August 24, 2022

Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1770-P: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

The undersigned pulmonary organizations and patient advocacy groups appreciate the opportunity to provide comments on the CY 2023 update to the physician fee schedule. Our comments respond to the section identified below and focus on the safety and effectiveness of direct supervision through virtual presence as it relates to cardiac and pulmonary rehabilitation programs.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS Expiration of PHE Flexibilities for Direct Supervision Requirements (II.D.2.a.)

Cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) programs are an important part of recovery for those with chronic heart and lung disease and who deal with acute events and exacerbations of their conditions. After hospitalization, it is the standard of care to provide outpatient cardiac or pulmonary rehabilitation services, consisting of exercise and education. These vital programs have been shown to reduce rehospitalization and all-cause mortality, as well as improve quality of life and lifestyle choices so patients may better self-manage these chronic conditions.

We strongly support the decision by CMS in previous rulemaking to allow the statutory provision regarding direct supervision of cardiac and pulmonary rehabilitation programs to be met through virtual presence via real-time, two-way audio/visual telecommunications technology. Although CMS notes in the CY 2023 proposed rule that it is not proposing to make this provision permanent, they continue to seek information on whether such a flexibility should be made permanent, or whether it would be more appropriate on a permanent basis to allow the direct supervision through virtual presence only for a subset of services due to potential concerns over patient safety.
CMS states that after December 31 of the year in which the public health emergency (PHE) ends, the pre-PHE rules for direct supervision at § 410.32(b)(3)(ii) would apply. We acknowledge the end of this temporary program and have grave concerns about patient access and adherence to these valuable programs if CMS chooses not to make permanent direct supervision through virtual presence via real-time, audio/visual telecommunications technology. We appreciate the opportunity to provide the comments below in support of our recommendations.

**Recommendation**

To meet Medicare statutory requirements, we strongly recommend CMS make permanent direct supervision through virtual presence via real-time, audio-visual telecommunications technology in the final CY 2023 update to the physician fee schedule so Medicare beneficiaries can continue to receive cardiac and pulmonary rehabilitation services that can improve their lives.

**Comments**

CMS seeks information to help alleviate concerns over patient safety issues related to direct supervision through virtual presence that can facilitate a decision on whether to make the provision permanent or whether it would be a more appropriate option to designate the provision for only a subset of services. From the Medicare perspective, this option to meet direct supervision requirements has only become available during the PHE. Thus, it is unlikely there are any peer-reviewed studies that focus on this aspect of virtual care. However, we have attached numerous studies that showcase the effectiveness and safety of virtual CR and PR services that we believe make a strong case for CMS to make the option of direct supervision through virtual presence permanent. The studies demonstrate virtual and hybrid delivery of CR and PR services provided by staff are safe, improve health outcomes and adherence, and address barriers to access. Based on the importance of these programs in improving patients’ lives and their quality of life, we believe the studies speak for themselves in addressing CMS’ concerns.

**Recommendation:**

CMS should not restrict direct supervision through virtual presence to a subset of services. The decision on whether to provide direct supervision through virtual presence via real-time, two-way audio/virtual telecommunications should be left up to the practitioner overseeing the patient’s care.

**Comments:**

With respect to the current statutory provision that only physicians can provide direct supervision of cardiac and pulmonary programs, our organizations believe they are clearly in the best position to determine whether direct supervision through virtual presence can be provided safely and effectively to their patients based on the individual’s medical needs, and they should be given the flexibility to make those decisions on a case-by-case basis. Thus, we do not believe CMS should be making decisions in lieu of clinical judgment as to whether a subset of services is more appropriate than others to receive this important option.
In previous comments, we stated that with more than 97 percent of CR and PR programs in the hospital outpatient setting, it is critical that direct supervision through virtual presence be an option for both the outpatient and physician office setting on a permanent basis. This is especially important because emerging data suggests a further benefit of PR: a reduction in mortality. A study by Lindenauer and colleagues\(^1\) found that, in persons hospitalized due to exacerbation of COPD, PR within 3 months of discharge vs. later or no PR, was associated with a highly significant lower risk of mortality at 1 year (hazard ratio, 0.63; i.e., a 37% lower risk of death over the year following discharge). The study utilized claims data of 197,376 Medicare beneficiaries discharged after hospitalization for COPD.

