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

REGION V
OFFICE OF
INSPECTOR GENERAL

October 20, 2003

Report Number: A-05-03-00070

Mr. Buzz Hermann
Metro Administrative Director
Cardiopulmonary Services
St. Charles Mercy Hospital
2600 Navarre Avenue
Oregon, Ohio 43616

Dear Mr. Hermann:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General final audit report entitled, "Review of Outpatient Cardiac Rehabilitation Services – St. Charles Mercy Hospital, Oregon, Ohio." 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-05-03-00070 in all correspondence relating to this report.

Sincerely,

Paul Swanson

Paul Swanson
Regional Inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:

Ms. Jackie Gamer, Regional Administrator
Centers for Medicare & 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

ST. CHARLES MERCY HOSPITAL OREGON, OHIO

October 2003

A-05-03-00070

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 & Medicaid Services (CMS) 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 St. Charles Mercy Hospital (the Hospital) for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- The Hospital's policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, "incident to" services, and Medicare covered diagnoses;

- Payments to the Hospital 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; and

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

RESULTS OF REVIEW

Even though physician supervision is assumed to be met in an outpatient hospital department, the Hospital 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 30 beneficiaries who received outpatient cardiac rehabilitation services during CY 2001, we determined that the Hospital was paid for:

- Services where the diagnoses used to establish the patients' eligibility for cardiac rehabilitation may not have been supported by medical records (six beneficiaries); and

- Multiple units of service for a single cardiac rehabilitation visit (one beneficiary).

From our sample, the Hospital claimed and received Medicare reimbursement for outpatient cardiac rehabilitation services, amounting to approximately $1,158, that did not meet Medicare coverage requirements, which may not have been supported by medical record documentation, or which were otherwise unallowable. Specific sampling and universe data, methodology, error

types and dollar values are included in APPENDICES A and B. The sample errors and Medicare payments are part of a larger statistical sample and will be included in a multi-state projection of outpatient cardiac rehabilitation service claims not meeting Medicare coverage requirements.

We attribute these questionable services to weaknesses in the Hospital'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 and that only one unit of service was billed to Medicare per cardiac rehabilitation 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 staff. We believe that the Hospital's fiscal intermediary, AdminaStar, should make a determination as to the allowability of the Medicare claims and appropriate recovery action.

RECOMMENDATIONS

We recommend that the Hospital:

- Work with AdminaStar to ensure that the Hospital's outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare coverage requirements for direct physician supervision and for services being provided "incident to" a physician's professional service.

- Work with AdminaStar to establish the amount of repayment liability for services provided to beneficiaries where medical documentation may not have supported Medicare covered diagnoses and for services not otherwise allowable.

- Implement controls to ensure that medical record documentation is maintained to support Medicare outpatient cardiac rehabilitation services.

- Implement controls to ensure that only one unit of service is billed to Medicare for each cardiac rehabilitation session provided.

AUDITEE'S COMMENTS

The Hospital indicated that, from previous correspondence with CMS Region V officials and AdminaStar during July and August 2001, it believes that the reliance on hospital "code" emergency response teams seems to meet the supervision requirements. Concerning the "incident to" requirements, it stated that the regulations for cardiac rehabilitation include little or no discussion of the need for the medical director to examine each beneficiary and develop a plan of care.

With regard to the sample results, the Hospital indicated that the fact that patients no longer experienced angina (post procedure) is not an indication that cardiac rehabilitation is not necessary. The Hospital believed that cardiac rehabilitation is the expected outcome from

treatment received prior to cardiac rehabilitation. It also noted that AdminaStar's local medical review policy, as of July 1, 2002, allows patients, who undergo angioplasty or coronary artery stenting for their angina, to be considered eligible for cardiac rehabilitation. The Hospital agreed with the other billing error and has modified its systems accordingly. In summary, it stated that it will work with AdminaStar to resolve issues as necessary.

The Hospital's comments are summarized at the end of the RESULTS OF AUDIT section of this report and are presented in their entirety as APPENDIX C.

OFFICE OF INSPECTOR GENERAL'S RESPONSE

We acknowledge that the Medicare Intermediary Manual states that the physician supervision requirement is generally assumed to be met where outpatient therapeutic services are performed on hospital premises. However, the Medicare Coverage Issues Manual (section 35-25 entitled Cardiac Rehabilitation Programs) more specifically requires that the services of nonphysician personnel be furnished under the direct supervision of a physician, who is immediately available and accessible for an emergency at all times. We could not conclude that the Hospital met this requirement. While we would also acknowledge that Medicare's 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.

