



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

July 16, 2003

Report Number: A-05-02-00084

Steve Francaviglia
Vice President, Cardiac Services
Saint Luke's Medical Center
2900 West Oklahoma Avenue
Milwaukee, Wisconsin 53201-2901

Dear Mr. Francaviglia:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) final report entitled, "Review of Outpatient Cardiac Rehabilitation Services – Saint Luke's Medical Center, Milwaukee, Wisconsin." A copy of this report will be forwarded to the action official noted below for review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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To facilitate identification, please refer to report number A-05-02-00084 in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Paul Swanson".

Paul Swanson
Regional Inspector General
for Audit Services

Enclosures – as stated

Page 2 – Mr. Steve Francaviglia

Direct Reply to HHS Action Official:

Ms. Jackie Gamer, Regional Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF OUTPATIENT CARDIAC
REHABILITATION SERVICES**

**SAINT LUKE'S MEDICAL CENTER
MILWAUKEE, WISCONSIN**



July 2003
A-05-02-00084

Office of Inspector General

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OAS FINDINGS AND OPINIONS

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 awarding agency will make final determination on these matters.



EXECUTIVE SUMMARY

BACKGROUND

This review is part of a nationwide analysis of Medicare reimbursement for outpatient cardiac rehabilitation services. The analysis was requested by the Administrator of the Centers for Medicare and Medicaid Services to determine the level of provider compliance with national Medicare outpatient cardiac rehabilitation policies.

OBJECTIVE

The overall objective of our review was to determine whether Medicare properly reimbursed Saint Luke's Medical Center (SLMC) for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- SLMC's policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, "incident to" services, and Medicare covered diagnoses.
- Payments to SLMC for outpatient cardiac rehabilitation services provided to Medicare beneficiaries during calendar year (CY) 2001 were for Medicare covered diagnoses, were supported by adequate documentation, and were otherwise allowable for reimbursement.
- Services related to outpatient cardiac rehabilitation services provided by SLMC were separately billed by and reimbursed to SLMC or any other Medicare provider.

RESULTS OF AUDIT

Even though physician supervision is assumed to be met in an outpatient hospital department, SLMC did not designate a physician to directly supervise the services provided by its cardiac rehabilitation program. In addition, contrary to current Medicare requirements, we could not identify the physician professional services to which the cardiac rehabilitation services were provided "incident to." In addition, from our specific claims review for a sample of 100 beneficiaries who received outpatient cardiac rehabilitation services during CY 2001, we determined that SLMC was paid for:

- Services with diagnoses establishing the patients' eligibility for cardiac rehabilitation which may not have been supported by medical records (22 beneficiaries);
- Multiple units of service for a single cardiac rehabilitation visit (72 beneficiaries);
- Inadequately documented outpatient cardiac rehabilitation services (6 beneficiaries); and
- Phase I inpatient cardiac rehabilitation services (2 beneficiaries).¹

From a projection of our statistical sample, we estimate that SLMC claimed and received Medicare reimbursement for outpatient cardiac rehabilitation services, amounting to

¹ The total number of errors is greater than the total sampled as some beneficiaries had more than one type of error.

approximately \$47,247, which did not meet Medicare coverage requirements, which may not have been supported by medical record documentation, or which were otherwise unallowable.

We attribute these questionable services to weaknesses in SLMC's internal controls and oversight procedures. Existing controls did not ensure that beneficiaries had Medicare covered diagnoses supported by the referring physician's medical records; that supporting documentation for Medicare billings and reimbursements for outpatient cardiac rehabilitation services was maintained; and that only Phase II (outpatient) cardiac rehabilitation services were billed to Medicare for outpatient services. In addition, SLMC staff believed that two units of service could be billed to Medicare when an initial new patient evaluation was performed on the same day as a regular cardiac rehabilitation exercise session.

Our determinations regarding Medicare covered diagnoses were based solely on our review of the medical record documentation. The medical records have not yet been reviewed by fiscal intermediary (FI) staff. We believe that SLMC's FI, United Government Services (UGS), should make a determination as to the allowability of the Medicare claims and appropriate recovery action.

RECOMMENDATIONS

We recommend that SLMC:

- Work with UGS to ensure that SLMC's outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare coverage requirements for direct physician supervision and for services provided "incident to" a physician's professional service.
- Work with UGS to establish the amount of repayment liability, estimated to be as much as \$47,247, for services provided to beneficiaries where medical documentation may not have supported Medicare covered diagnoses and for services not otherwise allowable.
- Bill only one unit of service per beneficiary for each cardiac rehabilitation session.
- Implement controls to ensure that medical record documentation is maintained to support Medicare outpatient cardiac rehabilitation services.
- Implement controls to ensure only Phase II (outpatient) cardiac rehabilitation services are billed to Medicare.

