# Preventive Medicine Research Institute

A non-profit public benefit institute dedicated to research, education, and service

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Chiquita Brooks-LaSure, MPP
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P, Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: **Comments on CMS-1753-P**—Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

Dear Administrator Brooks-LaSure,

My colleagues and I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed calendar year 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS) rule (Proposed Rule).[1]

We appreciate very much that CMS has been covering intensive cardiac rehabilitation (ICR) programs and traditional cardiac rehabilitation (CR) programs when offered virtually since last October in response to the COVID-19 Public Health Emergency (PHE). However, we are deeply concerned that this coverage is currently scheduled to cease at the end of the public health emergency (PHE) or at the end of this calendar year.

We respectfully request that provisional coverage of ICR programs (CPT/HCPCS codes G0422 and G0423) and traditional cardiac rehabilitation programs when offered virtually be continued until the end of CY 2023, as described in my comment dated September 13, 2021 to CMS-1751-P, so that beneficiaries may continue to safely access a critical benefit that would otherwise transition out of their reach. Unless something is done, according to Table 11 of the Federal Register, Medicare coverage for this scientifically proven intensive cardiac rehabilitation program when offered virtually will end at the end of this calendar year or at the end of the PHE.[2]

As my comment of September 13 detailed, there is already a mechanism in place—Category 3—that would continue providing Medicare coverage for ICR and traditional cardiac rehabilitation programs until the end of CY 2023 via the Physician Fee Schedule (PFS). This would enable us to gather more data for CMS on utilization, adherence, clinical outcomes, and costs during the next two years when this and other ICR programs as well as traditional cardiac rehabilitation programs are offered virtually. There are clearly enough interim data already to justify the usefulness of continuing to collect this information until CY 2023.

**Summary:** Here is a brief summary of the points made below in more detail describing why what we are requesting is to everyone's advantage:

1. The medical effectiveness of our lifestyle medicine program used in ICR when provided virtually via real-time synchronous communication (e.g., Zoom) with virtual direct physician supervision is comparable to when it is provided at an outpatient facility. However, because this coverage when offered virtually has only been in effect since last October, it is important to gather more data on utilization, adherence, clinical outcomes, and costs until the end of CY 2023 so that CMS can make a fully-informed decision about whether or not to make this coverage permanent. The ability to accomplish this is already available in Category 3 as described in my prior comment to CMS-1751-P. Allowing continuation of the 1135 waiver until the end of CY 2023 that allows people to register their home as an extension of the hospital outpatient facility (a PBD, or provider-based department, also known as a hospital without walls) would allow continued reimbursement for coverage of both ICR and traditional cardiac rehabilitation when offered at home virtually via the OPPS.

2. The safety of ICR and traditional cardiac rehabilitation programs when provided virtually at home is the same or better as when it is offered in an outpatient facility.

3. Direct physician supervision is safe when provided virtually using synchronous two-way audio/video communication technology in real time (e.g., Zoom) and should continue to be allowed via OPPS until at least the end of CY 2023. This step would also help fulfill the stated objective of this administration to ensure equitable access to healthcare for Medicare beneficiaries.

4. Providing ICR and traditional cardiac rehabilitation programs when offered virtually allows greater access, ensuring equitable availability to these proven programs for Medicare beneficiaries. COVID-19 severely exacerbated existing health equity gaps—for example, non-Hispanic black males had a 3-year reduction in life expectancy compared to a 0.7-year reduction for non-Hispanic white females between 2019 and the first half of 2020. Many patients who do not live within driving or commuting difference of one of the hospitals or clinics offering ICR and traditional cardiac rehabilitation programs would benefit from having these

available virtually, especially those living in rural areas. This would increase access to proven programs in order to reduce health disparities in vulnerable populations. Virtual ICR and traditional cardiac rehabilitation present opportunities to close these identified equity gaps by providing access to patients who face barriers to participation.

5. Since it is unlikely that the U.S. will achieve herd immunity to COVID-19 anytime soon given the Delta and newer variants and ongoing resistance to getting vaccinated, it is safer for cardiac patients to receive ICR programs and traditional cardiac rehabilitation programs when offered virtually in the safety of their home than being exposed to other patients in hospitals or clinics, especially since exercise (heavy breathing and perspiring) in a closed environment significantly increases the risk of transmission.

