CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 126	**Date: May 21, 2010**
	Change Request 6850

SUBJECT: Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

I. SUMMARY OF CHANGES: The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 established coverage provisions for cardiac rehabilitation (CR) programs and intensive cardiac rehabilitation (ICR) programs. The Centers for Medicare and Medicaid Services (CMS) decided to implement the statutory provisions through rule making, in the calendar year (CY) 2010 Physician Fee Schedule (PFS). To implement MIPPA CR and ICR coverage provisions CMS added section 410.49, Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage, to the Public Health Code of Federal Regulations (42 CFR). The CR and ICR coverage provisions included in new section 42 CF R 410.49 are effective January 1, 2010.

EFFECTIVE DATE: January 1, 2010
IMPLEMENTATION DATE: October 4, 2010

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/Table of Contents
N	15/232/Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment – Business Requirements

Pub. 100-02	Transmittal: 126	Date: May 21, 2010	Change Request: 6850

SUBJECT: Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

Effective Date: January 1, 2010
Implementation Date: October 4, 2010

I. GENERAL INFORMATION

A. Background: The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 established coverage provisions for cardiac rehabilitation (CR) programs and intensive cardiac rehabilitation (ICR) programs. The Centers for Medicare and Medicaid Services (CMS) decided to implement the statutory provisions through rule making, in the calendar year (CY) 2010 Physician Fee Schedule (PFS). On October 30, 2009, the CY 2010 PFS Final Rule with Comment was finalized and put on display and is available at http://edocket.access.gpo.gov/2009/pdf/E9-26502.pdf). The Final Rule was published in the Federal Register on November 25, 2009, and is available on pages 62004 - 62005.

To implement MIPPA CR and ICR coverage provisions CMS added section 410.49, *Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage*, to the Public Health Code of Federal Regulations (42 CFR). The CR and ICR coverage provisions included in new section 42 CF R 410.49 were effective January 1, 2010.

B. Policy: Effective January 1, 2010, Medicare Part B covers CR and ICR program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant; or,
- Other cardiac conditions as specified through a national coverage determination (NCD) (CR only).

ICR programs must be approved by CMS through the NCD process and must meet certain criteria for approval. Individual sites wishing to provide ICR services via an approved ICR program must enroll with their local Medicare contractor or MAC as an ICR program supplier using CMS 855B. Contractors and MACs must ensure that claims submitted from individual ICR sites are submitted by enrolled ICR program sites.

NOTE: Per the NCD process, the coverage analyses of the first ICR programs under evaluation will be completed no later than August 15, 2010. CMS anticipates future analyses of additional ICR programs. ICR programs that are approved through the NCD process will be identified in the NCD manual (Pub. 100-03), on the CMS Web site and in the Federal Register. Once ICR programs are approved through the NCD process, sites wishing to furnish ICR services via an approved ICR program may begin to enroll as ICR program suppliers using CMS 855B.

Regulations at 42 CFR 410.49 include all coverage provisions for CR and ICR items and services, identifies definitions, covered indications, settings, physician supervision requirements and physician standards, required CR and ICR components, limitations to the number of sessions covered, and the period of time over which the sessions may be covered.

CR and ICR programs must include the following components: 1) physician-prescribed exercise each day CR and ICR items and services are furnished; 2) cardiac risk factor modification; 3) psychosocial assessment; 4) outcomes assessment; and 5) an individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed and signed by a physician every 30 days.

CR sessions are limited to a maximum of 2 1-hour sessions per day up to 36 sessions furnished over a period of up to 36 weeks, with the option for an additional 36 sessions at Medicare contractor discretion over an extended period of time. ICR sessions are limited to 72 1-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.

NOTE: Once a beneficiary begins CR, he or she may not switch to ICR and once a beneficiary begins ICR, he or she may not switch to CR. Upon completion of a CR or ICR program, beneficiaries must experience another indication in order to be eligible for coverage of more CR or ICR. Should a beneficiary experience more than one indication simultaneously, he or she may participate in a single series of CR or ICR sessions (i.e., a patient who had a myocardial infarction within 12 months and currently experiences stable angina is entitled to one series of CR sessions, up to 36 1-hour sessions with contractor discretion for an additional 36 sessions; or one series of ICR sessions, up to 72 1-hour sessions over a period up to 18 weeks).

Contractors shall accept the inclusion of the KX modifier on the claim line(s) as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond 36 sessions of CR up to a total of 72 sessions meets the requirements of the medical policy or, for ICR, that any further sessions beyond 72 sessions within a 126 day period counting from the date of the first session or for any sessions provided after 126 days from the date of the first session meet the requirements of the medical policy.

