

Washington, D.C. 20201

AUG 18 2005

TO:

Mark B. McClellan, M.D., Ph.D.

Administrator

Centers for Medicare & Medicaid Services

FROM:

Daniel R. Levinson Daniel R. Levinson

Inspector General

SUBJECT:

Review of Medicare Outpatient Cardiac Rehabilitation Provided by Hospitals

(A-05-03-00102)

The attached final report consolidates the results of our audits of Medicare outpatient cardiac rehabilitation provided by 34 hospitals, as requested by the Centers for Medicare & Medicaid Services (CMS). Cardiac rehabilitation is a physician-supervised exercise program that includes specific types of exercises individually prescribed for each patient. Medicare reimburses hospital outpatient departments for cardiac rehabilitation services under the outpatient prospective payment system. For calendar year 2001 (our audit period), Medicare payments for these services totaled approximately \$44 million.

During our audit period, the Medicare Coverage Issues Manual set forth coverage requirements for outpatient cardiac rehabilitation services. The Coverage Issues Manual stated that hospitals were also subject to the rules for outpatient therapeutic services contained in the Medicare Intermediary Manual and the Medicare Hospital Manual. To be covered, outpatient cardiac rehabilitation services must be provided under the direct supervision of a physician and "incident to" a physician's professional services.

Our objective was to determine whether hospitals had complied with national Medicare outpatient cardiac rehabilitation coverage requirements for direct physician supervision and "incident to" services.

We found two very different sets of practices with respect to the provision of direct physician supervision. Twenty-nine of the 34 hospitals in our sample relied on emergency physicians or "code" teams in other parts of the hospital to provide physician supervision when the medical directors were not available, while the remaining 5 hospitals designated a particular physician to provide direct physician supervision.

We also found two very different sets of practices with respect to the physician (referring or hospital) whose professional services (assessing the course of treatment and the patient's

¹After our audit period, CMS replaced the Coverage Issues Manual with the National Coverage Determinations Manual. Section 35-25 of the Coverage Issues Manual was redesignated as section 20.10 of the National Coverage Determinations Manual, and the wording remained nearly identical. CMS also consolidated the Medicare Intermediary Manual, section 3112.4(A) and the Medicare Hospital Manual, section 230.4(A) into the Medicare Benefit Policy Manual, Chapter 6, section 20.4.1.

Page 2 - Mark B. McClellan, M.D., Ph.D.

progress and, when necessary, changing the course of treatment) the cardiac rehabilitation was provided "incident to." Thirty-two of the 34 hospitals considered the patient's referring physician as the physician whose professional services the cardiac rehabilitation was provided "incident to," while the other 2 hospitals relied on the professional services of a hospital physician.

We attribute this situation to inconsistent guidance in the Medicare Coverage Issues Manual, Hospital Manual, and Intermediary Manual. This inconsistency was confirmed by our interviews with hospital officials, most of whom believed that the guidance in the various Medicare manuals was confusing.

We recommend 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" and
- direct fiscal intermediaries to educate hospitals on the clarified national Medicare coverage policy for outpatient cardiac rehabilitation services.

In its comments on our draft report, CMS agreed to develop and publish provider education materials to clarify the direct physician supervision and "incident to" provisions of the cardiac rehabilitation benefit.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at george.reeb@oig.hhs.gov. Please refer to report number A-05-03-00102 in all correspondence.

Attachment

Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE OUTPATIENT CARDIAC REHABILITATION PROVIDED BY HOSPITALS



Daniel R. Levinson Inspector General

> AUGUST 2005 A-05-03-00102

Office of Inspector General

http://oig.hhs.gov

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The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

Cardiac rehabilitation is a physician-supervised exercise program that includes specific types of exercises individually prescribed for each patient. Medicare reimburses hospital outpatient departments for cardiac rehabilitation services under the outpatient prospective payment system. During 2001 (our audit period), Medicare payments for these services totaled approximately \$44 million.

During our audit period, national guidance was contained in three Centers for Medicare & Medicaid Services (CMS) manuals. The Medicare Coverage Issues Manual set forth coverage requirements for outpatient cardiac rehabilitation services. The Coverage Issues Manual stated that hospitals were also subject to the rules for outpatient therapeutic services contained in the Medicare Intermediary Manual and the Medicare Hospital Manual. To be covered, outpatient cardiac rehabilitation services must be provided under the direct supervision of a physician and "incident to" a physician's professional services.

CMS is considering expanding coverage of Medicare outpatient cardiac rehabilitation services. For assistance in making this decision, the Administrator of CMS asked the Office of Inspector General to review hospitals' compliance with current national Medicare coverage requirements.

