month after hospital discharge would benefit certain patients and serve to decrease re-hospitalization, physician visits, and worsening pulmonary status.

We recommend that eligibility to PR for long-haul COVID-19 beneficiaries with respiratory dysfunction should not be contingent on hospitalization but should be made by a physician

using clinical judgment. There are patients for which referral to PR is appropriate and in the best interest of the beneficiary's health, whether the patient was hospitalized or not.

Rationale: A recent observational study compared the results of PR of a larger group of severely impaired post-COVID-19 patients to individuals typically referred to PR.¹² Results demonstrated that improvements during PR were significantly higher for the post-COVID group, concluding that post-acute comprehensive pulmonary rehabilitation is associated with significant clinical and functional improvements in individuals who suffered from severe COVID-19 and underlines the importance of post-acute rehabilitation for COVID-19 recovery. Two recent studies of Medicare beneficiaries found significant differences in both the number of rehospitalizations ($p < 0.001$)¹³ and risk of death ($p < 0.001$) over 1 year between those beneficiaries who initiated PR within 90 days of hospitalization.³ While these findings did not include a COVID-19 population, the symptomatology is similar and would suggest that the exercise provided in PR is a promising therapy for long-COVID.

Regarding a 4-week delay period between hospital discharge and initiation of PR, research specific to outcomes of PR provided to COVID-19 survivors with on-going respiratory dysfunction shows the potential for positive outcomes. One study reviewed 40 recent publications suggesting that PR is appropriate in treating numerous physiologic and psychological needs of this patient population.¹⁴ Given the impaired lung function, one study recommends starting PR at the earliest possible opportunity, in advance of patients developing more severe or limited ventilatory capability.¹⁵ Another prospective observational cohort study of the benefits of PR in COVID-19 concluded that PR is a feasible, safe, and effective therapeutic option for COVID-19 patients independent of disease severity.¹⁶ It is critical that medical surveillance and education begin soon after hospitalization. Feedback from COVID-19 patients in PR has been overwhelmingly positive, given their prior lack of knowledge about how to use an inhaler, a spacer, oxygen, and how to regain strength and endurance.

We have concerns about PR eligibility being limited to hospitalized patients with post-acute sequelae of COVID-19 (PASC). Studies indicate that, in fact, hospitalization should not be a criterion for enrollment in PR. Evidence from the CDC states that,

“Some patients who have been infected with SARS-CoV-2, the virus that causes COVID-19, have new, recurring, or ongoing symptoms and clinical findings four or more weeks after infection, sometimes after initial symptom recovery. Post-COVID conditions can occur in patients who have had varying degrees of illness during acute infection, including those who had mild or asymptomatic infections.”¹⁷

Other studies have shown that only 8.4% of patients experiencing PASC were hospitalized¹⁸ and less than 50% of patients did not have a hospitalization.¹⁹ Furthermore, anecdotal reports from pulmonologists are that they are treating non-hospitalized COVID-19 patients with severe respiratory compromise who would equally benefit from PR.

Recommendation:

We recommend CMS consider additional categories of beneficiaries with non-COPD pulmonary diseases as appropriate to receive this high-value, evidence-based treatment.

Rationale: We would point out that there are beneficiaries with other pulmonary conditions who would benefit from receiving PR services, especially those diagnosed with adult respiratory distress syndrome (ARDS). Some patients with non-COPD diagnoses receive care under individual respiratory therapy services; however, the delivery of components of PR for beneficiaries with similar education and exercise training does not equate to the comprehensive approach of PR, which has proven to be effective in reducing exacerbations, re-hospitalizations, and improving survival.

IV. Addition of Two New CPT Codes for Pulmonary Rehabilitation

Earlier this year, the American Medical Association's (AMA) CPT Editorial Panel approved two new codes for pulmonary rehabilitation. These are:

- CPT 946X1 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)*)
- CPT 946X2 (*Physician or other qualified health care professional service for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)*)

It is our understanding that these PR codes were based on the procedure codes developed for cardiac and intensive cardiac rehabilitation, which include, "*with continuous electrocardiographic (ECG) monitoring, per session*" and "*without continuous electrocardiographic (ECG) monitoring, per session.*" In CMS' discussion of these new codes, they indicate they expect little to no utilization for CPT Code 946X1 and are seeking comment on the accuracy of their understanding. CMS also seeks comment on their revisions to the relative value rates used to determine payment which are lower than those recommended by the AMA's RUC committee.