Regarding the results of the statistical sample, for angina beneficiaries, the Medicare Coverage Issues Manual considers cardiac rehabilitation programs reasonable and necessary only for patients with a clear medical need and a documented diagnosis of stable angina. Our review of the medical records appeared to indicate that the beneficiaries did not continue to experience angina symptoms, post procedure and through completion of their Phase II cardiac rehabilitation program. Consequently, we could not conclude that these beneficiaries met the requirements of the Coverage Issues Manual. In addition, while participation in the cardiac rehabilitation program may have been the expected outcome of treatments received by these beneficiaries, the local medical review policy, in effect during our audit period, did not include provisions for Medicare coverage of outpatient cardiac rehabilitation based solely on treatment that involved angioplasty or stenting.

TABLE OF CONTENTS

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 & Medicaid Services. 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. Medicare coverage of cardiac rehabilitation programs is considered 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. 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 therapeutic services 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 based on an ambulatory payment classification. The fiscal intermediary for the Hospital is AdminaStar. For CY 2001, the Hospital provided outpatient cardiac rehabilitation services to 86 Medicare beneficiaries and received $26,605 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 the Hospital for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- The Hospital's policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, "incident to" services, and Medicare covered diagnoses;

- Payments to the Hospital 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; and

- Services related to outpatient cardiac rehabilitation services[1] provided by the Hospital were separately billed by and reimbursed to the Hospital or any other Medicare provider.

Scope

To accomplish these objectives, we reviewed the Hospital's current policies and procedures and interviewed staff to gain an understanding of the Hospital's management of its outpatient cardiac rehabilitation program and the billing procedures for cardiac rehabilitation services. In addition, we reviewed the Hospital's cardiac rehabilitation services documentation, inpatient medical records, referring physician referrals and supporting medical records, and Medicare reimbursement data for 30 beneficiaries who received outpatient cardiac rehabilitation services from the Hospital during CY 2001 as part of a multi-state statistical sample. We reviewed the Hospital'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.

Our sample included 30 of 86 Medicare beneficiaries who received outpatient cardiac rehabilitation services from the Hospital during CY 2001. We reviewed all Medicare paid claims for cardiac rehabilitation services provided to these 30 beneficiaries during CY 2001.

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

Methodology

We compared the Hospital's current policies and procedures for outpatient cardiac rehabilitation to national Medicare coverage requirements and the fiscal intermediary's local medical review policy and identified any differences. We documented how the Hospital's staff provided direct physician supervision for cardiac rehabilitation services and verified that the Hospital'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 the Hospital'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

[1] 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.

record and referral, and the Hospital's outpatient cardiac rehabilitation medical record. The medical records have not yet been reviewed by AdminaStar.

In addition, we verified that Medicare did not reimburse the Hospital 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 the Hospital, 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 the Hospital, located in Oregon, Ohio, during April and May 2003.

RESULTS OF AUDIT

Even though physician supervision is assumed to be met in an outpatient hospital department, the Hospital did not designate a physician to directly supervise the services provided by its cardiac rehabilitation program staff. 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." Furthermore, from our specific claims review for a sample of 30 beneficiaries receiving outpatient cardiac rehabilitation services during CY 2001, we determined that the Hospital was paid for:

- Services where the diagnoses used to establish the patients' eligibility for cardiac rehabilitation may not have been supported by medical records (six beneficiaries); and

- Multiple units of service for a single cardiac rehabilitation visit (one beneficiary).

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 the Hospital, no physician was actually designated to provide direct physician supervision to the cardiac rehabilitation exercise areas 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. A cardiac rehabilitation senior coordinator (registered nurse) was responsible for the day-to-day supervision and management of the cardiac rehabilitation area.

Although the Hospital's cardiac rehabilitation policies did not require the medical director to provide the direct physician supervision at all times that the exercise program was conducted, the Hospital's cardiac rehabilitation medical director was responsible for the cardiac rehabilitation program policies and procedures and could respond to any medical emergency (depending upon availability).

The Hospital's policies required the medical director to give input on medical concerns to assist the process of decision-making, problem-solving, monitoring, and evaluation of the cardiac rehabilitation program. In addition, the medical director was notified of any major program changes or problems and assisted in the development of all facets of the cardiac rehabilitation protocols and any standing orders.

