

Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs

A STATEMENT FOR HEALTHCARE PROFESSIONALS
FROM THE AMERICAN ASSOCIATION FOR
CARDIOVASCULAR AND PULMONARY REHABILITATION
AND THE AMERICAN HEART ASSOCIATION

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Outpatient cardiac rehabilitation/secondary prevention programs are characterized by comprehensive services including medical evaluation, prescribed exercise, and cardiovascular disease risk factor modification through evidence-based pharmacologic management of risk factors and behavioral interventions. This multifactorial process is designed to limit the adverse physiologic and psychological effects of cardiac illness, reduce the risk of sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the patient's psychosocial and vocational status.¹ Provision of these services is physician-directed and implemented by a team of healthcare professionals which may include nurses, exercise physiologists, dietitians, health educators, behavioral medicine specialists, and other healthcare professionals.²

Appropriate patient/physician interaction during cardiac rehabilitation is important from a clinical, as well as regulatory, perspective. In practice, the cardiac rehabilitation team interacts with a patient multiple times per week, which provides an opportunity to facilitate management of blood pressure and lipids, glycemic control, smoking cessation, medication compliance, and adherence to lifestyle modification. Although long-term management of these issues is the responsibility of the primary care physician and/or cardiologist, cardiac rehabilitation provides an opportunity for concentrated

risk factor modification during a critical period for the patient with coronary heart disease. By working closely with referring physicians, the cardiac rehabilitation team can assist the patient in reaching target goals more efficiently. The Medical Director is ultimately responsible to assure that systems are in place to facilitate this process and that appropriate communication with referring physicians is maintained.

This document will serve as a guide for the Medical Director of an outpatient cardiac rehabilitation/secondary prevention program to link the clinical aspects of physician involvement to the provision of services by program staff, while maintaining compliance with

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regulatory requirements. It is not meant to replicate the excellent reviews, practical guidelines, and scientific statements published elsewhere,³⁻⁷ which describe the rationale for, and detailed structure of, comprehensive cardiac rehabilitation programs. Rather, it provides an overview of specific responsibilities for the Medical Director of an outpatient cardiac rehabilitation and secondary prevention program. Patient participation in this programming is frequently the first step in developing a lifelong commitment to the secondary prevention of coronary heart disease.

MEDICAL DIRECTOR AS TEAM LEADER

The primary roles of the Medical Director, as leader of the multidisciplinary team, are to assure that the cardiac rehabilitation/secondary prevention program is safe, comprehensive, cost effective, and medically appropriate for individual patients. The Medical Director should have:

- expertise in cardiovascular disease management and secondary prevention,
- training and experience with exercise training of patients with heart disease, and
- interpersonal skills related to leading and participating in a multidisciplinary team.

The Medical Director's responsibilities relate primarily to oversight of program policies and procedures, but may include specific responsibilities for patient evaluation, management, and supervision. In many instances, a Program Director/Manager and staff, under the direction of the Medical Director, will be responsible for much of the daily program operations. With input from other members of the team, the Medical Director should oversee and provide direction in the processes of:

- program development, ongoing quality improvement, and clinical operations;
- patient referral;
- patient evaluation and goal development;
- program monitoring and exercise supervision; and
- strategies to facilitate compliance with reimbursement regulations.

Program Development and Operations

The Medical Director must directly participate in the processes of program development in the case of new programs; subsequent evaluation of program effectiveness, efficiency, and modification; and oversight of program operations. The Medical Director should:

- assure that policies and procedures are consistent with evidence-based guidelines and comply with regulatory and certification standards⁸⁻¹⁹;

- assure that appropriate staffing is available; and
- recognize local, regional, and national regulations for, and issues pertaining to, reimbursement for services.