AUDITEE'S COMMENTS

SLMC stated that it strongly believes that it is providing the outpatient cardiac rehabilitation area with proper physician supervision and that it has ensured that physicians are immediately available to respond to any emergency. SLMC further stressed that CMS' manuals do not include a requirement for designating a physician to provide direct supervision. Regarding the "incident to" requirements, SLMC stated that it considered the instructions in CMS' manuals confusing, if not contradictory. It considered our conclusion that SLMC failed to meet the

“incident to” requirement to be questionable. Concerning the sample results, SLMC indicated that it will make any changes necessary to comply with Medicare requirements. SLMC’s comments are summarized at the end of the RESULTS OF AUDIT section of this report and presented in their entirety as APPENDIX C.

OFFICE OF INSPECTOR GENERAL’S RESPONSE

We acknowledge that CMS’ Intermediary Manual states that the physician supervision requirement is generally assumed to be met where the services are performed on hospital premises. However, CMS’ Coverage Issues Manual requires that the services of nonphysician personnel be furnished under the direct supervision of a physician. We could not conclude that SLMC met the requirements. While we would also acknowledge that CMS’ instructions regarding “incident to” services may be confusing, we found no evidence of any hospital physician treating or assessing the beneficiaries during the cardiac rehabilitation exercise programs, as required by the Intermediary Manual.

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INTRODUCTION

BACKGROUND

Medicare Coverage

The Medicare program, established by title XVIII of the Social Security Act (Act), provides health insurance to people aged 65 and over, the disabled, people with end stage renal disease, and certain others who elect to purchase Medicare coverage. The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS). CMS currently covers Phase II outpatient cardiac rehabilitation programs conducted in specialized, free-standing cardiac rehabilitation clinics and in outpatient hospital departments under the “incident to” benefit (section 1861(s)(2)(A) of the Act).

Medicare coverage policy for cardiac rehabilitation services is found in section 35-25 of the Medicare Coverage Issues Manual. Under Medicare, outpatient cardiac rehabilitation is considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physicians, and (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months, (2) have had coronary artery bypass graft surgery, and/or (3) have stable angina pectoris. Services provided in connection with the cardiac rehabilitation program may be considered reasonable and necessary for up to 36 sessions, usually 3 sessions per week in a single 12-week period. Each cardiac rehabilitation session is considered to be one unit of service.

Cardiac rehabilitation is provided by nonphysician personnel, who are trained in both basic and advanced life support techniques and exercise therapy for coronary disease, under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require a physician to be physically present in the exercise room itself. For outpatient cardiac rehabilitation provided in a hospital, the Medicare Intermediary Manual states, “The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.”

In order to be covered under the “incident to” benefit in an outpatient hospital department, services 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. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician. However, 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 program.

Cardiac Rehabilitation Programs

Cardiac rehabilitation consists of comprehensive programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. Cardiac rehabilitation programs are typically divided into three phases, as follows:

- Phase I. Phase I rehabilitation is initiated in the acute convalescent period following a cardiac event during the hospital phase of treatment. This phase of cardiac rehabilitation is considered part of the hospital stay and is covered as part of the Medicare diagnosis-related group allowance for the hospital stay.
- Phase II. Phase II begins with a physician's prescription (referral) after the acute convalescent period and after it has been determined that 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 a physician who is on-site. Phase II outpatient cardiac rehabilitation is covered by Medicare.
- Phase III. Phase III begins after completion of Phase II and involves a less intensively monitored aerobic exercise program. Phase III level programs are considered maintenance and are not covered by Medicare.

Medicare reimburses outpatient hospital departments for cardiac rehabilitation services under the outpatient prospective payment system. Cardiac rehabilitation services are paid by a Medicare fiscal intermediary (FI) based on an ambulatory payment classification. The FI for Saint Luke's Medical Center (SLMC) is United Government Services (UGS). For calendar year (CY) 2001, SLMC provided outpatient cardiac rehabilitation services to 510 Medicare beneficiaries and received \$177,833 in Medicare reimbursements for these services.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our review is part of a nationwide analysis of Medicare reimbursement for outpatient cardiac rehabilitation services. The analysis was requested by the CMS Administrator to determine the level of provider compliance with Medicare coverage requirements for outpatient cardiac rehabilitation services. As such, the overall objective of our review was to determine whether Medicare properly reimbursed SLMC for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- SLMC's policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, "incident to" services, and Medicare covered diagnoses.
- Payments to SLMC for outpatient cardiac rehabilitation services provided to Medicare beneficiaries during CY 2001 were for Medicare covered diagnoses, were supported by adequate documentation, and were otherwise allowable for reimbursement.

