

Comment Letter Regarding National Coverage Policy for Cardiac Rehabilitation

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 445-G, Hubert Humphrey Building
200 Independence Av. SW
Washington, DC 20201

Dear Dr. McClellan:

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) and the American College of Cardiology (ACC) welcome the opportunity to comment on the proposed decision memo outlining changes to the national coverage policy for cardiac rehabilitation. AACVPR is the leading professional health care association focusing on cardiac and pulmonary rehabilitation, and its members include physicians, nurses, respiratory therapists, physical therapists, exercise physiologists and other allied health professionals. ACC is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

We commend the Centers for Medicare and Medicaid Services for promulgating the proposed revisions to its current cardiac rehabilitation policy and we believe that, overall, the revisions reflect thoughtful consideration of comments previously submitted by the AACVPR, the American College of Cardiology (ACC) and the American Hospital Association (AHA). We also believe that the new policy reflects the current state-of-the-art and clinical evidence supporting the efficacy of cardiac rehabilitation.

PRIMARY ISSUES:

Triggering Diagnoses: We commend CMS for expanding its coverage criteria for cardiac rehabilitation and support adoption of the proposed expanded diagnoses. We do strongly recommend, however, a slight change in wording to ensure that Medicare beneficiaries who have received stents and related procedures are not unintentionally excluded from coverage. To address that, *we recommend using the term percutaneous coronary intervention (PCI) rather than percutaneous transluminal coronary angioplasty (PTCA).*

We appreciate the diligent and comprehensive review of the heart failure literature and look forward to timely future discussions with CMS regarding the benefits of cardiac rehabilitation for patients with heart failure when pending studies are completed and formally reported.

Physician Supervision: We also support CMS' revisions to the physician supervision components of the policy. We regard this proposal as a major step forward and we commend the Agency for its acceptance of recommendations from AACVPR, ACC, and the American Hospital Association. We support the current Medicare policy that generally focuses on a 250 yard parameter for separate buildings on the hospital campus. *We do recommend, however, inclusion in the actual policy a specific reference that appears throughout various Medicare manuals – physician supervision is presumed to be met when provided on the hospital premises.*

Additionally, it is our understanding that CMS does recognize that it has inadvertently used a confusing term regarding physician supervision when it stated, "...if the services are furnished outside the hospital, they must be rendered under the **direct personal supervision** (emphasis added) of a physician who is treating the patient." *We recommend that CMS clarify its use of direct supervision in the final decision memorandum to ensure that providers and contractors are not inadvertently confused by this phrasing.*

"Incident to" Physician: CMS has stated that the "incident to" physician is the ordering physician. We do not support this singular approach for clinical as well as practical management reasons. If the ordering physician is also the physician who must meet the ongoing physician involvement requirements spelled out as part of CMS' definition of what constitutes "incident to" services, there are common and frequent scenarios where it is not clinically coherent to require the ordering physician to "*personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.*" While we agree with the appropriateness of this level of physician involvement, the ordering physician might be the cardiac surgeon or other physician who is not the clinically appropriate physician to provide oversight of the patient's progress through the CR program.

We also concur with the American Hospital Association's statement that limiting this designation to the ordering physician would be a particular problem in rural communities. According to the AHA, beneficiaries in rural areas often travel long distances to undergo surgery in a large urban hospital or regional referral center, and it is often this hospital's surgeon or interventional cardiologist who writes the order for the patient's cardiac rehabilitation services. The patient then returns to their local community hospital for the ordered cardiac rehabilitation services. In this very common scenario, the patient's ongoing care is provided by the patient's own cardiologist or primary care physician, not by the surgeon. It would be unreasonable to expect the patient to travel potentially hundreds of miles to their surgeon for these services.

Rural or small hospitals also may use cardiology consultants, who travel from nearby cities to help manage the care of the hospital's patients. In these cases, it is likely that the cardiology consultant is the ordering physician, and the patient's primary care physician or the hospital's cardiac rehabilitation program medical director then follows and manages the patient's on-going care. This level of flexibility should be preserved for patients who receive cardiac rehabilitation services in small or rural hospitals.

Finally, in some cardiac rehabilitation programs, the program medical director facilitates coordination of care related to exercise and secondary prevention issues, communicating closely with the patient's other physicians. In this scenario, the program medical director assumes the responsibility to assess the course of cardiac rehabilitation treatment and the patient's progress, facilitating change of the treatment regimen as appropriate.