**History/Background:** On August 12, 2010, after many years of review, CMS created a new benefit category, "intensive cardiac rehabilitation," (ICR), which provided Medicare coverage for intensive cardiac rehabilitation programs (CPT/HCPCS codes G0422 and G0423).[3]

The lifestyle medicine program offered in our ICR program is the only one scientifically proven in randomized controlled trials to often reverse the progression of even severe coronary heart disease by lifestyle changes alone, without drugs or surgery. The results of these clinical trials and demonstration projects were published in leading peer-reviewed journals, including *The Lancet*,[4] *Journal of the American Medical Association*,[5 6 7] the *American Journal of Cardiology*,[8 9 10 11 12] and others.[13 14 15 16 17 18 19]

Also, a panel of nutrition and health experts from *U.S. News & World Report* has rated what they called "The Ornish diet" as "#1 for Heart Health" for ten years from 2011-2021, which is the diet used in this intensive cardiac rehabilitation program.

Patients in this intensive cardiac rehabilitation program meet twice/week for nine weeks, for four hours per session:

- one hour of supervised aerobic exercise (the same as in traditional cardiac rehabilitation programs)
- one hour of stress management techniques such as meditation
- one hour of a support group
- one hour lecture plus a group meal

**Virtual ICR:** CMS has been providing reimbursement for ICR and traditional cardiac rehabilitation programs when offered virtually since October 2020. Aetna, which has been covering ICR programs when offered in the bricks & mortar world for many years, has also been reimbursing ICR programs since May of this year when offered virtually.[20]

We appreciate and strongly support that CMS has agreed to extend coverage of many telehealth programs when offered virtually through the end of CY 2023 in Category 3.

However, we are very concerned that CMS is proposing to exclude virtual outpatient intensive cardiac rehabilitation as well as traditional cardiac rehabilitation from the Category 3 list of payable telehealth services and end virtual "direct supervision" at the end of this calendar year or at the end of the PHE.[21] This would substantially compromise equitable access to evidence-based cardiac care for Medicare beneficiaries.

As described in my prior comment of September 13 regarding the PFS, we would be grateful if this ICR program could be moved to Category 3, which would continue to provide coverage when offered virtually until the end of CY 2023, as CMS has agreed to do with many other programs. We also support the inclusion of traditional cardiac rehabilitation programs in Category 3 as well.

This would enable us to gather more data on utilization, adherence, clinical outcomes, and costs during the next two years when our ICR program is offered virtually. There are clearly enough data already to justify the usefulness of gathering this information until CY 2023.

We agree with CMS that this extension would "allow [CMS] time to collect more information regarding utilization of these services during the pandemic, and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through our regular consideration process."[22] Also, this would enable us to reach many more patients who do not live within driving distance of one of the hospitals or clinics we've trained, especially those living in rural areas, thereby helping to reduce health disparities.

My colleagues and I are currently conducting the first randomized controlled trial to determine if intensive lifestyle changes may reverse the progression of early-stage Alzheimer's disease in collaboration with senior neurologists at Harvard Medical School, UCSD, and The Cleveland Clinic. This is the same lifestyle intervention as in our ICR program.

In March 2020, with the advent of COVID-19, it was no longer safe to meet in person with such a vulnerable population. Because of this, we virtualized this lifestyle intervention—patients continued to meet for four hours/session but all done via two-way Zoom in real time.

Each of these Zoom sessions is led by a modality specialist (e.g., exercise physiologist, certified stress management teacher, clinical psychologist, and registered dietitian) as well as a registered nurse at each session to monitor patient safety. Direct physician supervision is always available virtually.

We found that this lifestyle program is comparably effective when offered virtually in real-time via Zoom as it is in the bricks and mortar world. Also, direct physician supervision is

safe and effective when offered virtually in this way in real time. It enables us to reach patients at home wherever they live and, as described earlier, reduces health disparities.

**Medical Effectiveness:** We already have demonstrated that this ICR program achieves bigger changes in lifestyle and patient engagement, better clinical outcomes, and larger cost savings in the first year than any other lifestyle program we are aware of. For example, 94% of people who enrolled in this intensive cardiac rehabilitation program completed all 72 hours of the intervention after 9 weeks of this program, and 85-90% were still adhering after one year.