In persons with fibrotic interstitial lung disease (ILD) including idiopathic pulmonary fibrosis, Guler, et. al.,\(^2\) demonstrated that that those with greater improvement in exercise performance (assessed by six-minute walk distance) following PR had improved survival. Those persons with ILD who participated in at least 80% of planned PR sessions had a 33% lower risk of death. Both studies support PR as a high priority for persons with COPD and fibrotic ILD. Providing permanent direct supervision through virtual presence can significantly improve the ability of physicians to meet their patients’ needs to improve their health outcomes and reduce mortality.

Our professional societies and patient advocacy groups believe the attached studies provide clear evidence that the quality and safety of CR and PR services are not negatively affected when provided via telecommunications technologies and should provide a pathway for CMS to make the option of direct supervision through virtual presence permanent. We intend to make similar comments in the CY 2023 update to the hospital outpatient prospective payment rules.

We appreciate the opportunity to provide these comments. If you have further questions, please contact Karen Lui at karen@advocate4action.com.

Sincerely,

Alergy & Asthma Network  COPD Foundation  Dorney-Koppel Foundation
Alpha-1 Foundation  Heart Failure Society of America  Pulmonary Fibrosis Foundation
American Association of Cardiovascular and Pulmonary Rehabilitation  Respiratory Compromise Institute
American Association for Respiratory Care  Respiratory Health Association
American College of Cardiology  Society for Cardiovascular Angiography & Interventions
American Heart Association  The LAM Foundation
American Lung Association  The Society of Thoracic Surgeons
American Thoracic Society  US COPD Coalition
CHEST/American College of Chest Physicians

Attachment


CARDIAC REHABILITATION: Studies involving virtual and hybrid delivery of cardiac rehabilitation services demonstrate safety, improved outcomes over usual care, patient acceptance, and adherence.

I. Lear, SA, et al., tested the clinical effectiveness of a virtual cardiac rehabilitation program (vCRP) delivered exclusively using Internet-based technology\(^3\) in response to a call from American Heart Association Presidential Advisory for more robust research in this area.

- 72 participants were recruited and randomized to usual care (n=40) or the vCRP (n=38), with age of the participants at 58.4 in the UC group (52.8, 64.7) and 61.7 (51.3, 65.2) in the Intervention Group.
- Adherence to the vCRP intervention was based on website usage from the 34 completing vCRP participants.
  - A total of 41% of vCRP participants uploaded ≥32 exercise reports equating to an average of 2 exercise bouts per week.
  - A total of 26% of vCRP participants uploaded the required 8 blood pressure reports.
  - There were 122 one-to-one private chat sessions between the vCRP participants and the nurse, dietitian, or exercise specialist, which averages to 3.6 sessions per participant.
  - The average participant used 2.4, 2.6, and 2.7 hours of nursing, dietitian, and exercise specialist time, respectively.

- RESULTS: The vCRP was safe and superior to usual care in reducing CVD risk and sustaining this reduction delivered exclusively through the Internet to patients in small urban and rural locations.
  - Significant improvements in exercise capacity and dietary quality, with reductions in cholesterol levels was reported. As exercise capacity has a strong association with CVD mortality the authors noted it is a stronger prognostic indicator than other traditional risk factors.
  - After adjustment for the maximal time on the treadmill at baseline, age, sex, type 2 diabetes mellitus, and Internet use for health information, participants in the vCRP had a greater increase in maximal time on the treadmill by 45.7 (95% confidence interval, 1.04–90.48) seconds compared with the usual care group during the 16 months \( (P=0.045) \).
  - Of importance is that the benefits of the vCRP were sustained for a 12-month period after removal of the 4-month intervention. This is a key finding because recidivism in cardiac rehabilitation is commonplace after completion of a program, and the drop-out rates in these programs are as high as 35%.

\(^3\) Lear, SA, et. al., Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet. Circulation: Cardiovascular Quality and Outcomes. Volume 7, Issue 6, November 2014; Pages 952-959. https://doi.org/10.1161/CIROUTCOMES.114.001230.
II. Heindl B, et al.,\(^4\) conducted a review of hybrid cardiac rehabilitation (CR) studies, defined as any combination of supervised center-based and monitored home-based exercise where at least two of the core components are addressed.

- Nine studies were found comparing hybrid CR to 1) traditional center-based CR among coronary artery disease (CAD) patients, (2) usual care among CAD patients, and (3) usual care among heart failure (HF) patients.
- Each study typically began with a center-based component lasting 2-11 weeks and transitioned to a home-based component lasting 10-22 weeks, with 3-5 exercise sessions per week composed of either walking (usually with a treadmill) or cycling for 25-35 minutes at 60-75% maximal heart rate.
  - Patients recorded data from home exercise sessions, via either a digital heart rate monitor or accelerometer, into logbooks which were reviewed by a therapist at specified intervals (often via telephone).
  - Counseling on risk factor management was predominantly provided during the center-based component.