- Services related to outpatient cardiac rehabilitation services² provided by SLMC were separately billed by and reimbursed to SLMC or any other Medicare provider.

Scope

To accomplish these objectives, we reviewed SLMC's current policies and procedures and interviewed staff to gain an understanding of SLMC's management of its outpatient cardiac rehabilitation program and the billing procedures for cardiac rehabilitation services. In addition, we reviewed SLMC's cardiac rehabilitation services documentation, inpatient medical records, referring physician referrals and supporting medical records, and Medicare reimbursement data for a statistical sample of beneficiaries who received outpatient cardiac rehabilitation services from SLMC during CY 2001. Specifically, we reviewed SLMC's outpatient cardiac rehabilitation procedures for and controls over physician supervision, cardiac rehabilitation staffing, maintenance and availability of advanced cardiac life support equipment, and documentation of services provided and billed to Medicare.

We statistically selected 100 of 510 Medicare beneficiaries who received outpatient cardiac rehabilitation services from SLMC during CY 2001. We reviewed all Medicare paid claims for cardiac rehabilitation services provided to these 100 beneficiaries during CY 2001.

Our audit was conducted in accordance with generally accepted government auditing standards.

Methodology

We compared SLMC's current policies and procedures for outpatient cardiac rehabilitation to national Medicare coverage requirements and identified any differences. We documented how SLMC's staff provided direct physician supervision for cardiac rehabilitation services and verified that SLMC's cardiac rehabilitation program personnel were qualified in accordance with Medicare requirements. We also verified the availability of advanced cardiac life support equipment in the cardiac rehabilitation exercise area.

For each sampled beneficiary, we obtained the CY 2001 Medicare outpatient cardiac rehabilitation paid claims and lines of service and compared this data to SLMC's outpatient cardiac rehabilitation service documentation. We reviewed the medical records maintained by the cardiac rehabilitation program to determine whether services were provided "incident to" a physician's professional service. We also verified the accuracy of the diagnoses identified on the Medicare claims to each beneficiary's inpatient medical record, the referring physician's medical record and referral, and SLMC's outpatient cardiac rehabilitation medical record. The medical records have not yet been reviewed by FI staff.

² Examples of services considered related to outpatient cardiac rehabilitation included psychotherapy and psychological testing, physical and occupational therapy, and patient education services as a result of a cardiac related diagnosis. These services are generally considered to be included in the outpatient cardiac rehabilitation program and, generally, are not separately reimbursed by Medicare.

In addition, we verified that Medicare did not reimburse SLMC beyond the maximum number of services allowed. We obtained Medicare payment history data for our statistical sample of beneficiaries, identified any claims related to the outpatient cardiac rehabilitation services provided by SLMC, and ensured that services were not billed separately to Medicare.

In accordance with the intent of CMS' request for a nationwide analysis, we determined the extent to which providers were currently complying with existing Medicare coverage requirements. We performed fieldwork at SLMC, Milwaukee, Wisconsin, and at its rehabilitation centers at St. Luke's South Shore, Kenosha, and Waukesha, Wisconsin, during the period August 2002 through March 2003.³

RESULTS OF AUDIT

Even though physician supervision is assumed to be met in an outpatient hospital department, SLMC did not designate a physician to directly supervise the services provided by its cardiac rehabilitation program. In addition, contrary to current Medicare requirements, we could not identify the physician professional services to which the cardiac rehabilitation services were provided "incident to." In addition, from our specific claims review for a sample of 100 beneficiaries receiving outpatient cardiac rehabilitation services during CY 2001, we determined that SLMC was paid for:

- Services with diagnoses establishing the patients' eligibility for cardiac rehabilitation which may not have been supported by medical records (22 beneficiaries);
- Multiple units of service for a single cardiac rehabilitation visit (72 beneficiaries);
- Inadequately documented outpatient cardiac rehabilitation services (6 beneficiaries); and
- Phase I inpatient cardiac rehabilitation services (2 beneficiaries).

PHYSICIAN INVOLVEMENT IN OUTPATIENT CARDIAC REHABILITATION

Direct Physician Supervision

Medicare requirements for outpatient cardiac rehabilitation state that direct supervision means that a physician must be in the exercise area and immediately available and accessible for an emergency at all times the exercise program is conducted. The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.

