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## CMS Proposes Changes to Cardiac Rehabilitation Program Design and Physician Supervision Requirements

The Centers for Medicare and Medicaid Services (CMS) recently published two proposed rules that would have major effects on the provision of cardiac rehabilitation services in hospital departments and physician offices. In the CY 2010 Physician Fee Schedule (PFS) Proposed Rule, CMS proposed new standards for cardiac rehabilitation and intensive cardiac rehabilitation services, including program design, physician supervision, medical direction and intensive cardiac rehabilitation program certifications. In the CY 2010 Outpatient Prospective Payment System (OPPS) Proposed Rule, CMS further clarified the physician supervision requirements for cardiac rehabilitation and intensive cardiac rehabilitation services. These proposed rules, if adopted, will go into effect on January 1, 2010.

### I. Current Cardiac Rehabilitation Requirements

Since 1982, CMS has published strict coverage criteria for cardiac rehabilitation programs via the National Coverage Determination (NCD) process. The most recent

cardiac rehabilitation NCD was published March 22, 2006, and details Medicare's current coverage requirements for cardiac rehabilitation services.<sup>1</sup> Under the 2006 NCD, Medicare provides coverage for cardiac rehabilitation services for patients with certain medical conditions, including: 1) a diagnosis of acute myocardial infarction within the preceding 12 months; 2) coronary bypass surgery; 3) stable angina pectoris; 4) heart valve replacement or repair; percutaneous transluminal coronary angioplasty (PTCA); 5) coronary stenting; or 6) heart or lung transplant. Comprehensive cardiac rehabilitation programs must provide a comprehensive medical evaluation, a program to modify cardiac risk factors, prescribed exercise, education and counseling. These programs may generally include up to 36 one-hour sessions over 18 weeks, but may include up to 72 sessions over 36 weeks, if approved by the provider's local Medicare contractor.

Under the 2006 NCD, Medicare only covers cardiac rehabilitation when provided in a hospital, provider-based department of a hospital, or

<sup>1</sup> Medicare National Coverage Determination Manual, Section 20.10 (Effective March 22, 2006).



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physician's office. Each of these settings must have necessary cardiopulmonary emergency, diagnostic and therapeutic life-saving equipment immediately available, and must be staffed with personnel who are adequately trained in advanced life support techniques. Additionally, the cardiac rehabilitation services must be provided under the direct supervision of a physician.

In 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),<sup>2</sup> which added Medicare Part B (OPPS) coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs for patients with Chronic Obstructive Pulmonary Disease (COPD), cardiovascular disease and other related conditions, effective January 1, 2010. In response to the MIPPA legislation, CMS issued proposed regulations regarding the provision of cardiac rehabilitation services in the CY 2010 Medicare PFS Proposed Rule. CMS explained that, once adopted, the proposed rules would replace or modify the existing cardiac rehabilitation NCD. CMS issued further proposed regulations regarding physician supervision of cardiac rehabilitation services in the CY 2010 OPPS Proposed Rule.

## II. Proposed Program Requirements

Under the MIPPA legislation, cardiac rehabilitation programs will be required to include all the following components:

- Physician prescribed exercise each day cardiac rehabilitation services are furnished;
- Cardiac risk factor modification, including education, counseling and behavioral interventions, that are tailored to the patients' individual needs;

- Psychosocial assessment; and
- Outcomes assessment.<sup>3</sup>

The programs will also be required to prepare an individualized, written treatment plan reviewed and signed by a physician every 30 days. The treatment plan must describe the patient's diagnosis; the type, amount, frequency and duration of services to be furnished under the plan; and the individualized goals set for the patient.

In the 2010 PFS Proposed Rule, CMS offered proposed guidance to cardiac rehabilitation providers and suppliers regarding implementation of the MIPPA requirements.<sup>4</sup>

- Exercise. CMS explained that aerobic exercise training in using the muscles of ambulation must be a mandatory component of any cardiac rehabilitation program. CMS recommended that programs utilize both low- and high-intensity exercise and incorporate a combination of endurance, strengthening and stretching exercises.
- Cardiac Risk Factor Modification. CMS explained that cardiac risk factor modification services include education, counseling, and behavioral interventions that are tailored to fit the individual patient's needs. CMS proposed including services such as smoking cessation, nutritional education and meal planning, stress management, prescription drug education and management, and disease history education.
- Psychosocial Assessment. CMS proposed that all cardiac rehabilitation programs provide an initial assessment of all aspects of the individual's family and home situation that may affect the individual's treatment. Programs

<sup>2</sup> Pub. L. 110-275, Section 144(a).

