Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs: 2012 Update

A Statement for Health Care Professionals From the American Association of Cardiovascular and Pulmonary Rehabilitation and the American Heart Association

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Abstract—Medical directors of cardiac rehabilitation/secondary prevention (CR/SP) programs are responsible for the safe and effective delivery of high-quality CR/SP services to eligible patients. Yet, the training and resources for CR/SP medical directors are limited. As a result, there appears to be considerable variability throughout CR/SP programs in the United States in the roles, responsibilities, and engagement of CR/SP medical directors. Since the publication of the 2005 scientific statement from the American Heart Association and American Association of Cardiovascular and Pulmonary Rehabilitation regarding medical director responsibilities for outpatient CR/SP programs, significant changes have occurred. This statement updates the responsibilities of CR/SP medical directors, in view of changes in federal legislation and regulations and changes in health care delivery and clinical practice that impact the roles and responsibilities of CR/SP medical directors. (Circulation. 2012;126:2535-2543.)

Key Words: AHA Scientific Statements ■ cardiac rehabilitation ■ exercise training ■ medical director

Outpatient cardiac rehabilitation/secondary prevention (CR/SP) programs are recognized as a key component of the management of patients with a variety of cardiovascular conditions, including stable angina, recent myocardial infarction or acute coronary syndrome, or heart failure, or following coronary revascularization procedures, valve surgery, or cardiac transplantation. In addition to improving adherence to medication regimens and lifestyle recommendations, enhancing quality of life and psychosocial well-being, and increasing functional capacity, recent research has shown that participation in CR/SP programs reduces 5-year mortality by 25% to 46% and recurrent nonfatal myocardial infarction by 31%.1–3 Similar to many other therapeutic interventions, there is evidence that those who participate in more CR/SP sessions obtain greater benefits.1,3 As a result, referral to CR/SP programs is currently included in numerous clinical guidelines, with a high level of evidence and strength of recommendation.4–11 In addition, referral to CR/SP programs is incorporated into performance measure sets for myocardial infarction and chronic coronary artery disease.12,13

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Legislation passed by the US Congress in 2008 stipulated that a medical director is required for the operation of CR/SP programs, and that CR/SP is defined as “a physician supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment” (italics added). As a result of this legislation and changes in the science and practice of CR/SP, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) and the American Heart Association (AHA) deemed it important and necessary to update the 2005 AACVPR/AHA statement on the roles and responsibilities of CR/SP medical directors.

The purpose of this document is to provide an update regarding legislative, regulatory, programmatic, and clinical issues that impact CR/SP medical directors. It is not meant to repeat information regarding CR programming, which can be found in guidelines and statements elsewhere. Rather, it concentrates on the unique roles and responsibilities of the CR/SP medical director. This document describes relevant regulatory and legislative requirements, explains the clinical rationale behind the involvement of medical directors in CR/SP programs, includes information that helps physicians develop the specific skill sets needed to be effective medical directors, and provides resources that can be used by the medical director to promote evidence-based and cost-effective CR/SP services. Together, these should result in good patient outcomes, patient satisfaction, and employee satisfaction.

Medicare Regulations
Section 144 of the Public Law 110–275 titled, “Medicare Improvements for Patients and Providers Act of 2008,” established a new section of the Medicare statute for coverage and payment of cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services. On the basis of this specific legislative language, the Centers for Medicare & Medicaid Services (CMS) developed a revised Medicare provision for cardiac rehabilitation. Within the Medicare provision are requirements that address qualifications for medical direction and physician supervision, as well as roles and responsibilities of the medical director related to individual treatment plans and outcomes assessment.

Regulatory Requirements for the Physician Responsible for the CR/SP Program
The CMS defines a CR/SP medical director as a physician who oversees a CR/SP program at a particular site. The standards for this physician are the following:

- expertise in the management of individuals with cardiac pathophysiology;
- cardiopulmonary training in basic life support or advanced cardiac life support; and
- licensure to practice medicine in a state where the CR/SP program is offered.