At SLMC, no physician was actually designated to provide direct physician supervision to the cardiac rehabilitation exercise area, and no documentation existed in the cardiac rehabilitation program's medical records to support physician supervision during exercise sessions. On a day-to-day basis, the cardiac rehabilitation program was staffed and run by registered nurses, registered dietitians, exercise physiologists, and other staff. A clinical coordinator, who was an

³ Outpatient cardiac rehabilitation services provided at the South Shore, Kenosha, and Waukesha sites were billed under the SLMC Medicare provider number.

exercise physiologist or registered dietician, was responsible for the day-to-day supervision of the cardiac rehabilitation area.

SLMC's outpatient cardiac rehabilitation procedures stated that among other duties, the medical director was responsible for discussing and resolving patient care, treatment, and service management issues with respective medical staff. There did not appear to be a requirement that the medical director provide direct physician supervision or be in the exercise area and immediately available for an emergency at all times the exercise program is being conducted.

Instead, SLMC utilized a "code 4" emergency response team of physicians to "supervise" outpatient cardiac rehabilitation services. The "code 4" team was responsible for responding to any medical emergency that occurred throughout the hospital, including the cardiac rehabilitation exercise area. Cardiac rehabilitation staff believed that other physicians, located nearby the cardiac rehabilitation exercise area, could respond to any medical emergency and, thus, were also available to "supervise" cardiac rehabilitation services.

Although Medicare policy provides that physician supervision is assumed to be met in an outpatient hospital department, we believe that SLMC should work with UGS to ensure that the reliance placed on the "code 4" emergency response team to provide direct supervision specifically conforms with the requirements.

"Incident To" Physician Services

Medicare covers Phase II cardiac rehabilitation under the "incident to" benefit. In an outpatient hospital department, the "incident to" benefit does not require that a physician perform a personal professional service on each occasion of service by a nonphysician. However, during any course of treatment 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 program.

At SLMC, we could not identify the physician professional services to which the cardiac rehabilitation services were provided "incident to." According to SLMC's policies and procedures, each patient referred to SLMC's outpatient cardiac rehabilitation program attends a personal intake session to determine an individualized plan of care for exercise training and cardiac risk factor reduction education and counseling. This session includes, among other services, a focused physical assessment of the patient's condition and symptoms since discharge from the hospital, and a functional capacity assessment to help determine an individualized exercise prescription.

Based on the assessment, an individualized plan of care, which addresses the exercise plan, cardiac risk factor educational/counseling plan, psychosocial plan, discharge plan, and outcome measurement plan is developed. Patients generally attend the phase II cardiac rehabilitation program 3 days per week. An ongoing assessment is done by the cardiac rehabilitation clinician prior to each exercise session. This assessment includes a determination based on new onset of signs/symptoms, blood pressure, and heart rate and rhythm.

The intake sessions, as well as the ongoing assessments, were conducted by the registered nurses who staffed the cardiac rehabilitation unit. According to SLMC's policies and procedures, it appears that physicians, usually the referring physicians, were contacted by the cardiac rehabilitation staff only when a determination of the new onset of signs/symptoms was made during the ongoing assessments.

From our review of SLMC's outpatient cardiac rehabilitation medical records, we could not locate evidence of any physician professional services rendered to the patients participating in the program. Although required under the "incident to" benefit, there was no documentation to support that a physician personally saw the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment program. Accordingly, we believe that SLMC's cardiac rehabilitation program did not meet the requirements to provide an "incident to" service.

MEDICARE COVERED DIAGNOSES AND DOCUMENTATION

Medicare coverage considers cardiac rehabilitation services reasonable and necessary only for patients with a clear medical need, who are referred by their attending physician, and (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months, (2) have had coronary artery bypass graft surgery, and/or (3) have stable angina pectoris. Medicare only reimburses providers for Phase II outpatient cardiac rehabilitation services and allows one unit of service to be billed per cardiac rehabilitation session. Documentation for these services must be maintained in the patients' medical records.

Our statistical sample of 100 of 510 SLMC Medicare beneficiaries, with claims for outpatient cardiac rehabilitation services amounting to \$29,264 during CY 2001, disclosed that Medicare claims for 81 beneficiaries contained 102 errors. Some beneficiaries had more than one type of error.

Medicare Covered Diagnoses

Medicare paid SLMC for outpatient cardiac rehabilitation services with diagnoses establishing eligibility for cardiac rehabilitation which did not appear to be supported by the notes in the beneficiaries' medical records. As a result, we believe that Medicare may have inappropriately paid \$7,229 to SLMC for the cardiac rehabilitation services provided to these 22 beneficiaries.