Comment: Although we are disappointed that CMS has chosen to lower the practice expense and other calculations that go into determining the payment rates for the new PR CPT Codes, we are pleased that payment is significantly increased for PR services provided in physician offices and paid under the physician fee schedule.

With respect to CMS' analysis that 100 percent of the utilization of PR services currently billed under G0424 will be billed under CPT 946X2, it is more accurate to say the code will be billed more often than CPT 946X1. The treatment in PR is individualized. Some patients require continuous monitoring of oxygen saturation while other patients never or rarely desaturate and require little to no oximetry monitoring. This is especially true as a patient proceeds further in the pulmonary rehabilitation process. The goal of self-management includes education on how and when to use oximetry monitoring, so tapering this measurement is appropriate in some patients who improve enough to not require continuous observation of oxygen saturation levels. Some patients may require monitoring of blood pressure or blood glucose or other

physiologic or psychological measurements. These monitoring components are all part of a comprehensive PR program.

V. Conforming changes among rehabilitation services

To improve the consistency and accuracy across conditions of coverage for pulmonary and cardiac and intensive cardiac rehabilitation, CMS proposes to make numerous conforming changes with respect to terminology, regulatory text, and definitions. The changes are designed to emphasize similarities between the programs in the methods used to treat respiratory and cardiac diseases, the components that comprise the overall program requirements including direct physician supervision, and the resultant improvements in quality of life. CMS plans to largely maintain the CR/ICR regulatory text and align the PR regulatory text with it rather than the other way around based on previous input from stakeholders.

Comment: We agree that there are similarities among the pulmonary and cardiac rehabilitation programs and support the conforming changes CMS proposes.

VI. PR direct physician/patient contact

CMS proposes revisions to physician standards that delineate between “medical director” and “physician supervision.” Specifically, CMS plans to delete the requirement that the physician have “direct patient contact related to the periodic review of his or her treatment plan.” CMS views this requirement as burdensome and unnecessary because the physician is already required to review the patient’s plan every 30 days in consultation with staff. This is further supported by the fact that patients see PR staff at each session where there is an opportunity for staff to require direct physician/patient interaction as appropriate. Nonetheless, CMS is concerned whether this change may be potentially detrimental to the patient and asks for comments on the validity of removing the requirement.

Comment: We support eliminating the PR direct physician/patient contact requirement. We believe it is adequate to allow the physician the flexibility to provide direct patient contact where appropriate based on individual patient need, but it should not be a mandated requirement for the reasons CMS described in the proposed rule.

VII. Use of Modifier with Virtual Direct Supervision

In discussing the use of non-face-to-face services involving two-way audio/visual communications technology for direct supervision, CMS seeks comments on whether a service level modifier should be required to identify when the requirements for direct supervision were met virtually.

RECOMMENDATION

CMS should use a service-level modifier when direct supervision is being met via real-time audio/video communications technology.

Rationale: The current situation of having little data on utilization illustrates the usefulness of a modifier to better understand the extent to which virtual direct supervision is being used for CR/ICR/PR services. Use of the temporary PR telehealth code (physician office setting) and remote delivery of rehabilitation sessions under the Hospitals without Walls waiver do not adequately track current utilization of remote rehabilitation sessions. The degree of virtual direct supervision and remote delivery will be an estimate at best. This will be critical data to have going forward to address new virtual models of care.

We appreciate the opportunity to provide these comments and encourage CMS to consider the recommendations we have highlighted.

Sincerely,

Allergy & Asthma Network
Alpha 1 Foundation
American Association of Cardiovascular and Pulmonary Rehabilitation
American Association for Respiratory Care
American Lung Association
COPD Foundation
Dorney-Koppel Foundation
Pulmonary Fibrosis Foundation
Respiratory Compromise Institute
Respiratory Health Association
U.S. COPD Coalition

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