Attached is an article from the peer-reviewed *American Journal of Health Promotion* (AJHP) describing improved outcomes in all measures in 2,974 men and women from 24 different socioeconomically diverse sites in West Virginia, Nebraska, and Pennsylvania who participated in this ICR program offered and reimbursed by Highmark Blue Cross Blue Shield.[23]

Below is a chart summarizing similar clinical outcomes in all measures in 10,180 additional serial patients who went through this intensive cardiac rehabilitation program after nine weeks who were on maximal medical therapy at baseline (e.g., LDL-cholesterol was 90.1 mg/dl at baseline but still showed additional 20% reductions despite reducing medications):

74% reduction in reported angina after 9 weeks.

In addition to these results, many participants reduced or discontinued medications to lower BP, lipids, and blood sugar with approval of their physicians.

These improvements would have been even greater if medications were unchanged.

| | BASELINE | 9 WEEKS | CHANGE |
|---|---|---|---|
| Weight Loss | 199.6 | 189.6 | -5.0% |
| Total Cholesterol | 165.5 | 140.1 | -15.4% |
| LDL Cholesterol | 90.1 | 71.2 | -20.0% |
| Triglycerides | 146.7 | 129.4 | -11.8% |
| Systolic Blood Pressure | 128.1 | 121.7 | -5.9% |
| Diastolic Blood Pressure | 74.6 | 70.4 | -5.7% |
| HbA1c | 6.6 | 6.2 | -6.2% |
| Depression Score (CESD) | 11.1 | 5.7 | -48.6% |
| Exercise Capacity (Mets) | 3.7 | 5.5 | 45.9% |

**Cost Savings:** This intensive cardiac rehabilitation program is cost effective as well as medically effective. Highmark Blue Cross Blue Shield found that overall health care costs were *decreased by 50% in the first year* when compared to a control group matched for age, gender, and disease severity. Costs were reduced *four-fold in the first year* in patients who had made more than $25,000 in health claims in the prior year.

Mutual of Omaha found that they *saved almost $30,000/patient in the first year* in patients who went through this program compared to the control group. Almost 80% of patients who otherwise would have undergone revascularization were able to safely avoid it by choosing this lifestyle program as a direct alternative.[24]

President Clinton has talked publicly about how this intensive cardiac rehabilitation program has helped him reverse the progression of his coronary heart disease.[25]

My colleagues and I achieved similar adherence, engagement, and outcomes when this lifestyle program is offered virtually. Given these high levels of adherence, it is justifiable to determine if this level of adherence in cardiac patients can be maintained from data we can collect if this ICR program can be listed on Category 3 of the PFS so it can be offered virtually until the end of CY 2023.

**Virtual Direct Supervision Is Safe:** An important component of cardiac rehabilitation services is virtual direct supervision. Per CMS guidelines for cardiac rehabilitation programs, services must be performed under the direct supervision of a physician.

Direct supervision by a physician is performed equally effectively in a virtual setting as in a center-based setting. Providers furnishing virtual cardiac rehabilitation services during COVID-19 have become reliant on "direct supervision" which permits virtual supervision.

We urge CMS to maintain the policy of virtual direct physician supervision for ICR and traditional cardiac rehabilitation in place through CY 2023 so as to align with the CMS proposed end date for physician services added to the telehealth list on a Category 3 basis (PFS) and also to continue waivers to allow their home to be registered as an extension to a hospital outpatient facility (OPPS).

In a virtual program, the supervising physician is immediately available to join a two-way audio/video conference with both the patient and the other overseeing clinician (usually a nurse and a clinical exercise physiologist) monitoring the exercise session. This physician can communicate simultaneously with the patient and the clinician, or privately with the clinician. The supervising physician has immediate access to live patient vitals data, can communicate via live audio/video with the patient, and can intervene fully and effectively as they would in a center-based session.

Data cited below indicate that adverse events are exceptionally rare, particularly given that supervising physicians ensure that only clinically appropriate patients enter virtual ICR or traditional cardiac rehabilitation. Examples of when a supervising physician would be called include automatic vital sign derangement detection outside of expected limits and concerning symptoms (i.e., chest pain, light-headedness, etc.) reported by the clinical exercise physiologist or patient suggestive of a rare complication such as myocardial infarction.