A CR/SP medical director need not be a cardiologist, but he or she needs to be a licensed physician, whose scope of practice includes the treatment of cardiovascular disease (CVD). The term physician, as defined by CMS, means a doctor of medicine or osteopathy.

A medical director is responsible for directing the progress of individuals in the program, in consultation with the CR/SP staff. Although the medical director is not required to scrutinize the medical record of every patient, he or she should be aware of patients’ conditions and progress throughout their time in the program. This is most effectively done in close collaboration with the multidisciplinary team.

Outcomes Assessment
The CMS regulations state that outcomes are “. . . measured by the physician.” The process of outcomes assessment is a formal evaluation of the progress that a given patient achieves as a result of an individualized CR/SP treatment plan. CMS allows each program to determine which outcomes are more appropriately measured at the beginning and the end of the program and which outcomes would be more helpful to measure as the patient progresses through the program. This outcomes assessment is done in conjunction with the CR staff, with the expectation that the medical director is involved in this process.

Individualized Treatment Plan
It is important that the medical director and all CR/SP staff are familiar with an individual patient treatment plan; however, it is the responsibility of a physician to review, modify if needed, and sign the initial and subsequent individualized treatment plans (ITPs). This physician can be the medical director or one of the physicians involved in the patient’s cardiovascular care or secondary prevention. Specific components of the ITP are discussed later in this statement.

Regulatory Requirements for Medical Supervision
The CMS requirement of direct physician supervision for any therapeutic outpatient hospital service also applies to CR/SP programs. Currently, the CMS requires the immediate physical availability of the supervising physician and excludes remote access, such as by telephone or by other modes of communication, other than in person. CMS defines a supervising physician as one who is immediately available and accessible for medical consultations and medical emergencies at all times when the CR/SP program is in operation. CMS does not require that the medical director be the supervising physician; however, the medical director is responsible for ensuring that regulatory requirements for medical supervision of the CR/SP program are met.

The regulatory requirements for physicians providing direct physician supervision during exercise sessions are exactly the same as those listed earlier for the medical director. Although advanced practice nurses and physician assistants are increasingly assuming patient care roles that were previously the sole province and responsibility of physicians, current CMS guidelines do not permit such practitioners to fulfill the role of the supervising physician in CR/SP programs.

Regulatory Summary
From a regulatory perspective, the medical director is responsible for the following:
• ensuring that patients enrolled in the program meet qualifying diagnoses/medical conditions;
• providing oversight of patient progress and outcomes assessment;
• assuring appropriate supervised exercise for each patient, in consultation with the CR/SP staff;
• supervising the quality of care provided by the multidisciplinary CR/SP staff; and
• ensuring that regulatory requirements for medical supervision of the CR/SP program are met.

Qualifications and Skills for an Effective CR/SP Medical Director
Minimum qualifications of CR/SP medical directors as defined in current legislative and regulatory language are outlined earlier. In addition, medical directors should be appropriately credentialed within their institutions and should be contracted in such a way that they have the time to devote to the responsibilities that come with their role as a director. Medical directors must also make a commitment to staying abreast of new regulatory developments and participating in continuing medical education related to CVD in general and aspects of CVD prevention and rehabilitation in particular. Basic skills in data collection and analysis, outcomes assessment, and quality improvement strategies are highly desirable to facilitate communication with others in the health care organizations focused on these tasks.

Preventive cardiology encompasses many content areas, as described in detail in the American College of Cardiology, the AHA, and the American College of Physician competency statements. Although these reports were published to guide subspecialty training in CVD, and cardiovascular subspecialty training is not a prerequisite for directing a CR/SP program, these statements can serve as a roadmap for continuing medical education of CR/SP medical directors. Specifically, the medical director should acquire and maintain basic knowledge about the core competencies related to CVD, secondary prevention, data analysis, and program oversight outlined in Table 1.

Medical directors must possess sufficient leadership and communication skills, not only to lead a multidisciplinary team of health care professionals directly involved in provision of CR/SP services but also to communicate with a patient’s other healthcare providers and with administrative leadership. In an era of increasing accountability for health care outcomes and value-based purchasing, medical directors of CR/SP programs are uniquely positioned to help guide their health care organizations as they strive to become institutions that can demonstrate that they deliver high-quality preventive care for patients with CVD, which is cost-effective and improves patient outcomes.