Of the 100 sampled beneficiaries, eligibility for 16 beneficiaries was based on the diagnosis of acute myocardial infarction, eligibility for 56 beneficiaries was based on the diagnosis of coronary artery bypass graft surgery, and eligibility for 28 beneficiaries was based on the diagnosis of stable angina. For the 72 beneficiaries with diagnoses of acute myocardial infarction or coronary artery bypass graft surgery, medical records contained documentation to support the diagnoses. However, the medical records for 22 of the 28 beneficiaries with diagnoses of stable angina did not appear to indicate that the beneficiaries continued to experience stable angina post-procedure.

These 22 beneficiaries had initially been admitted to SLMC or another hospital with a diagnosis of either unstable⁴ or stable angina.⁵ During the inpatient stays, cardiac procedures such as stenting, angioplasty, or valve replacements were performed. Upon their discharge from the hospital, these beneficiaries were referred to the outpatient cardiac rehabilitation program by their physicians.

SLMC's cardiac rehabilitation program conducted an intake assessment with each beneficiary and either identified the beneficiary's diagnosis or relied on a preprinted physician referral as documentation of a Medicare covered diagnosis. SLMC's cardiac rehabilitation program staff did not maintain additional documentation indicating whether the angina symptoms continued to exist post-procedure, or to validate the diagnosis of stable angina.

To validate the diagnosis of stable angina, we obtained and reviewed the inpatient medical records as well as the medical records of the physicians who referred these 22 beneficiaries for cardiac rehabilitation. The medical records covered the dates of the beneficiaries' inpatient stays through their completion of Phase II of the cardiac rehabilitation program. Our review of these medical records did not appear to indicate that the beneficiaries continued to experience angina symptoms post-procedure and through their completion of Phase II of the cardiac rehabilitation program.

These questionable services are attributed to SLMC not ensuring that referrals for beneficiaries with Medicare covered diagnoses were supported by medical documentation prior to providing cardiac rehabilitation services and billing Medicare. From January to September 2001, SLMC's procedures did not require an individual referral identifying the Medicare covered diagnosis for each beneficiary referred to cardiac rehabilitation. Instead, a "standing order" signed by the referring physician was maintained by the cardiac rehabilitation center. The "standing order" authorized the cardiac rehabilitation staff to evaluate and register each of the physician's patients in the outpatient cardiac rehabilitation program, after inpatient discharge, using the inpatient diagnosis. Since October 2001, referring physicians provided a "check box" referral for each beneficiary that indicated the Medicare covered diagnosis.

Multiple Units Billed

Because SLMC's staff believed two units of service could be billed to Medicare, when an initial new patient evaluation was performed on the same day as a regular cardiac rehabilitation exercise session, SLMC billed Medicare and was paid for 2 units of services on the beneficiaries'

⁴ Unstable angina is not a Medicare covered diagnosis for outpatient cardiac rehabilitation.

⁵ Stable angina was defined as a pain or discomfort in the chest or adjacent areas caused by insufficient blood flow to the heart muscle. This chest pain is relieved by rest or medication within a short period of time (usually 15 minutes). Chest pain of a longer duration or pain appearing with a lower level of effort than before, even at rest, should be considered unstable angina. Symptoms of stable angina included a feeling of tightness, heavy pressure, or squeezing or crushing chest pain that is under the breastbone or slightly to the left; is not clearly localized; may radiate to the shoulder, arm, jaw, neck, back, or other areas; may feel similar to indigestion; is precipitated by activity, stress, or exertion; lasts 1 to 15 minutes; and is usually relieved by rest and/or nitroglycerin. This information was obtained from the MEDLINEplus Medical Encyclopedia, identified at the U.S. National Library and National Institute for Health website (<http://www.nlm.nih.gov/medlineplus/ency/article/000198.htm>).

first session at the outpatient cardiac rehabilitation center for 72 of the 100 sampled beneficiaries. Medicare reimbursed an additional \$1,188 to SLMC for these 72 beneficiaries with multiple unit billings.

Although Medicare policy counts a visit to the cardiac rehabilitation center as one unit of service, SLMC believed that one unit of service could be billed for providing the initial evaluation to set exercise parameters and establish protocols and a second unit of service could be billed for providing the regular rehabilitation exercise session. These services occurred on the same date within minutes of each other. At SLMC, cardiac rehabilitation clinician personnel, non-physician staff, such as a registered nurse or exercise therapist conducted the initial new patient interviews and evaluations. According to CMS policy, the initial new patient evaluation services are included with the regular cardiac rehabilitation exercise session, which are both provided during the same visit and are considered one session and one unit of service. Furthermore, Medicare policy only allows an evaluation service to be reimbursed when it is rendered by a physician.