OBJECTIVE

Our objective was to determine whether hospitals had complied with national Medicare outpatient cardiac rehabilitation coverage requirements for direct physician supervision and "incident to" services.

SUMMARY OF FINDINGS

We found two very different sets of practices with respect to the provision of direct physician supervision. Twenty-nine of the 34 hospitals in our sample relied on emergency physicians or "code" teams in other parts of the hospital to provide physician supervision when the medical directors were not available, while the remaining 5 hospitals designated a particular physician to provide direct physician supervision.

We also found two very different sets of practices with respect to the physician (referring or hospital) whose professional services (assessing the course of treatment and the patient's progress and, when necessary, changing the course of treatment) the cardiac rehabilitation was provided "incident to." Thirty-two of the 34 hospitals considered the patient's referring physician as the physician whose professional services the cardiac rehabilitation was provided

¹After our audit period, CMS replaced the Coverage Issues Manual with the National Coverage Determinations Manual. Section 35-25 of the Coverage Issues Manual was redesignated as section 20.10 of the National Coverage Determinations Manual, and the wording remained nearly identical. CMS also consolidated the Medicare Intermediary Manual, section 3112.4(A) and the Medicare Hospital Manual, section 230.4(A) into the Medicare Benefit Policy Manual, Chapter 6, section 20.4.1.

"incident to," while the other 2 hospitals relied on the professional services of a hospital physician.

We attribute this situation to inconsistent guidance in the Medicare Coverage Issues Manual, Hospital Manual, and Intermediary Manual. This inconsistency was confirmed by our interviews with hospital officials, most of whom believed that the guidance in the various Medicare manuals was confusing.

RECOMMENDATIONS

We recommend 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" and
- direct fiscal intermediaries to educate hospitals on the clarified national Medicare coverage policy for outpatient cardiac rehabilitation services.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its comments on our draft report, CMS agreed to develop and publish provider education materials to clarify the direct physician supervision and "incident to" provisions of the cardiac rehabilitation benefit. CMS's comments are included as Appendix C of this report.

TABLE OF CONTENTS

<u>Page</u>
INTRODUCTION1
BACKGROUND1
The Medicare Program1
Cardiac Rehabilitation1
Medicare Outpatient Cardiac Rehabilitation Services2
CMS Request for Audit4
OBJECTIVE, SCOPE, AND METHODOLOGY4
Objective4
Scope4
Methodology4
FINDINGS AND RECOMMENDATIONS
COMPLIANCE WITH PHYSICIAN SUPERVISION REQUIREMENTS5
Confusing Physician Supervision Criteria5
Physician Supervision at the Hospitals Reviewed6
Hospitals' Views on Physician Supervision
COMPLIANCE WITH "INCIDENT TO" REQUIREMENTS7
Confusing "Incident to" Criteria
"Incident to" Services at the Hospitals Reviewed8
Hospitals' Views on "Incident to" Services
RECOMMENDATIONS9
CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS10
APPENDIXES
A – SAMPLING METHODOLOGY
B – SAMPLED HOSPITALS AND OFFICE OF INSPECTOR GENERAL REPORT NUMBERS
C – CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

INTRODUCTION

BACKGROUND

The Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act (the Act), provides health insurance to people aged 65 and over, the disabled, and individuals with end stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

During our audit period, three CMS manuals provided national guidance to Medicare health care providers, as well as Medicare carriers and fiscal intermediaries. The Coverage Issues Manual set forth national criteria on the specific medical items, services, treatment procedures, and technologies that Medicare covers. These criteria applied nationwide and were binding on all Medicare carriers and intermediaries. The Hospital and Intermediary Manuals contained instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. Specifically, the Hospital Manual contained Medicare policies and procedures on the delivery of hospital services, claims processing instructions, billing procedures, coverage requirements, and related matters. The Intermediary Manual contained instructions and procedures for processing claims, including coverage limitations and requirements.¹

National guidance may be supplemented by local medical review policies developed by Medicare contractor medical directors. According to CMS's "Medical Review Technical Assistance" web page, these policies are an administrative and educational tool to assist providers, physicians, and suppliers in submitting correct claims for payment. The local policies outline how contractors will review claims to ensure that they meet Medicare coverage requirements. CMS requires that local policies be consistent with national guidance (although they may be more detailed or specific), developed with input from medical professionals (through advisory committees), and consistent with scientific evidence and clinical practice.

Cardiac Rehabilitation

Cardiac rehabilitation is a physician-supervised exercise program that includes specific types of exercises individually prescribed for each patient. Cardiac rehabilitation programs typically consist of the following three phases:

¹After our audit period, CMS replaced the Coverage Issues Manual with the National Coverage Determinations Manual. Section 35-25 of the Coverage Issues Manual was redesignated as section 20.10 of the National Coverage Determinations Manual, and the wording remained nearly identical. CMS also consolidated the Medicare Intermediary Manual, section 3112.4(A) and the Medicare Hospital Manual, section 230.4(A) into the Medicare Benefit Policy Manual, Chapter 6, section 20.4.1.