Responsibilities Related to Program Development and Operations
Responsibilities of the CR/SP program medical director include direct participation in the processes of program development in the case of new programs and of subsequent program oversight and in the evaluation of effectiveness. The medical director should ensure that the policies and procedures are consistent with evidence-based guidelines, comply with regulatory and certification standards, and recognize regulations for, and issues pertaining to, reimbursement for services. In addition, medical directors should promote policies and practices aimed at improving CR/SP access and delivery to all patients who could benefit, including traditionally underserved patient populations, and facilitate clear, concise program documentation that maximizes communication among those responsible for the health care of a patient. Specific responsibilities of a CR/SP medical director, related to program development and operations, are detailed in Table 2 and are explained in more detail later.

Tracking and Ensuring Program Effectiveness
The CR/SP medical director is responsible for overseeing the CR/SP program’s overall effectiveness in delivering high-quality CR/SP services to all eligible patients within the program service area. To carry out these responsibilities, the CR/SP medical director must oversee activities that utilize the following concepts and practices:

• Enlist the support of local and nonphysician leadership to support the role of CR/SP services in providing high-quality care to patients with CVD. Efforts to bridge the gap in the delivery of high-quality CR/SP services will be most successful when local leaders include CR/SP as a priority area of focus for local quality improvement.
Identify all eligible CR patients within the service area of the CR/SP program. Unless eligible patients are properly identified, the medical director and staff of a CR/SP program will have difficulty improving the impact of their services. Effective identification of eligible patients requires an active, collaborative approach with local hospitals and practices, in which there is recognition of joint accountability for identifying and treating all patients in need of CR/SP services.21,26 This approach is essential to extend the reach of CR/SP services to all eligible patients, but it is especially important for improving the delivery of care to those patient subgroups who are least likely to receive CR/SP services, including women, the elderly, and individuals from racial or ethnic minority groups.27–31 To improve utilization of CR/SP services, hospitals, outpatient practices, and CR/SP programs will need to use innovative strategies and delivery models, and health care systems will need to implement policies and strategies that reduce barriers.21,32,33

Deliver high-quality CR/SP services to eligible patients. The delivery of high-quality CR/SP services by CR/SP professionals to eligible patients requires that CR/SP programs incorporate a number of critical concepts, core components, and key competencies.16,25 Program certification is available for programs that meet quality standards.21,34

Table 2. Responsibilities of Cardiac Rehabilitation/Secondary Prevention Medical Directors*