In the event the medical director was not available to "supervise" and respond to an emergency, the Hospital's cardiac rehabilitation staff would contact other available cardiologists whose offices were located nearby. In addition, a "code" emergency response team could be called. The "code" emergency team was responsible for responding to any medical emergency that occurred throughout the hospital, including the cardiac rehabilitation exercise area. Cardiac rehabilitation staff also 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 the Hospital should work with AdminaStar to ensure that the reliance placed on other nearby physicians and the "code" emergency response team specifically conforms with the direct supervision 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 the Hospital, we could not identify the physician professional services to which the cardiac rehabilitation services were provided "incident to." According to the Hospital's policies governing its cardiopulmonary rehabilitation program, the Hospital's phase II program provided the patient with an individualized exercise program under the supervision of the patient's physician, a nurse, and a therapist. Prior to starting the phase II program, patients were requested to complete a Cardiac Rehabilitation Phase II Health Assessment, which identified attending physicians, date and type of cardiac event, risk factors, and current medications. In addition, a registered nurse also provided an assessment of the patients including height, weight, blood pressure, heart and lung sounds, incisions, edema, angina, and identified other problems such as eating, sleeping, current exercise levels, energy levels, and memory.

The cardiac rehabilitation nurses conducted initial new patient evaluations and documented progress notes in each patient's cardiac rehabilitation records after each visit throughout the rehabilitation program. In addition, registered nurses assessed all indications of early warning signs and symptoms, documented these issues in the patients' records, and discussed these issues with the cardiologist (medical director or other cardiologists) or the referring physician.

There were, however, no hospital physician evaluations documented in our sampled beneficiaries' records, indicating a hospital physician's involvement with the cardiac rehabilitation plan of care. According to the Hospital's cardiac rehabilitation medical director and senior coordinator, cardiac rehabilitation participants were not "officially" evaluated by the medical director (and documented in patients' medical records). However, the medical director did periodically observe some patients during exercise sessions. The Hospital's staff believed referring physicians would stop referring patients to the Hospital's cardiac rehabilitation program if the referring physicians perceived the Medical director was evaluating and providing primary cardiac care to their patients.

From our review of the Hospital's outpatient cardiac rehabilitation medical records, we could not locate evidence of any hospital 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 hospital 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 the Hospital'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 review of the records for 30 of 86 Medicare beneficiaries, with claims for outpatient cardiac rehabilitation services amounting to $8,543 during CY 2001, disclosed that Medicare claims for 7 beneficiaries contained 7 errors totaling $1,158.

Medicare Covered Diagnoses

Medicare paid the Hospital for outpatient cardiac rehabilitation services where the diagnoses used to establish eligibility for cardiac rehabilitation 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 $1,143 to the Hospital for the cardiac rehabilitation services provided to these 6 beneficiaries.

Of the 30 sampled beneficiaries, eligibility for 8 beneficiaries was based on the diagnosis of acute myocardial infarction, eligibility for 12 beneficiaries was based on the diagnosis of coronary artery bypass graft surgery, eligibility for 3 beneficiaries was based on a diagnosis of coronary artery bypass graft surgery and acute myocardial infarction, and eligibility for 7 beneficiaries was based on the diagnosis of stable angina.[2] For the 23 beneficiaries with diagnoses of acute myocardial infarction and/or coronary artery bypass graft surgery, medical records contained documentation to support the diagnoses. However, the medical records for six of the seven beneficiaries with diagnoses of stable angina did not appear to indicate that the beneficiaries continued to experience stable angina post-procedure.

Of the six beneficiaries, three beneficiaries were admitted to hospitals with diagnoses of angina, chest pain, or chest discomfort. During their inpatient stays, cardiac procedures such as stenting and angioplasty were performed. Two beneficiaries having atypical chest pain/palpitations and extremity weakness/numbness were admitted to hospitals for other procedures (e.g. heart ablation or various medical tests, such as MRI). One beneficiary did not have an inpatient stay prior to cardiac rehabilitation, but experienced various phases of stable angina, unstable angina, or no chest pain prior to cardiac rehabilitation. Upon discharge from the hospital or after being evaluated by their physicians, these beneficiaries were referred to the outpatient cardiac rehabilitation program by their physicians.