- **Phase I.** Phase I begins in the acute convalescent period following a cardiac event. This phase is considered part of the hospital stay and is covered under the Medicare diagnosis-related group allowance for the hospital stay.
- **Phase II.** Phase II begins after the acute convalescent period, with a physician's prescription, when the patient's clinical status and capacity will allow for safe participation in an individualized progressive exercise program. This phase requires close monitoring and is directed by an onsite physician. Medicare covers Phase II services conducted in specialized, freestanding cardiac rehabilitation clinics and in outpatient hospital departments under a benefit commonly referred to as "incident to," which is defined in section 1861(s)(2)(A) of the Act.
- **Phase III.** Phase III involves a less intensively monitored aerobic exercise program. Phase III programs are considered maintenance and are not covered by Medicare.

Medicare Outpatient Cardiac Rehabilitation Services

Medicare currently covers outpatient cardiac rehabilitation under the "incident to" a physician's professional services benefit and pays for these services only if direct physician supervision is provided. Medicare reimburses hospital outpatient departments for cardiac rehabilitation services under the outpatient prospective payment system, which is based on an ambulatory payment classification.² For calendar year (CY) 2001, these Medicare payments on behalf of 140,776 Medicare beneficiaries totaled approximately \$44 million. To receive such payments, hospitals must meet the criteria summarized below.

Criteria for Physician Supervision

According to section 35-25(A) of the Coverage Issues Manual:

Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible. The examples below are for illustration purposes only. They are not meant to limit the discretion of the contractor to make determinations in this regard.

- The case in which a contractor determines that the presence of a physician in an office across the hall from the exercise room who is available at all times for an emergency meets the requirement that the physician is immediately available and accessible; or

2

²Ambulatory payment classifications group together services, supplies, drugs, and devices that are used in particular procedures. Each classification has a separate payment rate that accounts for all items used in the procedure.

- The case in which a contractor determines that the presence of a physician in a building other than that containing the exercise room does not meet the requirement that the physician is immediately available and accessible

During our audit period, the Coverage Issues Manual stated that "Cardiac rehabilitation programs furnished by hospitals to outpatients are also subject to the rules described in the Intermediary Manual, section 3112.4 and the Hospital Manual, section 230.4." Specifically, section 3112.4 of the Intermediary Manual stated, "The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises." In addition, section 230.4 of the Hospital Manual stated that outpatient therapeutic services "must be furnished on a physician's order by hospital personnel under hospital medical staff supervision in the hospital."

Criteria for "Incident to" Services

Section 35-25 of the Coverage Issues Manual stated that outpatient hospital cardiac rehabilitation services were covered when "the nonphysician personnel are employees of either the physician, the hospital, or clinic conducting the program and their services are incident to a physician's professional services." The section further required that "A physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician."

The Coverage Issues Manual stated that "Cardiac rehabilitation programs furnished by hospitals to outpatients are also subject to the rules described in the Intermediary Manual, section 3112.4 and the Hospital Manual, section 230.4." Section 3112.4 of the Intermediary Manual required that for outpatient therapeutic services:

... to be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. ... during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.

Also, section 230.4 of the Hospital Manual stated that for outpatient therapeutic services "to be covered as incident to physicians' services, the services and supplies must be furnished on a physician's order by hospital personnel under hospital medical staff supervision in the hospital." According to the Hospital Manual, "There is no requirement that the physician who orders the hospital services be directly connected with the department which provides the services."

CMS Request for Audit

CMS is considering expanding the number of covered clinical indications for Medicare outpatient cardiac rehabilitation services. For assistance in making this decision, the Administrator of CMS asked the Office of Inspector General to review hospitals' compliance with current national Medicare coverage requirements.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether hospitals had complied with national Medicare outpatient cardiac rehabilitation coverage requirements for direct physician supervision and "incident to" services.

Scope

This review consolidates the results of our audits at 34 hospitals. We statistically selected 16 of the 34 hospitals from the 10 States with the highest total Medicare payments for outpatient cardiac rehabilitation services in CY 2001. In addition, we nonstatistically selected 18 hospitals in 11 other States. To obtain a mix of all types of hospitals, we based our nonstatistical selection on characteristics such as geographical location (urban or rural), size (number of beds), status (for-profit or not-for-profit), and ownership (private or government). (See Appendix A for specific sampling methodology.)