**RESULTS:** Compared with usual care, in patients with CAD, the studies concluded that “hybrid CR reduced cardiovascular events, and improved lipid profiles, exercise capacity, and health-related quality of life (HRQoL).”

- In patients with HF, compared with usual care, hybrid CR improved physical function, exercise capacity, and HRQoL.”
- Hybrid CR also led to similar short-term outcomes compared to traditional CR in patients with coronary artery disease (CAD), as well as increased adherence and reduced delivery costs.

III. A study by Keteyian SI, et al.,\(^5\) compared exercise training intensity during standard cardiac rehabilitation (S-CR) versus telehealth cardiac rehabilitation (TH-CR) as part of a Hybrid-CR (combined clinic- and remote home-/community-based) program.

- The over-all mean exercise training intensities during both the S-CR sessions and the TH-CR sessions from Hybrid-CR were not significantly different at 63±12% and 65±10%, respectively \( (P = .29) \).
  - While the authors acknowledged the model for Hybrid-CR using telehealth may not be feasible for some due to staff preparedness or limited access technology, it was noted that due to the pandemic, most health care systems are now better prepared to equip and assist CR staff with operationalizing a remote CR model that incorporates virtual telehealth.

**RESULTS:** There were no serious adverse events or falls that required hospitalization during or within 3 hours after completing a CR session.

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IV. Imran HM, et al.\(^6\), undertook a systematic review and meta-analysis of randomized controlled trials (RCT) to compare functional capacity and health-related quality of life (hr-QOL) outcomes in heart failure for 1) home-based cardiac rehabilitation (HBCR) and usual care, 2) hybrid-CR and usual care, and 3) HBCR and center-based CR (CBCR).

- 31 randomized controlled trials with a total of 1791 heart failure participants were identified.
  - Among 18 studies that compared HBCR and usual care, participants in HBCR had improvement of peak oxygen uptake (2.39 mL/kg per minute; 95% CI, 0.28–4.49) and hr-QOL (16 studies; standardized mean difference: 0.38; 95% CI, 0.19–0.57).
  - Nine RCTs that compared hybrid CR with usual care showed that hybrid CR had greater improvements in peak oxygen uptake (9.72 mL/kg per minute; 95% CI, 5.12–14.33) but not in hr-QOL (2 studies; standardized mean difference: 0.67; 95% CI, −0.20 to 1.54).
  - Five studies comparing HBCR with CBCR showed similar improvements in functional capacity (0.0 mL/kg per minute; 95% CI, −1.93 to 1.92) and hr-QOL (4 studies; standardized mean difference: 0.11; 95% CI, −0.12 to 0.34).

- **RESULTS**: Both HBCR alone and hybrid CR were at least as safe as CBCR and had the potential to improve clinical outcomes over usual care during short-term follow-up.

V. Ganeshan S. et al.,\(^7\) compared, in cardiac rehabilitation (CR) patients, the association of in-person, hybrid, and virtual CR with change in performance on the 6-minute walk test (6MWT) between enrollment and completion.

- Patients enrolled between October 2019 and May 2021 were categorized into in-person, hybrid, or virtual groups by number of in-person and virtual visits.
  - All patients received individualized exercise training and health behavior counseling.
  - CR was delivered to patients in the hybrid and virtual cohorts using synchronous video exercise and/or asynchronous telephone visits.
  - Measurement at CR enrollment and completion included the 6MWT, blood pressure (BP), depression, anxiety, waist-to-hip ratio, and cardiac self-efficacy.

- **RESULTS**: Hybrid and virtual CR were associated with similar improvements in functional capacity to in-person and have the potential to expand availability without compromising outcomes.

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\(^7\) Ganeshan, S, et. al., Clinical Outcomes and Qualitative Perceptions of In-person, Hybrid, and Virtual Cardiac Rehabilitation, Journal of Cardiopulmonary Rehabilitation and Prevention: April 13, 2022 - Volume - Issue - 10.1097/HCR.0000000000000688. doi: 10.1097/HCR.0000000000000688
o Of 187 CR patients 37/97 (38.1%) were in person patients and 58/90 (64.4) were hybrid/virtual patients (P=.001).

o Compared to in-person (51.5 ± 59.4 m) improvement in the 6MWT was similar in hybrid (63.4 ± 55.6; P = .46) and virtual (63.2 ± 59.6; P = .55) compared with in-person (51.5 ± 59.4).

o Hybrid and virtual patients experienced similar improvements in BP control and anxiety.

o While virtual patients experienced less improvement in depression symptoms, they generally had positive perceptions of hybrid and virtual CR.

o There were no statistically significant changes in waist-to-hip ratio or cardiac self-efficacy.