The Hospital'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. The Hospital'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 reviewed the Hospital's inpatient medical records and the medical records maintained by the physicians who referred these six 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. For the six beneficiaries, the 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 the Hospital not ensuring referrals for beneficiaries with Medicare covered diagnoses were supported by medical documentation prior to providing cardiac rehabilitation services and billing Medicare. Specifically, the Hospital's procedures did

[2] 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).

not require referring physicians to provide medical documentation supporting stable angina diagnoses used to justify phase II cardiac rehabilitation services provided at Medicare expense.

Multiple Units Billed

The Hospital's internal controls did not ensure that only one unit of service was billed per cardiac rehabilitation session. As a result, the Hospital billed and received reimbursement from Medicare on behalf of one of the sampled beneficiaries for two sessions of cardiac rehabilitation when only one session was provided on that particular date of service. Medicare made an inappropriate reimbursement of $15 to the Hospital for the extra session billed for the beneficiary.

Sample Results

The results from our sample will be included in a multi-state estimate of Medicare reimbursements 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, error types and dollar values.)

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

RECOMMENDATIONS

We recommend that the Hospital:

- Work with AdminaStar to ensure that the Hospital's outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare coverage requirements for direct physician supervision and for services being provided "incident to" a physician's professional service.

- Work with AdminaStar to establish the amount of repayment liability for services provided to beneficiaries where medical documentation may not have supported Medicare covered diagnoses and for services not otherwise allowable.

- Implement controls to ensure that medical record documentation is maintained to support Medicare outpatient cardiac rehabilitation services.

- Implement controls to ensure that only one unit of service is billed to Medicare for each cardiac rehabilitation session provided.

AUDITEE'S COMMENTS

In written comments to the draft report, the Hospital indicated that, from previous correspondence with CMS Region V officials and AdminaStar during July and August 2001, it believes that the reliance on hospital "code" emergency response teams seems to meet the supervision requirements. Concerning the "incident to" requirements, the Hospital stated that the regulations for cardiac rehabilitation include little or no discussion of the need for the medical director to examine each beneficiary and develop a plan of care. The Hospital believed that it complied with the requirements for cardiac rehabilitation, as delineated in the AdminaStar local medical review policy of July 2002. Specifically, the Hospital stated that since referrals from attending physicians establish medical necessity, there is no need for the medical director to assess the beneficiary and determine medical necessity. In addition, it indicated that services are provided when a physician is on the premises and available to perform medical duties at all times, as evidenced by the close proximity of the cardiac rehabilitation exercise area to the emergency room and immediate access to physician support. The Hospital believed that CMS' regulations regarding physician supervision and "incident to" requirements are often confusing and/or contradictory and are not clearly articulated.

With regard to the sample results, the Hospital indicated that the fact that patients no longer experienced angina (post procedure) is not an indication that cardiac rehabilitation is not necessary. Rather, cardiac rehabilitation is the expected outcome as a result of treatment received prior to cardiac rehabilitation. The Hospital also noted that AdminaStar's local medical review policy, as of July 1, 2002, allows patients, who undergo angioplasty or coronary artery stenting for their angina, to be considered eligible for cardiac rehabilitation. The Hospital agreed with the other billing error identified in our sample and has taken action to modify its systems to assure that only one charge will be generated per day. In summary, the Hospital stated that it will work with AdminaStar to resolve issues as necessary.

The Hospital's written comments are presented in their entirety as APPENDIX C.

OFFICE OF INSPECTOR GENERAL'S RESPONSE

We acknowledge that the Medicare Intermediary Manual states that the physician supervision requirement is generally assumed to be met where outpatient therapeutic services are performed on hospital premises. However, the Medicare Coverage Issues Manual (section 35-25 entitled Cardiac Rehabilitation Programs) more specifically requires that the services of nonphysician personnel be furnished under the direct supervision of a physician, who is immediately available and accessible for an emergency at all times. We could not conclude that physicians with other emergency room critical responsibilities would be immediately available at all times as required by the Coverage Issues Manual. With respect to "incident to" services, Section 35-25 of the 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. While we would also acknowledge that Medicare 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 Medicare Manuals.