Undocumented Services

SLMC's internal controls did not ensure supporting documentation for Medicare billings and reimbursements for outpatient cardiac rehabilitation services was maintained. As a result, SLMC was unable to locate supporting cardiac rehabilitation documentation for services provided to four beneficiaries or for specific dates of services for cardiac rehabilitation for two additional beneficiaries. Medicare made inappropriate reimbursements of \$818 to SLMC for the unsupported claims for these six beneficiaries.

Improperly Billed Phase I Services

Since SLMC's internal controls did not also ensure that only Phase II (outpatient) cardiac rehabilitation services were billed to Medicare for outpatient services, SLMC improperly billed Phase I, inpatient cardiac rehabilitation services, as Phase II, outpatient cardiac rehabilitation services. Medicare made reimbursements of \$29 to SLMC for Phase I cardiac rehabilitation services for these two beneficiaries.

Overall Projection

By projecting the results of our sample to the universe, we estimate that SLMC claimed and received \$47,247 in Medicare reimbursement for outpatient cardiac rehabilitation services that may not have met Medicare coverage requirements or were otherwise unallowable for payment. (See APPENDICES A and B for specific sampling and universe data, methodology, errors, and projected dollar error results.)

Our audit conclusions, particularly those regarding Medicare covered diagnoses, were not validated by medical personnel. Therefore, we believe that UGS should determine the allowability of the cardiac rehabilitation services and the proper recovery action to be taken.

RECOMMENDATIONS

We recommend that SLMC:

- Work with UGS to ensure that SLMC’s outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare coverage requirements for direct physician supervision and for services provided “incident to” a physician’s professional service.
- Work with UGS to establish the amount of repayment liability, estimated to be as much as \$47,247, for services provided to beneficiaries where medical documentation may not have supported Medicare covered diagnoses and for services not otherwise allowable.
- Bill only one unit of service per beneficiary for each cardiac rehabilitation session.
- Implement controls to ensure that medical record documentation is maintained to support Medicare outpatient cardiac rehabilitation services.
- Implement controls to ensure only Phase II (outpatient) cardiac rehabilitation services are billed to Medicare.

AUDITEE’S COMMENTS

SLMC stated that it strongly believes that it is providing the outpatient cardiac rehabilitation area with proper physician supervision and that it has ensured that physicians are immediately available to respond to any cardiac rehabilitation emergency. SLMC indicated that it provides this supervision through the physicians located in office suites near the exercise area, as well as the hospital’s emergency response team of physicians. SLMC further stressed that CMS’ manuals do not include a requirement for designating a physician to provide direct supervision.

With respect to the requirements for “incident to” services, SLMC stated that the instructions in CMS’ manuals are confusing, if not contradictory. SLMC considered our conclusion that SLMC failed to meet the “incident to” requirement to be questionable. Concerning the sample results, SLMC indicated that it will make any changes necessary to comply with Medicare requirements. SLMC’s comments are presented in their entirety as APPENDIX C.

OFFICE OF INSPECTOR GENERAL’S RESPONSE

We acknowledge that CMS’ Intermediary Manual (section 3112.4, entitled Outpatient Therapeutic Services) states that the physician supervision requirement is generally assumed to be met where the services are performed on hospital premises. However, CMS’ Coverage Issues Manual (section 35-25 entitled Cardiac Rehabilitation Programs) requires that the services of nonphysician personnel be furnished under the direct supervision of a physician. Accordingly, we could not conclude that SLMC’s reliance on nearby physicians and/or emergency physician teams met the “direct” supervision requirement specific to cardiac rehabilitation programs.

We would also acknowledge that CMS' instructions regarding "incident to" services may be confusing. However, with respect to "incident to" services, section 35-25 of CMS' Coverage Issues Manual requires that each patient be under the care of a hospital physician and section 3112.4 of the Intermediary Manual requires that 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, the patient's progress and, where necessary, to change the treatment regimen. Since we found no evidence of any hospital physician treating or assessing the beneficiaries, or providing direct supervision over the services, during the beneficiaries' participation in the cardiac rehabilitation exercise programs, we do not believe that SLMC complied with the "incident to" requirements.

APPENDICES

APPENDIX A

STATISTICAL SAMPLE SUMMARY OF ERRORS

The following table summarizes the errors identified during testing of our statistically selected sample of 100 Medicare beneficiaries who received outpatient cardiac rehabilitation services from SLMC during CY 2001. The total number of errors per diagnosis is greater than the total sample, as some beneficiaries had more than one type of error.