Patient Referral

All patients must be referred to the cardiac rehabilitation/secondary prevention program by a physician (or appropriate designee, ie, advanced nurse practitioner or physician assistant) who is licensed to practice medicine in the state in which the program is offered. The Medical Director is responsible for all policies related to the referral of appropriate patients, including inclusion and exclusion criteria, policies related to patients whose diagnoses do not allow for reimbursement of cardiac rehabilitation services, and the uninsured. The Medical Director must also recognize that cardiac rehabilitation and secondary prevention services are underutilized, particularly for minorities, women, and the elderly.²⁰ The Medical Director's emphasis on the value of these services for all potential candidates as an extension of the referring physician's care will enhance the referral process, while underscoring the continued involvement of the referring physician.²¹

Inclusion Criteria

Currently, Medicare regulations, which may also serve as an informal guideline for some other third-party payers, limit coverage for cardiac rehabilitation to the following diagnoses: post-myocardial infarction, post-coronary artery bypass surgery, and stable angina, with specified requirements and documentation for each. However, covered diagnoses may vary among payers and when policies suggest that a particular diagnosis will not be covered, most carriers have an appeal process which may result in coverage. Of note is the growing scientific evidence for the inclusion of patients with compensated heart failure, cardiac transplantation, and following percutaneous coronary intervention, and thus, there is increasing likelihood that such patients may already be or may become eligible for reimbursement by many providers.^{22,23} In addition, many stable patients are likely to benefit not only from exercise training, but from other aspects of behavior modification, including comprehensive and intensive risk factor reduction.

Exclusion Criteria

In general, patients with the following conditions should be excluded from the exercise training component of cardiac rehabilitation until these concerns can be resolved³:

- unstable angina,
- Class IV heart failure,

- uncontrolled sustained tachyarrhythmias or bradyarrhythmias,
- severe and symptomatic aortic or mitral stenosis,
- hypertrophic obstructive cardiomyopathy,
- severe pulmonary hypertension, and
- other conditions that could be aggravated by exercise such as
 - resting systolic blood pressure >200 mm Hg or resting diastolic blood pressure >110 mm Hg,
 - active or suspected myocarditis or pericarditis,
 - thrombophlebitis, and
 - recent significant systemic or pulmonary embolus.

Initial Evaluation and Goal Development

The Medical Director should assure that systems are present to obtain the following clinical information in order that the cardiac rehabilitation team can develop an appropriate patient-centered treatment plan:

- results of recent cardiac tests, including exercise and pharmacologic stress testing, with particular attention to inducible myocardial ischemia, coronary anatomy, left ventricular function, arrhythmias, and concomitant valvular disease;
- status of cardiopulmonary, orthopedic, and neuromuscular systems, as well as pain status, cognitive function, and psychological stressors;
- patient-specific symptoms of angina or anginal equivalents;
- detailed review of cardiovascular disease risk factors and their management;
- complete list of medications including all over-the-counter medications, supplements and herbs; dosing intervals; and suspected adherence to the drug regimen;
- comorbid conditions such as pulmonary, endocrine (especially diabetes), renal, and neurological illnesses; behavioral concerns; and musculoskeletal conditions, with attention to their impact on exercise, adherence, and disease progression;
- pertinent psychosocial (eg, depression, anger/hostility, social isolation, type A behavior) and occupational history; and
- baseline resting electrocardiogram, with attention to heart rate and rhythm, conduction abnormalities, and evidence of prior myocardial infarction.

Results from the initial evaluation must be documented to reflect the patient's current status and guide the development and implementation of:

- a patient-specific treatment plan that prioritizes goals and outlines intervention strategies for exercise training and cardiovascular disease risk reduction, and

- a follow-up plan that reflects progress toward goals and guides long-term secondary prevention strategies.

The American Heart Association (AHA) guidelines for comprehensive secondary prevention^{9,17} and those of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) provide a useful framework for evaluation and management.³ This information is also useful in risk stratifying patients for:

- disease progression and the likelihood of future cardiac events; and
- adverse cardiac events during exercise training which might determine whether exercise is contraindicated, and the level of medical supervision and monitoring recommended during the initial training period.

Comprehensive cardiac rehabilitation/secondary prevention programs should address each of the Core Components previously described by the AHA and AACVPR²⁴ including nutritional counseling; lipid, hypertension, and diabetes management; cessation of tobacco use; weight management; and psychosocial management, as well as physical activity counseling and exercise training. As physicians address the medical issues related to these core components, participation of patients in cardiac rehabilitation programs provides the framework for lifelong behavioral change and enables patients to meet target goals.

Initial patient evaluation and goal development is a team process, involving the patient, the referring physician, and cardiac rehabilitation clinicians, but coordinated by the program's Medical Director. Patient outcomes that reflect progress toward goals should be documented and tracked to identify specific areas that require further intervention and monitoring. Findings and recommendations resulting from the initial evaluation should be communicated to both the patient and the primary healthcare provider in order to develop strategies to support long-term goals. Tracking progress toward these goals can be incorporated into both individual patient reports as well as into composite reports for performance improvement projects. Sample forms that can be adapted for these purposes are available in several ACC/AHA and AACVPR documents.^{25,26} At discharge from cardiac rehabilitation, a summary of patient progress toward goals should be communicated with the patient's referring physician.

