



April 26, 2021

Ryan Howe, Ph.D.

Acting Director, Hospital and Ambulatory Policy Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore MD 21244

RE: Level of Supervision of Pulmonary, Cardiac, and Intensive Cardiac Rehabilitation Services under Physician Fee Schedule and Hospital Outpatient Services

Dear Dr. Howe:

Our organizations would like to offer comments on proposed changes to level of supervision requirements for pulmonary, cardiac, and intensive cardiac rehabilitation services under the Physician Fee Schedule and Hospital Outpatient services. In the proposed CY 2021 Hospital Outpatient Prospective Payment regulation¹, CMS proposed that direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services could be met virtually without requiring the physician's physical presence in that location. The rationale provided by CMS explained that this would continue to improve access for patients and reduce burden for providers after the end of the public health emergency (PHE). Virtual presence would be met through audio/video real-time communications technology (excluding audio-only), subject to the clinical judgment of the supervising physician.

CY 2021 final regulations under PFS and HOPPS made two significant changes:

1. Aligned the definitions of virtual direct supervision under the PFS (410.32) and OPSS (410.27). This provided clarity and consistency, allowing for practical application of this option.
2. Modified the proposed permanent status of virtual direct supervision from permanent to expiring at the end of the year that the public health emergency (PHE) expires. This was done to reconsider any potential negative impact of virtual direct supervision on the quality of pulmonary, cardiac, and intensive cardiac rehabilitation services.

COVID safety protocols have severely limited and continue to limit patient access to pulmonary, cardiac, and intensive cardiac rehabilitation services. The inclusion of direct supervision via virtual presence has improved access for patients during the PHE. It has allowed the relocation of pulmonary, cardiac, and intensive cardiac rehabilitation services from the hospital to satellite locations where there is not an MD or DO physically available. Rural and critical access hospitals (CAHs) have benefited from the direct supervision waiver by allowing the expansion of program

hours as these services cautiously and gradually re-open to full capacity *without* the restriction of a physician required to be *physically* available to serve in the direct supervision role. This flexibility has also benefitted these rehabilitation patients throughout the nation, regardless of geography, through enhanced access to care that should be permanently implemented in CY 2022 rulemaking.

The following information addresses comments submitted following the proposed permanent status for virtual direct supervision. Questions about safety and oversight were raised by some commenters in response to the CMS consideration of virtual direct supervision for pulmonary, cardiac, and intensive cardiac rehabilitation services.

Beneficiaries begin a cardiac, intensive cardiac, or pulmonary rehabilitation program with the development of an individualized treatment plan (ITP) with the patient. This includes an initial assessment and exercise prescription that is reviewed and signed by the medical director.

The safety of pulmonary rehabilitation has been well-substantiated. Rates of reported adverse events are very low at 0.4%.⁵

Data demonstrating low rates of serious cardiovascular events in cardiac rehabilitation go back to the 1980s. Findings from three well-known studies are as follows:

- 1 cardiac arrest per 111,996 patient-hours, 3.4 myocardial infarctions per 293,990 patient-hours, 1 death per 783,972 patient-hours⁶
- 1 event per 49,565 patient-hours of exercise training⁷
- In higher-risk patients with heart failure, there were similar rates of adverse safety events in patients randomized to cardiac rehabilitation, compared to patients randomized to usual care.⁸

CMS states it intends to monitor the use of interactive audio/video real-time communications technology to meet the direct supervision requirement through the PHE. The professional societies believe it will be evident that the quality and safety of pulmonary, cardiac, and intensive cardiac rehabilitation services are not negatively affected and, in fact, access to these services is improved with a virtual option for direct supervision.

Thank you for your attention to this matter. Please contact Karen Lui at karen@grqconsulting.com if any additional information would be helpful for setting policy proposals.

Sincerely,

American Association for Cardiovascular
and Pulmonary Rehabilitation
American Association for Respiratory Care
American College of Cardiology

American Heart Association
American Thoracic Society
CHEST/American College of Chest Physicians

References

1. Federal Register, Vol. 85, No. 156, Wednesday, August 12, 2020, pg. 48936.
2. AACVPR *Guidelines for Cardiac Rehabilitation Programs*, Human Kinetics, 2021.
3. AACVPR *Guidelines for Pulmonary Rehabilitation Programs*, Human Kinetics, 2020.
4. 42 CFR S410.47: Pulmonary rehabilitation program: Conditions for coverage.
5. Puhan MA, Gimeno-Santos E, Cates CJ, Troosters T. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2016 Dec 8;12(12):CD005305. doi: 10.1002/14651858.CD005305.pub4. PMID: 27930803; PMCID: PMC6463852.
6. Van Camp SP, Peterson RA. Cardiovascular complications of outpatient cardiac rehabilitation programs. *JAMA*. 1986 Sep 5;256(9):1160-3. doi: 10.1001/jama.256.9.1160. PMID: 3735650.
7. Pavy B, Iliou MC, Meurin P, Tabet JY, Corone S; Functional Evaluation and Cardiac Rehabilitation Working Group of the French Society of Cardiology. Safety of exercise training for cardiac patients: results of the French registry of complications during cardiac rehabilitation. *Arch Intern Med*. 2006 Nov 27;166(21):2329-34. doi: 10.1001/archinte.166.21.2329. PMID: 17130385
8. O'Connor CM, Whellan DJ, Lee KL, Keteyian SJ, Cooper LS, Ellis SJ, Leifer ES, Kraus WE, Blumenthal JA, Rendall DS, Miller NH. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. *JAMA*. 2009;301:1439-50.