Table 1. Summary of Errors by Beneficiary Diagnosis and Type of Error

Number of Sampled Beneficiaries with Diagnosis	Number of Sampled Beneficiaries with Errors	Medicare Covered Diagnosis	Beneficiaries Not Having Medical Documentation Supporting the Medicare Covered Diagnosis	Multiple Units Billed per Session	No Cardiac Rehabilitation Supporting Documentation	Billing Error-Phase I	Total Errors per Diagnosis
16	13	Myocardial Infarction	0	13	0	0	13
56	42	Coronary Artery Bypass Graft	0	40	3	0	43
28	26	Stable Angina Pectoris	22	19	3	2	46
100	81	Total	22	72	6	2	102

SAMPLING AND UNIVERSE DATA AND METHODOLOGY

We statistically selected a random sample of 100 Medicare beneficiaries who received outpatient cardiac rehabilitation services from SLMC during CY 2001. For each beneficiary, we obtained all Medicare claims reimbursement data for outpatient cardiac rehabilitation services and compared this data to SLMC’s outpatient cardiac rehabilitation service documentation. In addition, we determined whether the diagnoses identified on the Medicare claims were supported by each beneficiary’s inpatient medical records, the referring physician’s medical records and referral, and SLMC’s outpatient cardiac rehabilitation service records.

The point estimate of the sample appraisal was \$47,247 with a precision of plus-or-minus \$12,748 at the 90 percent confidence level.

Table 1. Calendar Year 2001 Outpatient Cardiac Rehabilitation Service Universe and Sampling Data and Projected Error Value

Universe	Population Value	Sample Size	Sample Value	Sampled Beneficiaries with Errors	Sample Errors Value	Projected Error Value (Midpoint)
510	\$177,833	100	\$29,264	81	\$9,264	\$47,247

APPENDIX C

SLMC's WRITTEN COMMENTS TO DRAFT REPORT



June 27, 2003

BY FEDERAL EXPRESS

Mr. Paul Swanson
Regional Inspector General for Audit Services
Region V - Office of Inspector General
Department of Health and Human Services
Office of Audit Services
233 North Michigan Avenue
Chicago, IL 60601

Re: Audit Report No. A-05-02-00084

Dear Mr. Swanson:

This letter is written in response to your letter dated May 2, 2003, in which you requested our written comments to your office's draft report entitled, "Review of Outpatient Cardiac Rehabilitation Services at St. Luke's Medical Center, Milwaukee, Wisconsin." We appreciate the opportunity to comment on the findings contained in the draft report as well as the time extensions you granted to us for submitting our comments. Our comments will primarily focus on the draft report's discussion and findings related to physician supervision and the "incident to" requirements.

The section of the draft report entitled, "Physician Involvement in Outpatient Cardiac Rehabilitation" which commences on page 4 requires further clarification. The draft report states that it is a Medicare requirement for the coverage of outpatient cardiac rehabilitation for a physician to be in the exercise area and immediately available and accessible for an emergency at all times the exercise program is conducted. However, the draft report goes on to state that "the physician supervision requirement is generally assumed to be met where the services are performed on hospital premises." These two statements on their face appear to be contradictory.

The draft report's finding that St. Luke's Medical Center ("SLMC") is deficient in meeting the direct physician supervision requirement because it has no physician designated to provide direct supervision of the cardiac rehabilitation exercise area is confusing, especially in light of Medicare's policy that direct physician supervision is assumed to be met in an outpatient hospital department. We could find no requirement for a designated physician in any of the applicable CMS manuals. SLMC has ensured that physicians are immediately available to respond to any emergency in the cardiac rehabilitation area and that seems to satisfy all written requirements.

The SLMC outpatient cardiac rehabilitation exercise area is located within the hospital facility and there are physicians located in office suites near the exercise area who are immediately available and accessible to assist the program's staff in an emergency. In addition, SLMC also utilizes an emergency response team of physicians who will respond to any medical emergency that occurs throughout the hospital, including the cardiac rehabilitation area.

In addition, the program's medical director administratively oversees the staff and is responsible for the program's policies, procedures, and protocols. It is part of the program procedures to communicate changes in a patient's condition to the patient's attending physician.

SLMC strongly believes that it is providing the outpatient cardiac rehabilitation area with proper physician supervision. To resolve the issues raised by the draft report regarding the level of physician supervision required for outpatient cardiac rehabilitation programs, SLMC has initiated conversations with James Cope, M.D., the Medical Director for its fiscal intermediary, UGS.

Another section of the draft report that caused considerable confusion is the subsection entitled, "Incident To' Physician Services" on page 5. The draft report states that Medicare covers Phase II cardiac rehabilitation under the "incident to" benefit of Medicare. According to the draft report, the "incident to" benefit does not require that a physician perform a personal professional service on each occasion of service provided by a non-physician, but that 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 program. This statement is consistent with Section 3112.4 of CMS's Intermediary Manual but is inconsistent with Section 230.4 of CMS's Hospital Manual. Both of these sections are entitled, "Outpatient Therapeutic Services."

