American Hospital Association

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January 20, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Proposed Decision Memo (PDM) for Cardiac Rehabilitation Programs (CAG-00089R)

Dear Dr. McClellan:

On behalf of the American Hospital Association's (AHA) 4,800 member hospitals, health care systems, and other health care organizations, and our 33,000 individual members, we appreciate this opportunity to comment on the Centers for Medicare & Medicaid's (CMS) proposed decision memo (PDM) for cardiac rehabilitation programs. The AHA, together with other national organizations, has worked with CMS on this issue for nearly seven years to ensure continued access to this important and highly effective service.

We believe that this PDM includes some important and long-overdue updates to cardiac rehabilitation services coverage under Medicare. We are pleased that CMS' proposed revisions reflect many of the previous recommendations submitted jointly by the AHA, the American Association for Cardiovascular and Pulmonary Rehabilitation and the American College of Cardiology, as well as current clinical evidence supporting the efficacy of comprehensive cardiac rehabilitation programs.

Indications and Limitations of Coverage
The AHA strongly supports the decision to expand the diagnoses covered under Medicare to include acute myocardial infarction, coronary artery bypass graft, stable angina pectoris, heart valve repair/replacement, percutaneous transluminal coronary angioplasty, and heart or heart-lung transplant. The research summarized in the PDM demonstrates that beneficiaries with these diagnoses will benefit from cardiac rehabilitation services, and the expansion of covered diagnostic categories will ensure that more beneficiaries have access to these important services.

Physician Supervision
While the AHA supports the physician supervision revisions made to the coverage policy, we believe the policy can be improved by a minor adjustment. The proposed policy states that cardiac rehabilitation services must be provided under the "direct supervision" of a physician. It

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then references several sections in the Medicare regulations that define "direct supervision" for services performed "incident to" a physician service in a hospital outpatient department and in a physician office. The CMS analysis section under "Physician Supervision" (but not in the proposed coverage policy) states: "The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises; the hospital medical staff that supervises the services need not be in the same department as the ordering physician."

The AHA recommends that this sentence, which is derived from Section 3112.4 A (Outpatient Therapeutic Services) of the *Medicare Intermediary Manual*, be placed directly in the coverage policy. This would clarify that for cardiac rehabilitation services provided on hospital premises, physician supervision can be provided as it is for other hospital outpatient department services; by relying on the hospital's emergency department medical staff, through the hospital's regular "code" team, or through another approach that assures the immediate availability of a physician for consultation or treatment in the event of a patient emergency.

Further, as "hospital premises" is not defined in the regulation, the AHA recommends that CMS clarify that a hospital's premises are not limited to the main building of the hospital but extend to the hospital's "campus" as defined in 42 CFR 413.65 (a)(2) ("the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus"). While some cardiac rehabilitation programs are located in the hospital's main building, others can be found close to, but not physically within, the main building. In emergencies, these programs have immediate access to physicians through the same approaches described above.

In addition, the physician "direct supervision" requirement for cardiac rehabilitation programs is not feasible for many critical access hospitals (CAHs). The current Medicare conditions of participation require CAHs to have physician services available for emergencies within 30 minutes of a request. Thus, a physician is not required to be present in an emergency department at all times. Requiring a physician to be "immediately available to furnish assistance and on the premises" for a cardiac rehabilitation patient in this same rural setting is not reasonable or practical. Highly skilled and trained staff monitor patients who participate in outpatient cardiac rehabilitation programs. To require an outpatient cardiac rehabilitation program to adhere to a higher standard than an emergency department is unreasonable and will force many CAHs to close their programs. Therefore, the AHA recommends that the physician availability standards in the final coverage policy for cardiac rehabilitation in CAHs mirror those currently applied to emergency department services for the same facilities.

"Incident to" Physician

The CMS analysis section, under "Incident to," states that the ordering physician is the "incident to" physician. The AHA strongly opposes this short-sighted and inflexible decision. Our concern is that the physician who orders the cardiac rehabilitation is often neither accessible nor appropriate to meet the on-going physician involvement requirements for "incident to" services.

Such services 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.*"

Limiting this designation to the ordering physician would be a particular problem in rural communities. 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 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 on-going 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 often 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.

The AHA recommends that, instead of a narrow policy defining the "incident to" physician as the ordering physician, CMS adopt our previous recommendation to broaden the definition. That is, there are three appropriate options for determining the physician to whom services are "incident to" – the ordering/referring physician; the patient's own primary care physician or cardiologist; or the cardiac rehabilitation program's medical director or program-affiliated physician. During the course of cardiac rehabilitation treatment, this physician would be responsible for assessing the course of treatment and the patient's progress. Where necessary, it should also be appropriate for the designated "incident to" physician to change the course of treatment, as long as the change is noted in the patient's medical record.

Components of Cardiac Rehabilitation Services

The AHA supports CMS' revised definition of cardiac rehabilitation as a comprehensive long-term program including a medical evaluation, cardiac risk factor modification (e.g. nutritional counseling), prescribed exercise, education and counseling. However, as several of these components are covered separately under Medicare, we request that CMS clarify proper billing procedure. For instance, may the hospital separately bill an evaluation and management code for the medical evaluation that is performed in the facility? If a beneficiary receives medically necessary services within the facility, such as individual psychosocial services or nutritional counseling, in conjunction with their course of cardiac rehabilitation, would these services be separately billable?

If these services are not separately billable by the facility, then the AHA recommends that upon finalization of the cardiac rehabilitation coverage requirements, the payment rate for the service be reconsidered. Each of these newly identified comprehensive program components result in additional direct and indirect costs to the facility, and the payment rate for the service should be

commensurate with the additional costs the facility will bear. The AHA recommends that the service be referred to the Advisory Panel on Ambulatory Payment Classification (APCs) Groups for reconsideration of the Healthcare Common Procedure Coding System (HCPCS) codes packaged within APC 0095, Cardiac Rehabilitation and that the APC payment rate be recalculated.

Duration
The AHA supports CMS' decision to lengthen the time over which a course of cardiac rehabilitation therapy may be provided and increase the number of sessions that may be provided over the allowed period. The PDM would allow a course of up to 36 cardiac rehabilitation sessions over 12 to 18 weeks without individual review by a Medicare contractor and up to 72 sessions of cardiac rehabilitation over 36 weeks with Medicare contractor review. This change will allow greater flexibility for beneficiaries, particularly those living in rural areas who may have difficulty traveling long distances several times a week to receive services.

However, we request that CMS clarify that the maximum time period to conduct cardiac rehabilitation with contractor review is 36 weeks, as included in the proposed policy, and not 24 weeks, as was stated in the CMS analysis section under "Number of Sessions and Frequency."

Rhythm Strips
In the CMS analysis section under "Number of Sessions and Frequency," CMS proposes removing language from the current national coverage decision (NCD) for cardiac rehabilitation specific to the use of electrocardiogram (ECG) rhythm strips. It then notes that the appropriate use of these services may be determined by the clinician "and the Medicare local contractor if the contractor determines such a policy is necessary in their geographic area." The AHA believes that this language is unnecessary and should not be included in the final NCD. Medicare contractors are already well aware of their discretionary authority to implement additional or stricter coverage requirements in their localities as long as such requirements are reasonable and do not directly contradict national coverage policy.

In conclusion, the AHA again thanks CMS for proposing changes that mark a significant improvement over existing policy. We believe that, with the incorporation of the changes we have recommended, more Medicare beneficiaries will be able to receive comprehensive and effective cardiac rehabilitation services. If you have questions on this comment letter, please feel free to contact me or Roslyne Schulman, AHA's senior associate director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President