As an alternative, *we recommend that CMS adopt a position that, for the purposes of cardiac rehabilitation, defines the "incident to" physician as the physician most clinically appropriate to manage issues which arise during the course of cardiac rehabilitation.* This definition affords important flexibility to the cardiac rehabilitation program but nevertheless requires identification of a specific physician at the commencement of cardiac rehabilitation. It is this physician who accepts clinical responsibility to assess the course of treatment and the patient's progress, changing the treatment regimen as appropriate.

Definition of Cardiac Rehabilitation: We strongly supports CMS' revised definition of cardiac rehabilitation as a comprehensive long term program including a medical evaluation, cardiac risk factor modification prescribed exercise, education and counseling. This is important recognition of the true core components of cardiac rehabilitation as it has evolved over the past two decades.

However, we do believe the CMS statement that cardiac rehabilitation services are "typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring" could be misinterpreted by contractors. There are many legitimate clinical scenarios where the beneficiary might not start cardiac rehabilitation within that time frame and contractors might infer from the CMS statement that rehabilitation that begins several months after discharge from the hospital does not meet the new entrance criteria. *We recommend that CMS instruct its contractors to provide reasonable flexibility for the commencement of cardiac rehabilitation. Alternatively, specific reference to a 1-3 week time frame could be deleted from policy.*

Rhythm Strips: We support CMS' revision regarding rhythm strips, but again we seek clarification regarding two aspects of the new policy. As proposed, a "clinician" is permitted to determine the appropriateness of the need for ECG monitoring, and we request that the definition of this clinician be clarified. Because the need for ECG monitoring for a specific patient is based on medical criteria, we suggest that the physician who is performing the medical evaluation for cardiac rehabilitation determine the need for ECG monitoring for that particular patient.

Secondly, we recognize that CMS wants to provide a certain level of latitude to its contractors to implement coverage decisions, but we must state our concerns with this specific instruction because it appears to give the contractor incredibly broad latitude. For example, the current policy gives the contractor latitude regarding physician supervision: *It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible.* A limited number of contractors unilaterally determined that every cardiac rehabilitation program, without exception, had the physician too remote, thereby requiring physician presence at all times. We are simply fearful that well intentioned contractors impose rules that are not clinically sound and inhibit true risk stratification.

We recommend that CMS modify its proposed policy to require the physician who performs the medical evaluation for cardiac rehabilitation to specify the appropriateness and need for ECG monitoring.

Duration: AACVPR also supports the CMS recommendation to expand the duration of cardiac rehabilitation to 18 weeks. This provides important flexibility, particularly to rural hospitals, where it is often difficult for cardiac rehabilitation patients to travel far distances 3 times a week for rehabilitation services.

SECONDARY ISSUES:

Stress testing: We support the removal of specific references to stress testing from this policy and assume that stress testing related to cardiac rehabilitation participation will be covered when reasonable and necessary, based upon CMS policy specific to stress testing.

Other Diagnostic and Therapeutic Services: As mentioned above, we support the revised definition of cardiac rehabilitation as a comprehensive service and support the appropriate deletion of related references to varied health services.

Staffing: We support the revised language regarding appropriate staffing for cardiac rehabilitation services, but we do seek clarification of an important component of staffing issues. First, as indicated above, on occasion a beneficiary may be referred by the program for specific nutritional counseling, psychosocial services, etc. We would find it useful for CMS to clarify which professionals on the cardiac rehabilitation team are authorized to make such referrals.

Secondly, although the proposed physician supervision requirements reflect a vast improvement over current policy, we would like additional clarification of the circumstances under which CMS will accept physician assistants, nurse practitioners and other recognized health professionals to provide certain services traditionally provided by physicians.

Facility: We support the revised language regarding facility requirements.

In conclusion, we believe that CMS has done an excellent job in revising its national coverage policy for cardiac rehabilitation and this new policy clearly reflects the current comprehensive nature of the services our members provide. With slight adjustment to certain aspects of the proposed policy, we heartily endorse and support this new approach.

Sincerely,

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Please feel free to contact the following individuals with any questions: Phillip Porte for the American Association of Cardiovascular & Pulmonary Rehabilitation (703-752-4353; Phil@GRQConsulting.com); Rebecca Kelly from the American College of Cardiology (301-493-2398 and RKelly@acc.org)