**Safety and Efficacy of Virtual ICR and CR:** The exercise component of intensive cardiac rehabilitation is the same as in traditional cardiac rehabilitation. As described below, the risk of traditional cardiac rehabilitation when offered virtually is no higher than when

offered in hospitals or clinics. The other aspects of ICR (meditation, support groups, and a whole foods plant-based diet) are beneficial and incur very low risk.

In many studies that directly compare virtual to center-based cardiac rehabilitation, there is no difference across the following key outcomes measures: (a) exercise capacity, (b) mortality and morbidity, (c) modifiable risk factors, (d) health-related quality of life, and (e) adherence. Some studies show that outcome measures are actually *better* in virtual cardiac rehabilitation.

For example, a randomized controlled trial, which included a six-year follow-up examining hospital versus home-based exercise training after coronary artery bypass graft surgery found that there were significant between-group differences in peak VO2 max in favor of the virtual cardiac rehabilitation group. Also, the total number of hospitalizations (cardiac and non-cardiac) was greater in center-based patients than in the home-based group participating in virtual cardiac rehabilitation (79 versus 42, $p<0.0001$). The authors reported there were no significant between-group differences in clinical events.[26]

A January 2021 publication from the American College of Cardiology concludes that "available data suggest that HBCR [home-based (or virtual) cardiac rehabilitation] is equivalent to CBCR [center-based cardiac rehabilitation]."[27]

During the COVID-19 pandemic in Canada and Japan virtual cardiac rehabilitation programs were "found to be as effective as on-site programs offered in hospitals."[28]

Several studies have shown that virtual cardiac rehabilitation achieves equivalent improvements in exercise capacity, measured by peak oxygen uptake as compared with center-based programs.

For example, the REMOTE-CR randomized controlled trial showed no significant differences between virtual cardiac rehabilitation with synchronous oversight compared with center-based rehabilitation, measured by change in VO2 max (adjusted mean difference = 0.51 (95% CI −0.97 to 1.98) mL/kg/min, $p=0.48$).[29]

The FIT@Home randomized controlled trial showed patients in both groups (virtual and center-based) improved their peak VO2 from baseline to discharge (center-based +11% $p < 0.01$, virtual + 15% $p < 0.01$) without significant between-group differences ($p = 0.25$).[30]

Another study concluded that the mean change in 6-minute walk test distance (to assess exercise capacity) was significantly greater for patients enrolled in virtual cardiac rehabilitation than in center-based rehabilitation (+101 versus +40 m; $P<0.001$).[31]

A randomized controlled trial investigating long-term exercise adherence after high-intensity interval training showed no significant difference between virtual and center-

based groups in change in VO2 max. Additionally, the virtual group showed a strong trend towards increased physical activity compared with hospital-based groups.[32]

Studies comparing virtual with center-based rehabilitation have reported that all-cause mortality data for up to 12 months after the intervention revealed no statistically significant difference in mortality between the groups. Two studies reported no difference in revascularization or recurrent myocardial infarction events between virtual and center-based programs.[33] [34] [35] [36] [37] [38]

A Cochrane Review of 23 trials that randomized a total of 2,890 participants found no evidence of differences between virtual and cardiac rehabilitation in clinical primary outcomes, including exercise capacity, for up to 12 months of follow up.[39]

Cardiac rehabilitation services using real-time audio/video technology have a strong safety profile, with an extremely low incidence of adverse events. Research since the 1980s has demonstrated the rare rates of serious cardiovascular events in cardiac rehabilitation. Only 1 cardiac arrest per 111,996 patient-hours, 3.4 myocardial infarctions per 293,990 patient-hours, and 1 death per 783,972 patient-hours.[40]

Several studies have shown that with appropriate screening and monitoring procedures, virtual cardiac rehabilitation is feasible and safe even in higher risk patients. For example, Dalal et al[41] and Jolly et al[42] found no significant difference in coronary revascularization or recurrent myocardial infarction events between home-based and center-based groups.

Oerkild et al stated that there were no between-group differences (home-based versus center-based) in the number and length of admissions and adverse events including myocardial infarction, progressive angina, decompensated congestive heart failure, severe bleeding, new malignant disease and performance of percutaneous coronary intervention.[43]

The HF-ACTION study assessed the safety of exercise training provided initially in a center but later at home. With 2,331 enrolled patients (higher risk per American Association of Cardiovascular and Pulmonary Rehabilitation guidelines[44]), no significant difference was reported between the exercise and usual care groups for the overall rate of hospitalization (1.9% versus 3.2%, respectively) or death (0.4% versus 0.4%, respectively) during or within 3 hours after exercise.