Exercise Supervision and Program Monitoring

Regulatory issues related to exercise supervision and program monitoring of the early outpatient cardiac rehabilitation/secondary prevention program (formerly

known as Phase II) continue to be in flux. The original regulations for the oversight of exercise supervision and program monitoring are described in the Medicare coverage guidelines 35–25 for cardiac rehabilitation (exercise supervision)² and the Medicare Carriers Manual, Part 3—Claims Process, Section 2050.1, Incident to Physician's Professional Services (program monitoring).²⁷ There is some ambiguity in these regulations related to physician involvement and supervision of exercise sessions, which has led to confusion in the industry, variability in Local Contractor Decision policies, and ultimately, to an Office of the Inspector General (OIG) audit of programs beginning in 2003. The final OIG report to the Centers for Medicare and Medicaid Services (CMS) recommended that CMS clarify national Medicare cardiac rehabilitation coverage requirements on (1) the provision of direct physician supervision and (2) the physician (referring or hospital) whose professional services the cardiac rehabilitation must be "incident to."²⁸ The remainder of this section offers insight into these regulatory issues from a clinical perspective and provides guidance for cost-effective physician involvement, while complying with current regulatory requirements.

Exercise Supervision

Supervision of the exercise program must be provided by personnel who are capable of conducting the program safely and effectively. All staff must have successfully completed a course in basic life support techniques, and must possess experience in exercise training for patients with coronary heart disease. Staff members who are responsible for advanced cardiac life support must have successfully completed the appropriate training course and be credentialed to provide such services. Services provided by nonphysician personnel must be furnished under the direct supervision of a physician. According to current CMS regulations, direct physician supervision of exercise must also be provided; that is, a physician must be in the area of the exercise program and immediately available and accessible for an emergency at all times while the exercise program is being conducted.² It does not require that a physician be physically present in the exercise room itself, provided that the physician is not too remote from the exercise area to be considered immediately available and accessible.^{2,27}

The issue of physician proximity to the exercise area is one of contention and confusion. Many of the individual OIG reports state that physician supervision is assumed to be met in a hospital setting, with the caveat that the supervising physician cannot be geographically remote or be involved in an activity that would preclude prompt response.²⁹ However, others state that reliance on a hospital code team or emergency room physician does not meet the criteria for direct supervision.²⁹ The

final OIG report recognizes both sets of practice with respect to provision of direct supervision, with a recommendation that CMS (1) clarify national Medicare cardiac rehabilitation coverage requirements on the provision of direct physician supervision and the physician (referring or hospital) whose professional services the cardiac rehabilitation must be "incident to" and (2) direct fiscal intermediaries to educate hospitals on the clarified national Medicare coverage policy for outpatient cardiac rehabilitation services.²⁸ The most recent AACVPR Guidelines suggest that physician supervision be defined by timeliness rather than proximity.³

It is imperative to maintain documentation of supervising physician participation and response time. In addition, the Medical Director should assure that program staff include Advanced Cardiac Life Support trained personnel, capable of rendering appropriate medical care in both emergent and nonemergent instances. Dependent upon facility policy approved by the Medical Director, standing orders may be in place to allow appropriately trained cardiac rehabilitation personnel to administer various levels of care in specifically delineated circumstances. Regular practice of emergency procedures should be conducted and documented.

Program Monitoring

Like many other therapeutic services, cardiac rehabilitation does not have a specific benefit category within Medicare law. These services are reimbursed under the nonspecific "incident to physician services" benefit category. "Incident to" services are designed to support and ensure the level of patient care during the course of treatment by the physician responsible for the patient's care. In the context of cardiac rehabilitation, this support includes fostering adherence with strategies to address cardiovascular disease risk factors such as dyslipidemia, hypertension, and hyperglycemia including medication regimens, as well as increasing functional capacity and promoting adherence to lifestyle modification. Behavioral counseling directed at appropriate diet and weight management, based upon the Therapeutic Lifestyle Change diet,¹¹ as well as smoking cessation, is also essential.