We visited the 34 hospitals to interview and observe the outpatient cardiac rehabilitation staff and to gain an understanding of the management of their outpatient cardiac rehabilitation programs. We also reviewed internal control procedures, in effect at the time of our visits, for direct physician supervision, "incident to" services, and outpatient cardiac rehabilitation staffing.

The Medicare contractors for 15 of the 34 hospitals did not have local medical review policies with respect to the direct physician supervision and "incident to" requirements. For most of the remaining 19 hospitals, our reports did not specifically address compliance with the contractors' local medical review policies.

Methodology

We compared the sampled hospitals' policies, procedures, and practices for outpatient cardiac rehabilitation services, in effect at the time of our visits, with national Medicare coverage requirements and identified any differences. We documented how hospital staff provided direct physician supervision and "incident to" services. During discussions with each hospital's staff, we solicited their comments with respect to the national coverage requirements. We also reviewed the outpatient cardiac rehabilitation programs' medical records for 480 statistically selected beneficiaries and 370 nonstatistically selected beneficiaries who received outpatient

cardiac rehabilitation services during CY 2001. We validated whether the national requirements for direct physician supervision and "incident to" services were met for these beneficiaries.

In individual reports to the 34 sampled hospitals, we recommended that the hospitals work with their fiscal intermediaries to ensure that their outpatient cardiac rehabilitation programs meet Medicare coverage requirements for direct physician supervision and "incident to" services. In written responses to our draft reports, the sampled hospitals generally concurred with our findings and recommendations. See Appendix B for a list of the 34 individual hospitals and the report numbers. Copies of these reports are available at http://oig.hhs.gov/.

We conducted our audits in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

We found two very different sets of practices with respect to the provision of direct physician supervision. Twenty-nine of the 34 hospitals in our sample relied on emergency physicians or "code" teams in other parts of the hospital to provide physician supervision when the medical directors were not available, while the remaining 5 hospitals designated a particular physician to provide direct physician supervision.

We also found two very different sets of practices with respect to the physician (referring or hospital) whose professional services (assessing the course of treatment and the patient's progress and, when necessary, changing the course of treatment) the cardiac rehabilitation was provided "incident to." Thirty-two of the 34 hospitals considered the patient's referring physician as the physician whose professional services the cardiac rehabilitation was provided "incident to," while the other 2 hospitals relied on the professional services of a hospital physician.

We attribute this situation to inconsistent guidance on coverage of cardiac rehabilitation services in the Medicare Coverage Issues Manual, Hospital Manual, and Intermediary Manual. This inconsistency was confirmed by our interviews with hospital officials, most of whom believed that the guidance in the various Medicare manuals was confusing.

COMPLIANCE WITH PHYSICIAN SUPERVISION REQUIREMENTS

Confusing Physician Supervision Criteria

While most hospitals used the less stringent criteria for physician supervision of outpatient therapeutic services as set forth in the Intermediary and Hospital Manuals, some hospitals applied the criteria for outpatient cardiac rehabilitation services in the conditions for coverage found at section 35-25(A) of the Coverage Issues Manual. The Intermediary Manual stated that "The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises." In contrast, the Coverage Issues Manual, section 35-25(A) stated that "Services of nonphysician personnel must be furnished under the direct supervision of a physician."

We conferred with several CMS officials about the wording in these manuals. These officials stated that the Coverage Issues Manual requirements for direct physician supervision must be met. The officials explained that those requirements reflected a National Coverage Decision, and pursuant to section 1862(a)(1) of the Act, that specifically limits Medicare coverage of cardiac rehabilitation services and that provides narrower requirements than those generally applicable to outpatient therapeutic services. According to the officials, these limitations apply irrespective of the setting (a hospital outpatient department located on or off a hospital campus as well as a specialized freestanding clinic) in which the services are performed. Direct physician supervision, as defined in section 35-25(A) of the Coverage Issues Manual, means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times during the exercise program.

Physician Supervision at the Hospitals Reviewed

Of the 34 hospitals reviewed, 29 conducted their outpatient cardiac rehabilitation programs by relying on emergency physicians or code teams to provide physician supervision. Generally, these hospitals conducted their outpatient cardiac rehabilitation programs as follows:

- On a day-to-day basis, nonphysician cardiac rehabilitation coordinators or managers staffed and conducted the outpatient cardiac rehabilitation programs. These staff generally included registered nurses, exercise physiologists, registered dieticians, and other staff.
- Medical directors were responsible for the policies and procedures of the hospitals' outpatient cardiac rehabilitation programs.
- Medical directors generally were not required to provide direct physician supervision.
- During outpatient cardiac rehabilitation exercise sessions, medical directors may have been in the exercise area, in their offices seeing patients, in the cardiac catheterization laboratory, or elsewhere in the hospital.
- Hospital staff believed that medical directors could respond to an emergency in the
 exercise areas when not performing other duties. In the event the medical directors were
 not available, the outpatient cardiac rehabilitation staff relied on emergency code teams
 to respond to medical emergencies throughout the hospitals.