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<thead>
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<tr>
<td>Supervise qualified, multidisciplinary CR/SP staff to deliver high-quality care to eligible patients</td>
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<td>Ensure the CR/SP team meets and maintains core competencies</td>
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<td>Promote continuing education for CR/SP team</td>
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<td>Ensure that policies and procedures are consistent with evidence-based practice guidelines and regulatory and certification standards</td>
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<td>Ensure that appropriate emergency response is available</td>
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<td>Provide medical advice to CR/SP team for specific patients as needed</td>
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<td>Demonstrate that the CR/SP program meets standards of care</td>
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<td>Ensure referral and enrollment of appropriate patients</td>
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<td>Work with the CR/SP team and facility administrators to identify eligible patients within the program’s service area</td>
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<td>Stress the benefits of CR/SP to health care professionals, patients, and families</td>
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<td>Ensure that policies and systems promote referral of all appropriate patients, including ethnic minorities, the elderly, and women</td>
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<td>Promote automatic or facilitated referral systems if needed</td>
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<td>Oversee implementation or continued use of a database that allows the CR/SP program to assess the percent of eligible patients who actually enroll and complete the prescribed course of CR/SP</td>
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<td>Oversight of the ITP</td>
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<td>Ensure that policies and procedures are in place to formulate, implement, and modify a clear, concise, and logically organized ITP</td>
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<td>Facilitate development of a program record that shows a clear, concise, logical, and organized ITP</td>
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<td>Work with staff to ensure that the ITP can match the needs of individual patients</td>
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<td>Help CR/SP programs use risk stratification to provide patient-specific strategies for risk reduction, modify exercise protocols, and determine the level of medical supervision and monitoring needed for individual patients</td>
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<td>Ensure appropriate exercise prescription, in conjunction with CR/SP staff</td>
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<td>Ensure that systems are in place for individualized education, counseling, and behavioral intervention about cardiac risk factor modification</td>
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<td>Ensure that the ITP is reviewed and signed periodically by a physician</td>
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<td>Promote communication with referring physicians about individual patient outcomes and progress toward goals</td>
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<td>Direct progress of individual patients</td>
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<td>Be aware of the patient’s conditions and progress through the program</td>
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<td>Help CR/SP staff solve problems and communicate with referring health care practitioners about deviations from individual patient goal attainment</td>
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<td>Educate patients and health care professionals</td>
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<td>Participate in patient education sessions when appropriate</td>
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<td>Educate CR/SP staff about emerging concepts in treatment and diagnosis of cardiovascular disease</td>
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<td>Facilitate education of junior health care professionals about CR/SP</td>
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<td>Ensure outcomes assessment</td>
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<tr>
<td>Promote utilization of information management and data collection systems that assist in outcomes assessment and quality improvement practices</td>
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<tr>
<td>Work with the CR/SP team to ensure appropriate outcomes assessment for individual patients</td>
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<td>Ensure that the program is successful in the attainment of meaningful patient and program outcomes</td>
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<td>Ensure collection of program outcomes and analysis of data</td>
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<tr>
<td>Work with the CR/SP team to apply quality improvement strategies for program improvement</td>
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CR/SP indicates cardiac rehabilitation and secondary prevention; ITP, Individualized Treatment Plan.
*From American Association of Cardiovascular and Pulmonary Rehabilitation19 and Hamm et al.25
Apply quality improvement strategies through a continuous improvement cycle that includes the following steps:

- agree on targets to measure that will demonstrate high-quality CR/SP care;
- assess current performance and gaps in performance relevant to these targets; and
- adjust the CR/SP program policies and processes to improve performance.

Utilize data collection systems that assist in the implementation and assessment of quality improvement practices in the CR/SP program. Medical directors should consider utilizing a database to track composite program outcomes, including those related to enrollment in CR/SP after referral, completion of the prescribed course of CR/SP, improvements in lifestyle habits and functional capacity, control of CVD risk factors, use of preventive medications, and frequency of recurrent cardiovascular events, hospitalizations, or death rates.

Issues Related to Patient Referral
Effective referral to and enrollment in CR/SP programs by eligible patients can be greatly influenced by the medical director’s endorsement and promotion of patient participation in CR/SP within the medical community, and by encouraging the use of effective tools such as automated or facilitated CR/SP referral systems.

Medical directors must work with the CR/SP team and facility administrators to develop policies related to the referral of all medically appropriate patients, both during hospitalization and in the outpatient setting. The medical director’s emphasis on the value of CR/SP 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 health care practitioner.

Inclusion and Exclusion Criteria
Currently, CMS regulations provide CR/SP coverage for the following diagnoses:

- acute myocardial infarction within the preceding 12 months;
- coronary artery bypass surgery;
- stable angina pectoris;
- heart valve repair or replacement;
- percutaneous transluminal coronary angioplasty or coronary stenting; and
- heart or heart-lung transplant.

However, covered diagnoses vary among payers, with many recognizing the growing scientific evidence of the benefits of cardiac rehabilitation in patients with heart failure, including those with ventricular assist devices, and less frequently, in patients with intermittent claudication due to peripheral artery disease. When policies suggest that a particular diagnosis will not be covered, most carriers have an appeal process that may result in coverage if appropriate documentation, showing medical necessity of the CR/SP services, is provided. In addition, while some patients may be restricted to participate in only certain aspects of the exercise program because of musculoskeletal or neurological issues or relative contraindications to exercise, enrollment should still be considered so that these patients can benefit from the other components of the program. Approaches to such patients should be individualized and may require guidance by the medical director.