Regarding the results of our statistical sample, for angina beneficiaries, the Medicare Coverage Issues Manual considers cardiac rehabilitation programs reasonable and necessary only for patients with a clear medical need and a documented diagnosis of stable angina. Our review of the medical records indicated that the beneficiaries did not continue to experience angina symptoms, post procedure and through completion of their Phase II cardiac rehabilitation program. Consequently, we could not conclude that these beneficiaries met the requirements of the Coverage Issues Manual at the time of referral and acceptance to the program. In addition, while participation in the cardiac rehabilitation program may have been the expected outcome as a result of the treatments received by these beneficiaries, the local medical review policy, in effect during our audit period, did not include provisions for Medicare coverage of outpatient cardiac rehabilitation based solely on treatment that involved angioplasty or stenting.

APPENDICES

APPENDIX A

STATISTICAL SAMPLE SUMMARY OF ERRORS

The following table summarizes the errors identified during testing of 30 Medicare beneficiaries who received outpatient cardiac rehabilitation services from the Hospital during CY 2001. The 30 beneficiaries were part of a multi-state statistical sample. The results from our sample will be included in a multi-state estimate of Medicare errors for outpatient cardiac rehabilitation services that may not have met Medicare coverage requirements or were otherwise unallowable for payment.

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	Total Errors per Diagnosis
8	0	**Myocardial Infarction (MI)**	0	0	0
12	0	**Coronary Artery Bypass Graft (CABG)**	0	0	0
3	1	**MI and CABG**	0	1	1
7	6	**Stable Angina Pectoris**	6	0	6
30	**7**	**Total**	**6**	**1**	**7**

APPENDIX B

SAMPLING AND UNIVERSE DATA AND METHODOLOGY

We randomly selected a sample of 30 Medicare beneficiaries who received outpatient cardiac rehabilitation services from the Hospital during CY 2001. For each beneficiary, we obtained all Medicare claims reimbursement data for outpatient cardiac rehabilitation services and compared this data to the Hospital'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 the Hospital's outpatient cardiac rehabilitation service records.

The results from our sample will be included in a multi-state estimate of Medicare reimbursements for outpatient cardiac rehabilitation services that may not have met Medicare coverage requirements or were otherwise unallowable for payment.

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

Universe	Population Value	Sample Size	Sample Value	Sampled Beneficiaries with Errors	Sample Errors Value
86	$26,605	30	$8,543	7	$1,158

APPENDIX C

AUDITEE'S WRITTEN COMMENTS TO DRAFT REPORT

MERCY
Health Partners

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September 8, 2003

OVERNIGHT MAIL

Mr. Paul Swanson
Regional Inspector General for Audit Services
Dept. of Health and Human Services
Office of Audit Services
233 North Michigan Ave.
Chicago, Il 60601

RE: Report No. A-05-03-00070

Dear Mr. Swanson:

The following is our response to U.S. Department of Health and Human Services, Office of Inspector General draft report entitled, "Review of Outpatient Cardiac Rehabilitation Services at St. Charles Mercy Hospital, Oregon, Oh." Thank you for allowing us this opportunity to comment on the Report.

1) **Comment:** It was found that in one instance, St. Charles Mercy Hospital billed for two sessions when only one session was provided.

   Response: This represented one error in the 30 charts reviewed. As these 30 charts represent as many as 1,080 sessions (30 charts times maximum of 36 sessions per beneficiary), we do not believe that any "trend" toward overbilling exists. We have, however, modified our systems to review daily the patient charges to assure only one charge will be generated per day. The dollar amount involved represents only $15 and we will work with Adminastar on this issue.

2) **Comment:** Six beneficiaries with diagnoses of stable angina did not appear to indicate that he/she continued to experience stable angina post-procedure. Stable angina was defined as a pain or discomfort in the chest or adjacent areas caused by insufficient blood flow to the heart muscle.

Response: In reviewing the six beneficiary records, it was noted that three beneficiaries had cardiac procedures such as stenting and angioplasty, two were admitted to the hospital for other procedures such as heart ablations and other testing, and last one had various phases of stable angina, unstable angina, and finally no chest pain. These patients were either hospitalized or underwent outpatient treatment for heart issues and cardiac rehabilitation was part of the standard treatment plan for patients exhibiting these types of signs and symptoms. The fact that these patients no longer experienced angina is not an indication that cardiac rehab is not necessary, but rather is the expected outcome as a result of the treatment received prior to cardiac rehab. Patients should no longer have chest pain after treatment. If chest pain continues, then additional medical intervention is appropriate. The diagnoses that are considered appropriate for cardiac rehab need to reflect these advances in medical care for cardiac patients. A cardiac rehabilitation service is considered part of the continuum of care and standard of care for patients with stable angina.