<sup>3</sup> *Id.*

<sup>4</sup> 74 FR 33520, 33607-08 (July 13, 2009).



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will be expected to make referrals to support groups, community and/ or home care services as necessary. The psychosocial assessment should be re-evaluated prior to each 30-day review of the patient's individualized treatment plan.

- **Outcomes Assessment.** CMS proposed requiring programs to perform patient assessments using measurable outcomes at the beginning of the cardiac rehabilitation program, prior to each 30-day review, and at the end of the cardiac rehabilitation program. The proposed measures include the patients resting and exercising systolic and diastolic blood pressure, weight, BMI, amount and dosages of medications, self-reported quality of life, and behavioral measures (e.g. smoking cessation, increased activity levels, change in exercise levels). CMS clarified that these assessments should not be separately billed, as reimbursement is included in the cardiac rehabilitation payment.
- **Individualized Treatment Plan.** MIPPA requires that a physician establish a written individualized treatment plan and conduct subsequent reviews every 30 days. CMS clarified that the initial plan may be developed either by the referring physician or the physician supervising the patient's cardiac rehabilitation. The plan must specify the type, amount, frequency and duration of the treatment services. The plan must also include measurable and expected outcomes and estimated

timetables to achieve those outcomes.

### **III. Proposed Supervision of Cardiac Rehabilitation Services**

#### Direct Supervision of Cardiac Rehabilitation Services

Under the MIPPA legislation, a physician must be immediately available and accessible for both medical consultations and medical emergencies at all times when cardiac rehabilitation services are being furnished.<sup>5</sup> In the 2010 Medicare PFS Proposed Rule, CMS explained that this MIPPA supervision requirement would be met under the "direct supervision" standard that is currently applied to cardiac rehabilitation services under the 2006 NCD. Specifically, for cardiac rehabilitation services provided in a physicians' office, the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service or procedure.<sup>6</sup> In provider based hospital departments, the physician must be on the premises of the location (currently interpreted by CMS to mean "in the provider based department")<sup>7</sup> and immediately available to furnish assistance and direction throughout the performance of the procedure.

In the 2010 PFS Proposed Rule, CMS also explained that if, in the future, the agency amended its definitions of "direct supervision," CMS would provide additional guidance regarding the physician

<sup>5</sup> Pub. L. 110-275, Section 144(a).

<sup>6</sup> 42 C.F.R. § 410.26(b)(5).

<sup>7</sup> Effective January 1, 2009, CMS abandoned its longstanding policy of presuming direct supervision in on-campus provider based hospital departments. In the 2009 OPPS final rule, CMS announced that it would require physicians to be present in on-campus provider based hospital departments whenever services are rendered in order to meet the direct supervision standard. The relevant portions of the preamble are located at 73 FR 68702-68704 (November 18, 2008). More information on the current direct physician supervision rule is available in the CMS Implements Significant Changes to the Direct Physician Supervision Standard in On-Campus Provider-Based Hospital Outpatient Departments December 12, 2008 client advisory available at [www.hdjn.com](http://www.hdjn.com).



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supervision standard for cardiac rehabilitation services. On July 1, 2009, the same day CMS published the 2010 PFS Proposed Rule, CMS published the 2010 OPPS Proposed Rule, in which CMS did propose changes to its current “direct supervision” definitions. Specifically, for on-campus provider based departments, CMS proposed allowing the supervisory physician to be present on the same campus, in the hospital, or in the on-campus provider-based department of the hospital.<sup>8</sup> This Proposed Rule was a welcomed change for providers who are currently required to have the supervising physician in the on-campus provider based department whenever cardiac rehabilitation services are rendered. The 2010 OPPS Proposed Rule would not change the location requirements for cardiac rehabilitation services provided in off-campus provider based departments or physician offices.

The 2010 OPPS proposed rule also included other changes to the “direct supervision” definition that are not applicable to cardiac rehabilitation services. Specifically, CMS proposed allowing certain non-physician practitioners (specifically Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists and Certified Nurse Midwives) to provide direct supervision over hospital outpatient services that they may themselves perform.<sup>9</sup> In the 2010 Proposed Rule CMS clarified that this relaxed supervision staffing requirement would not apply in the cardiac rehabilitation setting, where direct supervision would still need to be provided by a doctor of medicine or osteopathy.<sup>10</sup>

In the 2010 Medicare PFS Proposed Rule, CMS also proposed training and qualification standards for physicians who provide direct supervision of cardiac rehabilitation services.<sup>11</sup> Specifically, CMS proposed requiring that the physician have expertise in cardiac pathophysiology resulting from training or experience in cardiovascular disease management and exercise training of heart disease patients. The physician would also have to be licensed to practice medicine in the State in which the cardiac rehabilitation program is located.