Tracking and Monitoring CR/SP Program Referral
To help measure and subsequently improve the gap in the delivery of CR/SP services to eligible patients, performance measures have been developed, published, and endorsed and are being implemented throughout the United States. Hospitals and outpatient practices that provide care for patients with CVD are expected to report on their adherence to these performance measures. Outpatient practices will be subject to CMS chart-review audits for their adherence to CR/SP referral performance measures, beginning in 2014. The CMS has stated that the referral measure pertaining to the hospital inpatient setting would also be beneficial in the future from a continuity-of-care perspective. Medical directors for CR/SP programs can serve as a resource to hospitals and outpatient practices as they incorporate CR/SP referral performance measures into the tracking and monitoring of their processes of care using national databases. These databases include the following:

- **Inpatient database systems.** The American College of Cardiology Foundation and AHA have combined efforts in the ACTION Registry—Get With The Guidelines registry—to help with point-of-care prompts and automated system that help inpatient health care teams refer patients to CR/SP programs and help hospitals track the referral rates of eligible patients to such programs. The Society for Thoracic Surgery database also collects information on surgical patients who have undergone coronary artery bypass surgery, heart valve surgery, and heart transplantation, making them eligible for CR/SP services.

- **Outpatient database systems.** The Guideline Advantage, a collaboration by the American Cancer Society, the American Diabetes Association, and the AHA/American Stroke Association and the American College of Cardiology Foundation’s PINNACLE registry, part of the American College of Cardiology Foundation’s national cardiovascular data registry, help outpatient practices track the referral of eligible patients to CR/SP programs. The PINNACLE registry has been designated by CMS to qualify as part of the physician quality reporting system, which currently rewards practices financially for submitting quality-of-care data for their practice to CMS.

Facilitating Individualized Patient-Centered Care
The medical director is defined as a physician that oversees or supervises the cardiac rehabilitation program at a particular site. The AHA guidelines for secondary prevention and those of the AACVPR provide a useful framework for evaluation, goal development, outcomes tracking, and emergency management. This information is also useful to risk stratify patients for the following conditions: (1) disease progression and the likelihood of future cardiac events and (2) adverse cardiac events during exercise training. Medical
Directors should help CR/SP program staff utilize risk stratification to

- individualize exercise-training protocols;
- determine the level of monitoring needed during exercise training;
- guide individualized secondary prevention education, counseling, and treatment goals; and
- advise out-of-program exercise activities.

Medical director participation in staff and patient education sessions can be invaluable to reinforce basic principles of secondary prevention and provide information about recent developments in cardiovascular treatments and diagnostic procedures, so that the CR/SP team can be more effective in individualizing risk stratification and treatment plans. Evaluation and goal development should address each of the core components of secondary prevention relevant to a particular patient, as previously described by the AHA and the AACVPR.16

**Individualized Treatment Plan**

The medical director should ensure that policies and procedures are in place to formulate and implement an ITP for each participant, which is used to set goals with the participant, track progress, and communicate with other health care professionals. Successful implementation of an ITP requires timely flow of information from the program to other health care practitioners involved in the patient care and from these health care practitioners to the program. The medical director should help the CR/SP program staff develop systems and processes to facilitate this information flow.

The ITP is described in CMS regulation20 as a written plan tailored to each individual patient that includes all of the following:

- a description of the individual’s diagnosis;
- the type, amount, frequency, and duration of the items and services furnished under the plan; and
- the goals set for the individual under the plan.

Note that the ITP must be reviewed and approved by a physician, typically the referring physician or medical director, upon patient initiation of CR/SP, and at least every 30 days thereafter, until completion of early outpatient (phase II) CR/SP.20 To be clinically useful, the ITP should reflect the patient’s current status and guide the development and implementation of the following:

- a patient-specific treatment plan that prioritizes goals and outlines intervention strategies for exercise training and CVD risk reduction and
- a followup plan that reflects progress toward goals and guides long-term secondary prevention strategies, including strategies to improve medication compliance.