It should be noted that Adminastar revised the Indications and Limitations of Coverage and/or Medical Necessity as of 7/1/2002. At that time, patients with stable angina pectoris (dx:413.0, 413.9) that undergo PTCA or coronary artery stenting for their angina are considered eligible for cardiac rehabilitation.

The review of claims conducted by the Office of Inspector General did not consist of a statistically valid sample of claims. The claims for stable angina patients were specifically selected. Stable angina patients actually represent a small portion of our total cardiac rehab patients.

3) **Comment**: St. Charles Mercy Hospital needs to work with Adminastar to ensure that the reliance placed on physicians, other than the medical director, to provide supervision when the medical director is not available, specifically conforms to the Medicare requirements for appropriate supervision.

Response: As noted in the report, Medicare policy provides that physician supervision is assumed to be met in an outpatient hospital department. The Emergency Department is located very near the Cardiac Rehab Department. The hospital "code" emergency response team is available in the event a medical emergency does occur.

Catholic Health Partners was in contact with both Region V officials in Chicago as well as our local Intermediary, Adminastar regarding the issue of physician supervision in Cardiac Rehabilitation Programs. The Region V Regional Medical Officer, Trent Haywood, MD, reported that there were "a variety of acceptable supervision arrangements for cardiac rehab services." Our question was then referred to Dr. Richard Baer, Medical Director, Adminastar Federal. Dr. Baer wrote that:

> "Services rendered within a hospital outpatient department, including cardiac rehabilitation services, are considered "incident to" a physician's (MD/DO) services and require physician supervision. The physician supervision requirement is presumed to be met, however, when services are performed on hospital premises (i.e. in an area certified as part of the hospital). This is because in a hospital, a qualified physician or "code team" is most often in the same building and is immediately available." (Letter attached)

From our previous correspondence with Adminastar our "code team" approach seems to meet the supervision requirements.

We think it is important to note that it is a rare situation for a patient to have need for medical services while in cardiac rehab. Patients who are not stable are not eligible for participation. The emphasis on the supervision requirement for patient safety is not proven by the actual experience of the cardiac rehab industry.

4) **Comment**: St. Charles was not in compliance with Medicare requirements for services being provided "incident to" a physician's professional services.

Response: In reviewing the regulations for cardiac rehab, there has been little or no discussion of the need for the medical director to exam each beneficiary and develop a care plan. The cardiologist in the community who has prescribed this course of treatment for the patient has already performed a complete exam of the patient and is continuing to follow the patient's progress with the cardiac rehab staff. To have the medical director repeat this work and bill the program for these professional services would simply increase Medicare's expenses without providing additional value. If the medical director did suspect a problem with a patient in the program, the medical director would have the authority and responsibility to exam the patient. To date, this situation has not occurred. We believe that the most cost effective way of providing cardiac rehab services is to provide the services of the medical director on an exception only basis. As noted, the registered nurses in the Cardiac Rehab Department do an assessment of the patient and the patients are required to complete a Cardiac Rehabilitation Phase II Health Assessment. Given all of this documentation, along with the referral from the cardiologist or other physician in the community, there are enough safeguards in the system to prevent a patient with an inappropriate diagnosis participating in the program.

All referring physicians receive a discharge summary from the clinic upon the patient's completion of the program. If an issue or problem occurs, the cardiac rehab staff contacts the referring physician to discuss and make a revision in the treatment plan.

Review of Cardiac Rehabilitation Local Medical Review Policy

Our local Intermediary, Adminastar had issued a Local Medical Review Policy (LMRP) regarding Cardiac Rehabilitation in July 2002. This was the third revision since the original LMRP was published in December

1999. We look to these LMRP for guidance on programs such as cardiac rehab. In light of the report, below find a review of the LMRP to determine its guidance regarding the issues identified in the OIG Report.

Quoting from the Adminastar Local Medical Review Policy (LMRP) for Cardiac Rehabilitation effective July, 2002,

A) "Phase II cardiac rehabilitation programs would be considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physician, and have at least a moderate level of risk stratification."

This states that the referral from the attending physician would establish medical necessity. There is no indication that the medical director needs to review the case and determine medical necessity.