VI. Jafri SH, et. al,8 compared outcomes of patients (mean age: 72, 98% male) who were referred and attended a home-based cardiac rehabilitation (HBRC) program vs patients referred but did not attend HBCR (Non-HBCR) from 3 to 12 months of the referral date. HBRC consisted of face-to-face entry exam with exercise prescription, weekly phone calls for education and exercise monitoring, with adjustments where applicable, for 12-weeks and an exit exam.

• Primary outcome was composite of all-cause mortality and hospitalizations with all-cause hospitalization; secondary outcomes were all-cause hospitalization, all-cause mortality, and cardiovascular hospitalizations, separately.
  o Primary outcome occurred in 30 patients (19.1%) in the HBCR group and 30 patients (30%) in the non-HBCR group (adjusted HR=0.56, CI 0.33-0.95, P=.03).
  o All-cause mortality occurred in 6.4% of patients in the HBCR group and 13% patients in the non-HBCR group 3 to 12 months after HBCR referral (adjusted HR=0.43, CI 0.18-1.0, P= .05).
  o There was no difference in cardiovascular hospitalizations (HBCR: 5.7% vs non-HBCR: 10%, adjusted HR 0.57, CI 0.22-1.4, P=.23) or all cause hospitalizations at 3 to 12 months between the groups (HBCR: 12.7% vs non-HBCR: 21%, adjusted HR 0.53, CI 0.28-1.01, P= .05).

• RESULTS: The study concluded that “HBCR among referred patients was associated with a lower risk of the combined all-cause mortality and all-cause hospitalizations up to 12 months. Based on the outcomes, HBCR is a reasonable option that can improve access to CR for patients who are not candidates of or cannot attend CBCR.”

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Studies show that pulmonary rehabilitation programs are safe and yield positive outcomes in a variety of ways.

I. A 2019 study conducted by Knox et al.\(^9\), assessed the feasibility, safety, and effectiveness of a virtual pulmonary rehabilitation program in a real-world setting. The study was conducted in Wales as part of a group of hospitals that covers a semi-rural population of 400,000 people living across a large geographical area.

- The program consisted of a hospital cardiopulmonary center (hub) and a rural village hall and community independent living center (spokes) linked by a real presence video conferencing system with interactive screens.
  - The age of those in the hub (n=24) was 68.6 (12.8); the age in the spoke (n=21) was 70.1 (10.8) with a P-value=0.67 (-8.93-5.79). All participants had moderate to severe COPD, with Medical Research Council (MRC) breathlessness score ≥3, on optimal medications, no exacerbations within 6 weeks, and had varying degrees of airflow obstruction.
  - Mean attendance was 11.0 sessions in the hub and 10.5 sessions in the spoke (P=0.65).
    - There was a single (mild) AE (hypoglycemia) in all three hub programs and no AEs in the three spoke programs.
    - Mean COPD Assessment Test scores improved from 25.3 to 21.5 in the hub (P<0.001, 95% CI 2.43–5.17) and from 23.4 to 18.8 (P<0.001, 2.23–7.02) in the spoke group, with no difference between the groups (P=0.51, –3.35–1.70).
    - Mean incremental shuttle walk test scores improved from 142 to 208 m (P<0.001, 75–199) in the hub and from 179 to 316 minutes in the spoke (P<0.001, 39.3–92.4), with a greater improvement in the spoke (P=0.025, 9.31–133).
    - Twenty-one patients saved a total of 8,609.8 miles over the three programs by having the PR in their local spoke, rather than traveling to the usual nearest (hospital) hub.

RESULTS: Video conferencing, which links a local site to a standard PR program is feasible, safe, and demonstrates at least equivalent short-term clinical gains.

II. A 2021 literature review conducted by Rawal, et. al.,\(^10\) noted that “less than 3% of eligible candidates for PR attend one or more sessions after hospitalization due to many barriers, including the ongoing COVID-19 pandemic.

- Emerging alternative models of PR delivery such as home-based PR, tele-rehabilitation, web-based PR, or hybrid models can help address these barriers.