Ideally, goals and progress are measured in a quantitative fashion, and they differentiate between short-term goals that may be reasonably accomplished during CR/SP enrollment and long-term goals that require additional time and are attainable by the patient with continued lifestyle modification and medical management. Findings and recommendations resulting from the initial evaluation should be communicated to both patients and their health care providers in order to develop strategies to support long-term goals. Patient outcomes that reflect progress toward goals should be documented and tracked to identify specific areas that require further intervention and monitoring during future outpatient encounters.35,41

CMS regulations require that an assessment be performed at a minimum at the beginning and the end of the CR/SP program, and it should include “objective clinical measures of exercise performance and self-reported measures of exertion and behavior,” as well as other data on goals identified in the ITP.20(p62004) At completion of early outpatient CR/SP, a summary of patient progress toward goals should be communicated to the patient and his or her referring and other appropriate physicians and health care providers, to facilitate ongoing, long-term CR/SP therapies.

**The Role of the CR/SP Medical Director in Professional Education**

Cardiac rehabilitation and secondary prevention medical directors and their programs are uniquely positioned to educate and train students and health care professionals from many disciplines, involved in cardiac rehabilitation and/or secondary prevention of CVDs. This education can range from seminars or lectures, to informal observational activities, to structured rotations in the CR/SP program as part of a formal education or training program. Cardiology fellowship training requirements, for example, include exposure to and training in CR/SP.24,50 Similarly, many undergraduate and graduate programs in exercise physiology and other disciplines require hands-on training in a clinical setting. If such training opportunities are made available in a CR/SP program, the CR/SP medical directors should be actively involved in developing goals and objectives for these rotations in collaboration with the trainees’ advisor(s) and consistent with relevant graduation requirements. The CR/SP medical director must ensure that trainees are appropriately credentialed at the institution, trained in protection of personal health information, and meet other regulatory requirements.

**Summary and Conclusions**

Since publication of the first AHA/AACVPR statement regarding the roles and responsibilities of the CR/SP medical director in 2005,15 changes in regulations, health care delivery, and clinical practice have made the role of the medical director even more critical for delivery of quality CR/SP programming. Strong participation by a knowledgeable CR/SP medical director, working collaboratively with the CR/SP team and referring health care practitioners, is essential to ensure that treatment is individualized, communication is optimized, and outcomes are tracked to improve individual patient outcomes and overall program effectiveness. Moreover, because underutilization of CR/SP remains a problem, particularly for those who can benefit the most, CR/SP medical directors must work within their communities to develop systems and programs to reach these patients. The
role of the CR/SP medical director as a team leader remains a core concept, but it is even more critical to understand the role within changing health care delivery models, the increasing emphasis on patient-centered outcomes, and the need to deliver cost-effective care. Leading the CR team and medical community toward effective changes and continuous improvement in CR/SP program delivery and patient outcomes is arguably one of the most important roles for CR/SP medical directors, now and in the coming years.

References


### Disclosures

**Appendix 1. AACVPR/AHA Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs: 2012 Update, Author Relationships With Industry**

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<th>Writing Group Member</th>
<th>Employment</th>
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*This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all writing group members are required to complete and submit. A relationship is considered to be “significant” if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person’s gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be “modest” if it is less than “significant” under the preceding definition.

†Modest.
### Appendix 2. AACVPR/AHA Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs: 2012 Update, Reviewer Relationships With Industry*

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<td>Eileen Collins</td>
<td>Edward Hines Jr. VA Hospital and University of Illinois at Chicago</td>
<td>None</td>
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<td>Carl Lavie</td>
<td>John Ochsner Heart and Vascular Institute</td>
<td>None</td>
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*This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be “Significant” if (a) the person receives $10,000 or more during any 12-month period, or 5% or more of the person’s gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10,000 or more of the fair market value of the entity. A relationship is considered to be “modest” if it is less than “significant” under the preceding definition.†Modest.‡Significant.
Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs: 2012 Update: A Statement for Health Care Professionals From the American Association of Cardiovascular and Pulmonary Rehabilitation and the American Heart Association

Marjorie King, Vera Bittner, Richard Josephson, Karen Lui, Randal J. Thomas and Mark A. Williams

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