B) "Cardiac rehabilitation programs may be provided either by the outpatient department of a hospital or in a freestanding cardiac rehabilitation facility. Services provided in a facility which is not licensed as part of a hospital must be provided under the rules for services furnished "incident to" physicians' services."

Following this guidance, "incident to" requirements are not indicated as applicable to the hospital setting.

C) "Cardiac rehabilitation services must be conducted only when a physician is on the premises and is available to perform medical duties at all times the facility is open."

The Medical Director at Adminastar Federal (our local Intermediary) wrote in his "Medical Director's Corner" in July, 2002 that the purpose of the physician supervision requirement is to ensure there is a physician available to immediately evaluate the patient in the event of arrhythmia or other complication of the cardiac rehabilitation services. The St. Charles Mercy Hospital Cardiac Rehab area is no more than 50 yards from the Emergency Department. The close proximity to ER ensures

immediate access to physician support. The response time for the code team could be measured in seconds. Because of this, we believe that we meet the "immediately available" standard.

D) "New patient comprehensive evaluation, including history, physical, and preparation of initial exercise prescription. One comprehensive evaluation is allowed and separately payable at the beginning of the program if not already performed by the patient's attending physician, or if the evaluation performed by the patient's attending physician is not acceptable to the program's director."

This section of the LMRP indicates that the program medical director does not need to do a reevaluation of the patient if the patient's referring physician has performed this service. We have followed this guidance in the past and have not encountered any patient issues. The cardiologists that refer to our program have all performed an assessment prior to the referral and we do not feel the need to repeat this.

E) "A routine cardiac rehabilitation visit must include at least one of the following services in order to be reimbursed:

1. Continuous ECG telemetric monitoring during exercise

2. ECG rhythm strip with interpretation and physician's revision of exercise prescription

3. Physician evaluation to assess patient performance, adjust medication or other treatment changes. This physician evaluation is considered an element of the cardiac rehabilitation visit and is not a separately payable service. Additional physician payment would require documentation of a separately identifiable evaluation and management (E/M) service."

Based upon this definition of a rehab visit, we always provide the first service and bill under that element.

We believe that we have complied with the requirements as delineated in the Adminastar LMRP of July 2002. The introduction of the "incident to" requirements in the OIG review is not the same requirements as provided to us through the LMRPs the Intermediary has previously released. Our program is structured in a way to allow for the most efficient provision of service in the most cost effective way. To require additional services from the medical director would simply increase the cost of providing the service without adding an increase in value to the patient. We respectively ask that you evaluate this requirement against the actual performance of programs such as ours in terms of both improvement in quality of life to the patient and safety in providing the service. The ultimate goal of Medicare should be the same as ours, that of providing excellent quality care to the patient in the most cost effective manner.

We would like to point out that the operation of our program is similar to the majority of programs. We became certified in 2001 soon after the American Association of Cardio-Vascular and Pulmonary Rehabilitation (AACVPR) began offering certification. Our Senior Clinical Coordinator maintains membership in both the AACVPR and the Ohio Association of Cardio-Vascular and Pulmonary Rehabilitation. This allows us to stay current with the industry standards on Cardiac Rehab.

In reading the "Review of Outpatient Cardiac Rehabilitation Services at St. Luke's Medical Center, Milwaukee, Wisconsin", we are in agreement with their Response of June 27, 2003. Specifically we agree that the regulations were often confusing and or contradictory. The physician supervision issue as well as the "incident to" physician services are not clearly articulated in the Regulations. Our Intermediary did not provide a clear interpretation of these Regulations when we queried them in the attached letter.

Please be assured that St. Charles Mercy Hospital takes the OIG Report very seriously and will take whatever corrective action is necessary. We will work with our local Intermediary, Adminastar to resolve issues as necessary. Because of the confusion regarding physician supervision and "incident to" requirements, we recommend that CMS issue additional clarifying guidance and allow a period of time for all Cardiac Rehab Programs to come into

compliance as necessary. Given the confusion both by the Providers and Intermediary regarding this, we ask that the guidance be applied on a prospective basis only.

If you have any further questions, please feel free to call me at 419-251- 4960. You may also contact our Regional Director of Corporate Responsibility, Beth Hickman, at 419-251-1849.

Sincerely,

Buzz Hermann
Metro Administrative Director
Cardiopulmonary Services

Attachments

cc: Marc Gustafson