The remaining five hospitals conducted their outpatient cardiac rehabilitation programs by designating a physician to provide direct physician supervision. Generally, these hospitals conducted their outpatient cardiac rehabilitation programs as follows:

• On a day-to-day basis, nonphysician cardiac rehabilitation coordinators or managers staffed and conducted the outpatient cardiac rehabilitation programs. These staff

³Now termed "National Coverage Determination."

generally included registered nurses, exercise physiologists, registered dieticians, and other staff.

- The hospitals' policies and procedures required a physician to be onsite during the exercise sessions.
- The physicians providing direct supervision were accessible at all times during the exercise programs and were immediately available in case of a medical emergency.

Hospitals' Views on Physician Supervision

Most hospitals believed that the requirement for direct physician supervision in the Coverage Issues Manual conflicted with the requirements in the Intermediary and Hospital Manuals. Most hospitals also believed that their programs met the Hospital Manual requirements. According to these hospitals, the Intermediary Manual statement that "The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises" eliminated the need to designate specific physicians to provide direct physician supervision and be immediately available for emergencies in the exercise area.

In addition, some hospitals believed that direct physician involvement was not justified because of the low patient risk of needing emergency care and the cost of providing a physician. These hospitals believed that patients were not likely to require emergency physician services and that assigning a physician to provide direct supervision during exercise sessions was not cost effective given the Medicare reimbursement rate for outpatient cardiac rehabilitation services. Other hospitals believed that a physician should be designated to provide direct physician supervision. According to these hospitals, the physicians providing direct supervision should be accessible at all times during the exercise programs and be immediately available in case of a medical emergency.

COMPLIANCE WITH "INCIDENT TO" REQUIREMENTS

Confusing "Incident to" Criteria

Most hospitals allowed the patient's referring physician to qualify for purposes of the "incident to" requirement. This practice appeared to be consistent with guidance in both the Intermediary and Hospital Manuals, which did not specify the physician (referring or hospital) whose

⁴Our review indicated that during CY 2001, only 6 of the 34 sampled hospitals experienced emergency situations that required the cardiac rehabilitation medical director and/or emergency code teams to respond during cardiac rehabilitation exercise sessions.

⁵For sampled hospitals, the Medicare amount actually paid to hospitals for one beneficiary's outpatient cardiac rehabilitation session ranged from \$12.64 to \$19.23 (excluding Maryland hospitals). Since 1977, Maryland's hospitals have operated under a waiver from Medicare's reimbursement methodology for hospital services. Under the waiver, Medicare reimburses Maryland hospitals on the basis of rates approved by the State's Health Services Cost Review Commission. Consequently, sampled Maryland hospitals received Medicare reimbursement ranging from \$42.92 to \$67.29 for one beneficiary's outpatient cardiac rehabilitation session.

professional services the cardiac rehabilitation must be "incident to." However, a smaller group of hospitals required that the cardiac rehabilitation be "incident to" the professional services of a hospital physician, rather than the referring physician. This approach receives support from the Coverage Issues Manual's definition, for purposes of cardiac rehabilitation, of a "hospital outpatient department or physician-directed clinic," which stated that "Each patient is under the care of a hospital or clinic physician" (Coverage Issues Manual, section 35-25).

We conferred with several CMS officials about the wording in these manuals. In their opinion, for outpatient cardiac rehabilitation services to be reimbursed "incident to" a physician's professional services, the physician must be a hospital physician who personally renders professional services to the patient on a periodic basis and is responsible for the patient's treatment and plan of care. A hospital physician means that the physician is an employee of or under contract with the hospital. In the opinion of these CMS officials, outpatient cardiac rehabilitation services may not be considered "incident to" the services of a patient's referring physician.

"Incident to" Services at the Hospitals Reviewed

Of the 34 hospitals reviewed, 32 believed that they met "incident to" requirements by providing outpatient cardiac rehabilitation services "incident to" the professional services of the beneficiaries' referring physicians. Generally, these hospitals conducted their outpatient cardiac rehabilitation programs as follows:

- On a day-to-day basis, nonphysician staff (registered nurses, exercise therapists, etc.) conducted outpatient cardiac rehabilitation programs "incident to" referring physicians' services.
- These staff conducted new patients' initial evaluations and orientation sessions, prepared exercise plans based on their evaluations, and conducted ongoing assessments at subsequent visits throughout the beneficiaries' outpatient cardiac rehabilitation.
- In some cases, outpatient cardiac rehabilitation medical directors signed the exercise plans but did not assess the beneficiaries.
- Normally, nonphysician cardiac rehabilitation staff contacted physicians (the outpatient cardiac rehabilitation medical directors and/or referring physicians) only when they identified new symptoms during the ongoing assessments.
- In some cases, nonphysician staff contacted the referring physicians (nonhospital physicians) to report these new symptoms and notified the medical directors only if the referring physicians could not be contacted.
- Nonphysician cardiac rehabilitation staff normally provided each referring physician with interim status reports assessing the beneficiaries' progress.