#### Medical Director Supervision of Cardiac Rehabilitation Programs

The MIPPA legislation also requires that all cardiac rehabilitation programs be “physician supervised.”<sup>12</sup> In the 2010 PFS Proposed Rule, CMS interpreted this requirement to mean more than mere “direct supervision” of cardiac rehabilitation services. CMS explained that it interprets the “physician supervised” requirement to mean that all cardiac rehabilitation programs must be overseen by an appropriately trained Medical Director.<sup>13</sup> Under the 2010 PFS Proposed Rule, CMS would require the Medical Director to be trained and proficient in cardiovascular disease management and exercise training of heart disease patients. The Medical Director would also have to be licensed to practice in the State in which the cardiac rehabilitation services were provided. Finally, the Medical Director would, in consultation with other staff, need to be involved in directing the progress of individuals in

<sup>8</sup> 74 FR 35232, 35366-70 (July 20, 2009).

<sup>9</sup> 74 FR 35232, 35366 (July 20, 2009).

<sup>10</sup> 74 FR 35232, 35362 (July 20, 2009). More information on the 2010 OPPS Proposed Rule Physician Supervision Standards is available in the Providers Catch a Break—CMS Issues New Physician Supervision Standards in 2010 OPPS Proposed July, 9, 2009 client advisory available at [www.hdjn.com](http://www.hdjn.com)

<sup>11</sup> 74 FR 33520, 33610 (July 13, 2009).

<sup>12</sup> Pub. L. 110-275, Section 144(a).

<sup>13</sup> 74 FR 33520, 33608 (July 13, 2009).



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the program. CMS also clarified that the Medical Director may both oversee the program as a whole, and provide direct supervision of program services, provided that all other direct supervision requirements are met.

#### **IV. Proposed Intensive Cardiac Rehabilitation Certification Requirements**

Under the MIPPA legislation, Medicare would provide coverage for up to 72 one-hour sessions of intensive cardiac rehabilitation services over an 18 week period.<sup>14</sup> Intensive cardiac rehabilitation programs would be required to abide by the same requirements as cardiac rehabilitation programs. However, intensive cardiac rehabilitation programs would also have to meet new program qualification standards set forth in the MIPPA.<sup>15</sup> To become qualified, an intensive cardiac rehabilitation program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following criteria:

- Positively affected the progression of coronary heart disease;
- Reduced the need for coronary bypass surgery; or
- Reduced the need for percutaneous coronary interventions (PCIs).

The program must also demonstrate through peer-reviewed, published research that it accomplished a statistically significant reduction for patients in 5 or more specific measures, including:

- Low density lipoproteins;
- Triglycerides;
- Body mass index;
- Systolic blood pressure;
- Diastolic blood pressure; and

- The need for cholesterol, blood pressure, and diabetes medications.

In the 2010 PFS Proposed Rule, CMS proposed requiring programs to apply for designation as qualified intensive cardiac rehabilitation programs.<sup>16</sup> Only CMS designated programs would be eligible for Medicare coverage. To obtain CMS designation, applicant programs would be required to submit a detailed description of the program's services, the capabilities of the facility providing the services, and the capabilities of program staff. Applicant programs would also be required to submit peer-reviewed, published research, specific to the actual program applying for approval, which clearly demonstrate that the program accomplishes the MIPPA required outcomes.

Upon receipt of an intensive cardiac rehabilitation application, CMS would either notify the applicant program of any missing information or inadequacies in their submissions or notify the applicant of its designation as an intensive cardiac rehabilitation program. CMS proposed identifying designated programs on the CMS Website and in the Federal Register. Designated programs would be required to demonstrate continued compliance with MIPPA standards every year by submitting specific outcomes assessment information for all patients who initiated and completed the full ICR program during preceding year.

#### **V. Opportunities for Comment**

CMS is accepting comments on both the 2010 Physician Fee Schedule Proposed Rule and the 2010 Outpatient Prospective Payment System Proposed Rule until August 31, 2009. The final 2010 PFS and

<sup>14</sup> Pub. L. 110-275, Section 144(a).

<sup>15</sup> Pub. L. 110-275, Section 144(a).

<sup>16</sup> 74 FR 33520, 33609 (July 13, 2009).



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OPPS rules will likely be issued in October of 2009 with a January 1, 2010 effective date.

For more information about CMS' proposed cardiac rehabilitation and intensive cardiac rehabilitation coverage requirements, please

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