The investigators also identified 1,053 patients from the HF-ACTION trial who had an implantable cardioverter-defibrillator at baseline and were randomized to the above exercise intervention versus control. Exercise training was not associated with the occurrence of implantable cardioverter-defibrillator shock (hazard ratio, 0.9 [95% CI, 0.7–1.2]). Other adverse events were similar between groups.[45]

Even the minimal risk of a cardiac event while exercising (which is no higher when cardiac rehabilitation is offered virtually) is more than offset by avoiding the risk of being exposed to COVID-19 by other cardiac patients, who are an especially vulnerable population to COVID-19, when intensive cardiac rehabilitation is offered only in the bricks and mortar world.

**Influence of COVID-19 on Risk of ICR and CR:** Since it is unlikely that the U.S. will achieve herd immunity any time soon given the Delta variant and ongoing resistance to getting vaccinated, it is much safer for cardiac patients to receive this intensive cardiac rehabilitation program when offered virtually in the safety of their home than being exposed to other patients in many hospitals or clinics, especially since exercise (heavy breathing and perspiring) increases the risk of transmission.[46]

An additional benefit to offering this intensive cardiac rehabilitation program virtually is that it may also reduce deaths from COVID-19 by increasing resilience to infection rather than only avoiding it.

For example, a recent study of almost 600,000 people by researchers at Harvard Medical School and King's College, London, found that a dietary pattern characterized by healthy plant-based foods (part of this intensive cardiac rehabilitation intervention) was associated with a 41% lower risk of severe COVID-19. These association may be particularly evident among individuals living in areas with higher socioeconomic deprivation.[47]

A study of 2,884 frontline doctors and nurses with extensive exposure to COVID-19 who were following plant-based diets were 73% less likely to develop moderate to severe illness.[48]

**Improved Access, Adherence, and Patient Satisfaction:** Also, many patients who do not live within driving distance of one of the hospitals or clinics we have trained could benefit from having our ICR program available virtually, especially those living in rural areas. The Government Accountability Office confirmed that telehealth during the PHE has improved access to care.[49]

A study from the Veterans Health Administration found that patients offered a referral to virtual or center-based cardiac rehabilitation were four times more likely to participate than those offered referral to center-based programs alone.[50] The "Home-based versus center-based cardiac rehabilitation Cochrane Review" found virtual cardiac rehabilitation to be associated with higher adherence (RR 1.04, 95% CI 1.01 to 1.07).[51] The FIT@Home (n=90) randomized controlled trial showed that patient satisfaction was higher in the virtual cardiac rehabilitation group (p=0.02).[52]

**Other Benefits of ICR:** We found that these same lifestyle changes also may reverse the progression of early-stage prostate cancer;[53] beneficially change gene expression;[54] reverse

the progression of type 2 diabetesADD REF AJHP; and lengthen telomeres.[55] [56] The reason that these same lifestyle changes beneficially affect so many chronic diseases is that they share common biological mechanisms, including chronic inflammation, overstimulation of the sympathetic nervous system, changes in oxidative stress, angiogenesis, telomeres, the microbiome, and others.[57]

In summary, there is clearly enough information already to justify to continue providing coverage for ICR and traditional cardiac rehabilitation programs when offered virtually and to continue to allow direct supervision by a physician to be performed in a virtual setting with two-way communication in real time until at least the end of CY 2023.

The ability to accomplish this is already available in Category 3 as described in my prior comment to CMS-1751-P of September 13, 2021. Also, allowing continuation of the 1135 waiver until the end of CY 2023 that allows people to register their home as an extension of the hospital outpatient facility (a PBD, or provider-based department, also known as a hospital without walls) would allow continued reimbursement for coverage of both ICR and traditional cardiac rehabilitation when offered at home virtually via the OPPS.

This will allow CMS to gather additional information for two more years on patient engagement, safety, outcomes, and cost savings, which will be to everyone's advantage.

Thank you so much for your consideration, which my colleagues and I sincerely appreciate. Please let me know if you have any questions or would like any additional information.

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