From a regulatory perspective, in order to be considered as "incident to" a physician's professional services, Medicare requires, in part, that the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness. The benefit does not require that a physician perform a personal professional service on each occasion of service by a nonphysician. However, during any course of treatment by auxiliary personnel, the physician must personally see the patient periodically and often enough to assess the course of treatment and the patient's progress and, where necessary, to change the treatment

program.²⁷ Although the nonphysician program staff is typically responsible for providing cardiac rehabilitation and secondary prevention services, there must be evidence that a physician regularly participates in the management of the patient's care during this time to meet the "incident to" a physician's professional services. It is inappropriate for a patient to participate in an 8- to 12-week program of outpatient cardiac rehabilitation and not see a physician to assess the course of treatment and, when necessary, adjust the treatment plan. Such an approach does not meet existing Medicare requirements for "incident to" services. Physician participation in the management of patients as a part of cardiac rehabilitation programming must be documented.

At this time, no guideline has been provided by CMS as to the frequency with which "face-to-face" patient-physician visits should occur in order to meet the "incident to physician" regulatory requirements. The recommendation of this writing group is that such interactions take place at least once midway through an 8- to 12-week period of early outpatient rehabilitation.

There also remains some controversy regarding which specific physician(s) would be eligible to provide these services (eg, the program Medical Director, designated program-affiliated physician, and/or the patient's primary care physician, cardiologist, or other referring physician). As no guideline exists, program staff must document these "incident to" visits and obtain records pertaining to such visits, paying particular attention to examples that reflect interaction between physicians and program staff related to patient care. If the encounter is with the program's Medical Director, documentation is simple, whereas documentation of an encounter with the beneficiary's referring cardiologist or primary care physician becomes more complex.

Finally, what might be appropriate for "incident to" in one geographic area might not match the practice in another area. It is also important to be familiar with any specific requirements identified by the local fiscal intermediary in its local coverage decision, including those related to billing and documentation.

ALTERNATIVE DELIVERY MODELS

When patients do not participate in traditional outpatient cardiac rehabilitation programming, the Medical Director, in conjunction with the program staff, should identify and consider alternative mechanisms for providing long-term supervision. Several models hold promise, both as an alternative to traditional outpatient cardiac rehabilitation programming and for the provision of ongoing supervision after completion of a traditional program. These models include nurse-coordinated care management programs³⁰; self-directed individual

patient monitoring using various tools (which can be evaluated by the physician periodically) to record adherence to exercise, diet, medication regimen, and other risk interventions³¹; and community-based group follow-up, using nurses and other allied healthcare providers to assist patients in maintaining adherence.³² Regardless of the mechanism for supervision, the program Medical Director must emphasize, at every opportunity, the importance of the patient's commitment to these efforts. This long-term commitment will decrease the risk of secondary events, while significantly improving general health and well-being.³³

SUMMARY AND CONCLUSIONS

Lifelong adherence to regular physical activity, a heart-healthy diet, a prescribed medication regimen, and smoking cessation is needed to maintain the benefits of cardiac rehabilitation/secondary prevention programs. Monitoring patient progress toward achieving goals is a responsibility of the Medical Director and staff of the cardiac rehabilitation/secondary prevention program. Close interaction with the patient's primary care provider, cardiologist, or cardiovascular surgeon, who cares for the patient's cardiovascular health, is essential. Cardiac rehabilitation/secondary prevention programs play a pivotal role in fostering a patient's commitment to lifestyle modification, but individual patient-physician interaction linked to evidence-based guidelines is key to maintaining this process. Medical Directors of cardiac rehabilitation/secondary prevention programs are uniquely positioned to assure that secondary prevention programs function effectively to improve quality of care for patients with cardiovascular disease.

The interactive role of the multiple physicians and team members involved in the patient's care cannot be overemphasized in the process of cardiac rehabilitation and secondary prevention. The active leadership of the Program Medical Director is key. The Medical Director's role is pivotal to develop and implement program policies and procedures, assure appropriate patient assessments are completed and an individualized plan of care for each patient is developed, assure patient safety, and insure that patient and program outcomes are consistent with current clinical practice standards. Optimal outcomes of cardiac rehabilitation/secondary prevention rely on a multidisciplinary rehabilitation team approach, with strong leadership and direction provided by the program Medical Director.

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