The requirements for billing outpatient therapeutic services contained in Section 230.4 of the Hospital Manual are the following:

Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physician in the treatment of patients. Such services include clinic services and emergency room 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, or if outside the hospital, under the direct personal supervision of the physician who is treating the patient. For example, if a hospital respiratory therapist goes to a patient's home to give treatment and no physician accompanies him, therapist services are not covered.

There is no requirement that the physician who orders the hospital services be directly connected with the department which provides the services.

Accordingly, the instructions provided by CMS to hospitals in the Hospital Manual set forth standards that are different than the instructions provided in the Intermediary Manual. Moreover, Section 2050 of the Carrier's Manual in its discussion of "incident to" services adds to the confusion because while its discussion of the requirements for physician offices "incident to" services appears to follow the requirement in the Intermediary Manual, a statement is then made that such requirements are not applicable to hospital services. It is our understanding that Section 1861(s) of the Social Security Act has two subsections that deal with "incident to" services. Subsection (2)(A) provides coverage for services and supplies furnished incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills. Subsection (2)(B) provides coverage for hospital services incident to physician services rendered to outpatients and partial hospitalization services incident to such services. Section 2050 of the Carrier's Manual, CMS specifically states the following:

Certain hospital services may also be covered as incident to a physician services under Section 1861(s)(2)(B) of the Act. Payment for these services is made under Part B to a hospital by the hospital's intermediary and are not subject to the same requirement as services covered under Section 1861(s)(2)(A).

In light of the arguably confusing, if not contradictory, instructions contained in the CMS's manuals, the draft report's conclusion that SLMC failed to meet the "incident to" requirement is questionable. SLMC provided outpatient cardiac rehabilitation services in accordance with Section 230.4 of the Hospital Manual. Specifically, all cardiac rehabilitation services were provided on a physician order by hospital personnel under hospital medical staff supervision in the hospital.

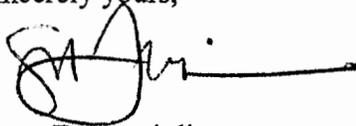
Lastly, we would like to address the unfavorable perception of our program and our program staff implied by the draft report. The program staff, including the medical director, registered nurses, registered dietitians, and exercise physiologists are all appropriately licensed or certified. In addition, each registered nurse is certified in advanced cardiac life support. The language of the report on the top of page 5 implies that our outpatient cardiac rehabilitation program is not appropriately staffed or supervised. With respect to the management/supervision of cardiac rehabilitation services, SLMC's has a leadership team that manages the cardiac rehabilitation program. Our leadership team includes a medical director, a regional manager, a regional supervisor, and two clinical coordinators. Each position includes a job description delineating the job responsibilities, qualifications and competencies needed to perform the respective jobs. The draft report states, "A Clinical coordinator, who was an exercise physiologist or registered dietitian, was responsible for the day-to-day operation of the cardiac rehabilitation area." In actuality, the leadership team is responsible for patient care, managing

the budget, ensuring appropriate staffing levels, coordinating staff education, consulting with medical staff regarding policies and procedures, and coordinating performance improvement activities. The leadership team includes several disciplines that are typically involved in cardiac rehabilitation programs. Job responsibilities are assigned according to the specialization and credentials of the staff members. The staffing and competencies of the staff of our cardiac rehabilitation program are in compliance with the competency guidelines for program personnel published by the American Association of Cardiovascular and Pulmonary Rehabilitation.

We are reviewing and addressing all of the categories of errors contained in the draft report. Even though we question many of the findings contained in the draft report, we have taken the findings very seriously and are currently evaluating our program and will make any changes necessary in order to comply with Medicare's requirements. Because of the confusion concerning physician supervision and "incident to" requirements, we believe that it is important for us to first obtain clarification of these requirements prior to implementing any corrective actions. As you recommended, we will work closely with the medical director at UGS in making the appropriate changes.

We appreciate the opportunity to respond in writing to the findings of the draft report. If you have any questions, please do not hesitate to contact the undersigned

Sincerely yours,

A handwritten signature in black ink, appearing to read "S. Francaviglia", with a long horizontal line extending to the right.

Steve Francaviglia
Vice President, Cardiac Services

bcc: Mark P. Ambrosius
Mary Robinson
Gail Buenger
C. Frederick Geilfuss, II
Maria E. Gonzalez Knavel