At the remaining two hospitals reviewed, the beneficiaries were under the care of a hospital physician who personally saw them sufficiently often to assess their treatment and progress and, when necessary, to change the treatment program. Generally, these hospitals conducted their outpatient cardiac rehabilitation programs as follows:

- On a day-to-day basis, nonphysician staff (registered nurses, exercise therapists, etc.) conducted outpatient cardiac rehabilitation programs "incident to" hospital physicians' services.
- During the outpatient cardiac rehabilitation programs, hospital physicians conducted ongoing assessments of each beneficiary's progress.
- Hospital physicians documented their services through written, signed, and dated notes in each beneficiary's outpatient cardiac rehabilitation medical record.

Hospitals' Views on "Incident to" Services

Most hospitals believed that the "incident to" criteria set forth in the Coverage Issues Manual appeared to conflict with those set forth in the Hospital and Intermediary Manuals. At most of the hospitals, officials believed that the beneficiaries' referring physicians should be the most actively involved physicians in cardiac rehabilitation and considered the "incident to" physicians. The officials did not believe that another hospital physician, including the medical director, should be involved with the beneficiaries' care or assessment of their progress. Some hospitals were reluctant to require their outpatient cardiac rehabilitation medical directors or other hospital physicians to conduct assessments or be actively involved in the beneficiaries' cardiac rehabilitation. In addition, medical directors and outpatient cardiac rehabilitation staff believed that referring physicians would take exception to having the medical director or another hospital physician treat or assess their patients and might stop referring patients to the outpatient cardiac rehabilitation program.

Other hospitals believed that the physician whom the outpatient cardiac rehabilitation services were "incident to" should be a hospital physician. These officials believed that the beneficiaries should be under the care of a hospital physician who personally saw them and assessed their treatment and progress.