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• The purpose of the review was to determine if alternative delivery models watered down the effectiveness of PR.
  o Their literature search, using PubMed, CINAHL, and Medline to identify relevant articles through 1 May 2021, identified 26 studies related to pulmonary rehabilitation of which 10 were randomized controlled trials (RCTs), 15 were cohort studies, and 1 was a case series.
  o RESULTS: Use of remotely based PR is a feasible and effective option to deliver PR, especially for patients with significant barriers to conventional clinic-based PR. Telerehabilitation was found to be both a feasible and an efficacious option for select patients with lung disease and outcomes across the studies demonstrated similar benefits to traditional PR programs.

NOTE: The studies listed below represent a screen shot of the Tables presented in the Rawal, et. at., study. The reference numbers in brackets relate to those in the study and are not accessible as an active hyperlink in these comments.
### Tele-rehabilitation Alone (Pre vs. Post Intervention)

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<th>Study</th>
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<td>Paneroni et al., 2021 [27]</td>
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<td>None reported</td>
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<tr>
<td>Wotton et al., 2020 [28]</td>
<td>Case Series</td>
<td>COVID-19/ n = 3</td>
<td>Weekly call by physiotherapist</td>
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<td>Smart phone application; pre-recorded videos</td>
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<td>Real time video conferencing with Physiotherapist</td>
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<td>Hoass et al., 2016 [31]</td>
<td>Cohort Study/ Efficacy and Feasibility Study</td>
<td>COPD/ n = 10</td>
<td>Pre-recorded session by physiotherapist</td>
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<td>Marquis et al., 2014 [32]</td>
<td>Cohort Study/ Efficacy and Feasibility Study</td>
<td>COPD/ n = 26</td>
<td>Combined Real-time video conferencing by physiotherapists and unsupervised sessions</td>
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<td>Albores et al., 2013 [33]</td>
<td>Cohort Study/ Efficacy and Feasibility Study</td>
<td>COPD/ n = 25</td>
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<td>Holland et al., 2013 [34]</td>
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<td>COPD/ n = 8</td>
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<td>Wardini et al., 2013 [35]</td>
<td>Cohort Study/ Feasibility Study</td>
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<td>Increased adherence</td>
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<td>Tossignani et al., 2012 [36]</td>
<td>Cohort Study/ Feasibility Study</td>
<td>COPD/ n = 3</td>
<td>Real time video conferencing with physiotherapist</td>
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### Tele-rehabilitation vs. No Rehabilitation

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<tr>
<th>Study</th>
<th>Intervention Description</th>
<th>Outcome Measures</th>
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<tr>
<td>Gonzalez-Gerez et al., 2021</td>
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<td>Twice weekly calls by physiotherapist</td>
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<tr>
<td>Li et al., 2021 [38]</td>
<td>RCT/ Efficacy Trial</td>
<td>COVID-19/ n = 59 vs. n = 61</td>
<td>Smartphone-based application</td>
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<td>Bhart et al., 2019 [39]</td>
<td>Cohort Study/ Feasibility and Efficacy Study</td>
<td>COPD/ n = 80 vs. n = 160</td>
<td>Physiotherapist by real-time video conferencing</td>
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<tr>
<td>Tsai, 2017 [40]</td>
<td>RCT/ Efficacy Trial</td>
<td>COPD/ n = 37 vs. n = 37</td>
<td>Real-time broadcast by physiotherapist</td>
<td>Not mentioned</td>
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AE: Adverse Event; AECOPD: Acute Exacerbation of Chronic Obstructive Pulmonary Disease; CAT: COPD Assessment Test; CET: Constant work rate Exercise Test; COPD: Chronic Obstructive Pulmonary Disease; CRQ: Chronic Respiratory Questionnaire; ESWT: Endurance Shuttle Walk Test; EQ-VAS: EuroQol Visual Analog Scale; GAD: Generalized Anxiety Disorder; MRC: Medical Research Council; mMRC: Modified Medical Research Council; LMS: Lower limb muscle Strength; PCS: Physical Component Score; PHQ-9: Primary Health Questionnaire-9; PR: Pulmonary Rehabilitation; RCT: Randomized Control Trial; SF-12: Short Form Health Survey-12; SGRQ: St George’s Respiratory Questionnaire; STS: Sit To Stand; VR: Virtual Reality; 6MWT: 6 Minute Walk Test. * Not mentioned—Studies did not look for adverse events. ** None reported: Studies reported the absence of adverse events.