See Pub. 100-06, Medicare Financial Management Manual, chapter 6, section 420, and Pub. 100-04, Medicare Claims Processing Manual, chapter 26, section 10.8.3, chapter 32, section 140, and Pub. 100-08, Medicare Program Integrity Manual, chapter 10, section 2.2.8 for detailed information regarding CR and ICR policy and claims processing.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6850.1	See Pub. 100-04 for detailed Business Requirements.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6850.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sarah McClain, Coverage, 410-786-2994, sarah.mcclain@cms.hhs.gov, Pat Brocato-Simons, Coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Michelle Atkinson, coverage, 410-786-2881, michelle.atkinson@cms.hhs.gov, Bill Ruiz, Institutional Claims Processing, 410-786-9283, William.ruiz@cms.hhs.gov , Tom Dorsey, Practitioner Claims Processing, Thomas.Dorsey@cms.hhs.gov, 410-786-7434, Alisha Banks, Provider Enrollment, 410-786-0671, alisha.banks@cms.hhs.gov, Richard Cuchna, CWF Inquiry Screens, 410-786-7239, richard.cuchna@cms.hhs.gov

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

A. For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MACs)*:
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

Table of Contents

(Rev.126, 05-21-10)

232 - Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

(Rev.126, Issued: 05-21-10, Effective: 01-01-10, Implementation: 10-04-10)

Cardiac rehabilitation (CR) services mean a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment, outcomes assessment, and other items/services as determined by the Secretary under certain conditions. Intensive cardiac rehabilitation (ICR) services mean a physician-supervised program that furnishes the same items/services under the same conditions as a CR program but must also demonstrate, as shown in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Effective January 1, 2010, Medicare Part B pays for CR/ICR programs and related items/services if specific criteria is met by the Medicare beneficiary, the CR/ICR program itself, the setting in which is it administered, and the physician administering the program, as outlined below:

CR/ICR Program Beneficiary Requirements:

Medicare covers CR/ICR program services for beneficiaries who have experienced one or more of the following:

- *Acute myocardial infarction within the preceding 12 months;*
- *Coronary artery bypass surgery;*
- *Current stable angina pectoris;*
- *Heart valve repair or replacement;*
- *Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;*
- *Heart or heart-lung transplant.*
- *For CR only, other cardiac conditions as specified through a national coverage determination (NCD).*

CR/ICR Program Component Requirements:

- *Physician-prescribed exercise. This physical activity includes aerobic exercise combined with other types of exercise (i.e., strengthening, stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items/services are furnished.*

- *Cardiac risk factor modification. This includes education, counseling, and behavioral intervention, tailored to the patients' individual needs.*

- *Psychosocial assessment. This assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation. It should include: (1) an assessment of those aspects of the individual's family and home situation that affects the individual's rehabilitation treatment, and, (2) a psychosocial evaluation of the individual's response to, and rate of progress under,*

the treatment plan.

- *Outcomes assessment. These should include: (i) minimally, assessments from the commencement and conclusion of CR/ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning and end of the program, and, (ii) objective clinical measures of the effectiveness of the CR/ICR program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.*

- *Individualized treatment plan. This plan should be written and tailored to each individual patient and include (i) a description of the individual's diagnosis; (ii) the type, amount, frequency, and duration of the CR/ICR items/services furnished; and (iii) the goals set for the individual under the plan. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.*

As specified at 42 CFR 410.49(f)(1), CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the contractor under section 1862(a)(1)(A) of the Act. ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR/ICR Program Setting Requirements:

CR/ICR services must be furnished in a physician's office or a hospital outpatient setting (for ICR, the hospital outpatient setting must provide ICR using an approved ICR program). All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items/services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.

ICR Program Approval Requirements:

All prospective ICR programs must be approved through the national coverage determination (NCD) process. To be approved as an ICR program, it must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (i) positively affected the progression of coronary heart disease, (ii) reduced the need for coronary bypass surgery, or, (iii) reduced the need for percutaneous coronary interventions.

An ICR program must also demonstrate through peer-reviewed, published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before CR services to after CR services: (i) low density lipoprotein, (ii) triglycerides, (iii) body mass index, (iv) systolic blood pressure, (v) diastolic blood pressure, and (vi) the need for cholesterol, blood pressure, and

diabetes medications.

A list of approved ICR programs, identified through the NCD process, will be posted to the CMS Web site and listed in the Federal Register.

Once an ICR program is approved through the NCD process, all prospective ICR sites wishing to furnish ICR items/services via an approved ICR program may enroll with their local contractor to become an ICR program supplier using the designated forms as specified at 42 CFR 424.510, and report specialty code 31 to be identified as an enrolled ICR supplier. For purposes of appealing an adverse determination concerning site approval, an ICR site is considered a supplier (or prospective supplier) as defined in 42 CFR 498.2.

CR/ICR Program Physician Requirements:

Physicians responsible for CR/ICR programs are identified as medical directors who oversee or supervise the CR/ICR program at a particular site. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program. The medical director, as well as physicians acting as the supervising physician, must possess all of the following: (1) expertise in the management of individuals with cardiac pathophysiology, (2) cardiopulmonary training in basic life support or advanced cardiac life support, and (3) licensed to practice medicine in the state in which the CR/ICR program is offered. Direct physician supervision may be provided by a supervising physician or the medical director.

(See Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 140.2, for specific claims processing, coding, and billing requirements for CR/ICR program services.)