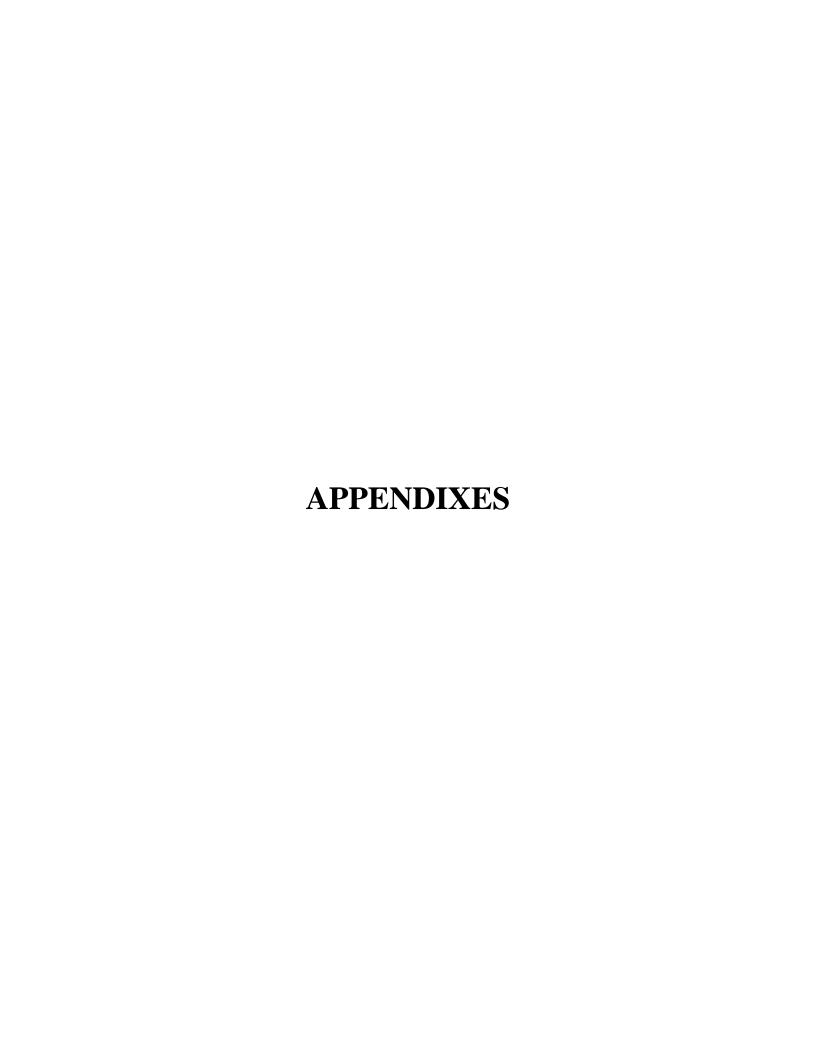
RECOMMENDATIONS

We recommend 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" and
- direct fiscal intermediaries to educate hospitals on the clarified national Medicare coverage policy for outpatient cardiac rehabilitation services.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its June 21, 2005, comments on our draft report, CMS agreed to develop and publish provider education materials to clarify the direct physician supervision and "incident to" provisions of the cardiac rehabilitation benefit. Appendix C presents those comments. CMS also offered several technical comments, which we have incorporated in this final report where applicable.



SAMPLING METHODOLOGY

To review hospital outpatient cardiac rehabilitation services nationwide, we selected a statistical sample of 16 hospitals in 10 States and a nonstatistical sample of 18 hospitals in 11 States.

STATISTICAL SAMPLE

The audit population included all Medicare beneficiaries with paid claims for hospital outpatient cardiac rehabilitation services with dates of service during calendar year (CY) 2001. Medicare reimbursed 2,910 hospitals approximately \$44 million for outpatient cardiac rehabilitation services provided to 140,776 beneficiaries.

From the audit population, we identified the 10 States that received the highest Medicare reimbursement for hospital outpatient cardiac rehabilitation services during 2001. The 10 States, in descending order, were California, Florida, Illinois, Texas, Ohio, Maryland, Michigan, Wisconsin, New York, and Pennsylvania. In these States, 1,194 hospitals received Medicare reimbursement totaling approximately \$21.5 million for outpatient cardiac rehabilitation services (49 percent of the nationwide total).

From these States, we included in the sampling frame only those hospitals that received more than \$10,000 each in Medicare reimbursement for outpatient cardiac rehabilitation services. Using this \$10,000 threshold, the sampling frame included all beneficiaries who received outpatient cardiac rehabilitation services from 736 hospitals in the 10 States. The 736 hospitals provided the services to 55,423 beneficiaries and received Medicare reimbursement totaling approximately \$19.1 million for these services (44 percent of the nationwide total).

Using the sampling frame, we selected a stratified multistage random sample. The sampling frame for the first stage consisted of hospitals from the top 10 States that received more than \$10,000 each in Medicare reimbursement for hospital outpatient cardiac rehabilitation services during CY 2001. We divided hospitals from the top 10 States into 2 strata (based on total Medicare payments for hospital outpatient cardiac rehabilitation services). The first stratum contained all hospitals that received more than \$70,000 each in Medicare reimbursement for hospital outpatient cardiac rehabilitation services. This stratum included 25 hospitals that received \$2.72 million in Medicare reimbursement for outpatient cardiac rehabilitation services for 4,797 beneficiaries. The second stratum included 711 hospitals that received \$16.43 million in Medicare reimbursement (those receiving more than \$10,000 but less than \$70,000 for outpatient cardiac rehabilitation services). We statistically selected 8 hospitals from each stratum (16 total) using random numbers.

The sampling frame for the second stage consisted of all beneficiaries from each of the 16 hospitals selected in the first stage. For each of the 16 hospitals, we randomly selected 30 beneficiaries for whom we reviewed all outpatient cardiac rehabilitation services and documentation to support those services. Thus, the total sample size consisted of 30 beneficiaries from each of the 16 randomly selected hospitals for a total of 480 beneficiaries.

NONSTATISTICAL SAMPLE

We selected 18 hospitals in 11 States not included in the statistical sample. We nonstatistically selected these hospitals based on characteristics such as geographical location (urban or rural), size (number of beds), status (for-profit or not-for-profit), and ownership (private or government). Once the hospitals were identified, we selected a sample of 370 beneficiaries.

SAMPLED HOSPITALS AND OFFICE OF INSPECTOR GENERAL REPORT NUMBERS

Report		
Number	Hospital	City, State
A-01-03-00506	Manchester Memorial Hospital	Manchester, CT
A-01-03-00507	William W. Backus Hospital	Norwich, CT
A-01-03-00514	Berkshire Medical Center	Pittsfield, MA
A-01-03-00516	Cooley Dickinson Hospital	Northhampton, MA
A-02-03-01013	Orange Regional Medical Center–Horton Campus	Middletown, NY
A-02-03-01016	Robert Wood Johnson University Hospital Hamilton	Hamilton, NJ
A-02-03-01022	Rahway Memorial Hospital	Rahway, NJ
A-02-03-01026	Meadowlands Hospital Medical Center	Secaucus, NJ
A-03-03-00004	Shady Grove Adventist Hospital	Gaithersburg, MD
A-03-03-00006	Washington Adventist Hospital	Takoma Park, MD
A-03-03-00007	Holy Cross Hospital	Silver Spring, MD
A-03-03-00009	Pottsville Hospital	Pottsville, PA
A-03-03-00011	Anne Arundel Hospital	Annapolis, MD
A-04-03-01002	Memorial Hospital Jacksonville	Jacksonville, FL
A-04-03-01004	Health South Sea Pines Rehabilitation Hospital	Melbourne, FL
A-04-03-01005	Central Florida Regional Hospital	Sanford, FL
A-04-03-01006	Morton Plant Hospital	Clearwater, FL
A-05-02-00084	St. Luke's Medical Center	Milwaukee, WI
A-05-03-00056	Evanston Northwestern Healthcare	Evanston, IL
A-05-03-00070	St. Charles Mercy Hospital	Oregon, OH
A-05-03-00084	Northern Michigan Hospital	Petoskey, MI
A-05-03-00097	Northfield Hospital	Northfield, MN
A-06-03-00033	Good Shepherd Medical Center	Longview, TX
A-06-03-00039	Deaconess Hospital	Oklahoma City, OK
A-06-03-00041	Wilson N. Jones Medical Center	Sherman, TX
A-06-03-00053	Norman Regional Hospital	Norman, OK
A-07-03-00153	Cloud County Health Center	Concordia, KS
A-07-03-00156	Community Memorial Healthcare	Marysville, KS
A-07-03-00157	Butler County Health Care Center	David City, NE
A-07-03-00158	Spencer Municipal Hospital	Spencer, IA
A-09-03-00043	Redding Medical Center	Redding, CA
A-09-03-00045	Mountain View Hospital	Las Vegas, NV
A-09-03-00052	Tucson Medical Center	Tucson, AZ
A-10-03-00009	Salem Hospital	Salem, OR



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

(F)

Administrator
Washington, DC 20201

DATE:

JUN 2 1 2005

TO:

Daniel R. Levinson

Inspector General

FROM:

Mark B. McClellan, M.D. Ph.D.

Administrator

SUBJECT:

Office of the Inspector General's Draft Report: "Review of Medicare Outpatient

Cardiac Rehabilitation Provided by Hospitals" (A-05-03-00102)

Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report about the delivery of cardiac rehabilitation services in the hospital outpatient setting. This report was prepared at the request of the Centers for Medicare & Medicaid Services (CMS) to assist in determining whether hospitals complied with national Medicare outpatient cardiac rehabilitation coverage requirements for direct physician supervision and "incident to" services. We appreciate the OIG's thoughtful research on how cardiac rehabilitation services are being provided to Medicare beneficiaries in the outpatient setting and will use the findings from this study to inform our discussions as we move forward to address these issues.

Medicare covers outpatient cardiac rehabilitation under the "incident to" a physician's professional services benefit. To be eligible for payment, the services must be performed under direct physician supervision.

The CMS provides policy direction to the carriers and fiscal intermediaries (FIs) who process Medicare claims through a combination of manual instructions and guidance documents.

At the time of the OIG audits, Medicare policy for cardiac rehabilitation services was provided in three CMS manuals. The Hospital and Intermediary Manuals contained the instructions, policies, and procedures for implementing statutes and regulations. We are currently in the process of replacing our manuals with an Internet Only Manual. The Hospital and Intermediary Manuals will be combined into the Medicare Benefit Policy Manual, which is available on the CMS Web site at: www.cms.hhs.gov/manuals/, not only to the carriers and intermediaries, but also to providers and the general public.

The former Coverage Issues Manual, now the National Coverage Determinations Manual, contains national criteria for specific medical items, services, treatment procedures, and

Page 2 – Daniel R. Levinson

technologies that Medicare covers. In addition, the carriers and FIs may issue local policy guidance on specific topics. That guidance must be consistent with national policy. It is developed with input from medical professionals in accord with scientific evidence and clinical practice.

The OIG report finds that the guidance regarding what constitutes direct physician supervision and "incident to" a physician's services is unclear to providers and to the Medicare contractors and that CMS should revise the guidance set forth in its policy manuals to make it more consistent and easily understood. The OIG also recommended that CMS direct FIs to educate hospitals on the clarified national Medicare coverage policy for outpatient cardiac rehabilitation services.

We will include development and publication of provider education materials and Medlearn Matters articles in our activities to clarify aspects of the cardiac rehabilitation benefit as recommended by the OIG.