January 12, 2004

Our Reference: Report Number A-02-03-01013

Mr. Jeffrey Hirsch
Chief Executive Officer
Orange Regional Medical Center – Horton Campus
60 Prospect Avenue
Middletown, New York 10940

Dear Mr. Hirsch:

Enclosed are two copies of the Office of Inspector General report entitled “Review of Outpatient Cardiac Rehabilitation Services at Orange Regional Medical Center – Horton Campus.” A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

Final determinations as to actions taken on all matters reported will be made by the HHS action official named below. 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG, OAS reports issued to the Department’s grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.)
To facilitate identification, please refer to Report Number A-02-03-01013 in all correspondence relating to this report.

Sincerely,

[Signature]
Timothy J. Horgan
Regional Inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:

Mr. James T. Kerr
Regional Administrator
Centers for Medicare & Medicaid Services, Region II
U.S. Department of Health and Human Services
26 Federal Plaza, Room 3811
New York, New York 10278
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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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.

Currently, the CMS covers outpatient cardiac rehabilitation programs conducted in specialized, freestanding cardiac rehabilitation clinics and in outpatient hospital departments under the “incident to” benefit [§1861(s)(2)(A) of the Social Security Act]. Medicare coverage policy for cardiac rehabilitation services is found in §35-25 of the Medicare Coverage Issues Manual. Under 42 Code of Federal Regulations §482.24(b), the hospital must maintain a medical record for each inpatient and outpatient.

Outpatient cardiac rehabilitation is considered reasonable and necessary only for patients with a clear medical need, who are referred by their attending physicians, and have a documented Medicare covered diagnosis for cardiac rehabilitation. Services provided in connection with cardiac rehabilitation programs must be rendered under direct physician supervision and be “incident to” the professional services of a physician.

OBJECTIVE

The overall objective of our review was to determine whether Medicare properly reimbursed the Orange Regional Medical Center – Horton Campus (Horton) for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- Horton’s policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, “incident to” services and Medicare covered diagnoses.

- Payments to Horton 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.

RESULTS OF REVIEW

According to the Medicare Intermediary Manual (Intermediary Manual), §3112.4, the physician supervision requirement is generally assumed to be met for outpatient cardiac rehabilitation services provided on hospital premises. Although Horton’s cardiac exercise room is physically located within the Cardiac Department of the hospital, and an attending physician, present on the floor at all times, could respond to emergencies 24 hours per day, seven days per week, there was no physician specifically designated to directly supervise the cardiac rehabilitation program.
According to the Intermediary Manual, §3112.4, to be covered under the “incident to” benefit in an outpatient hospital department, services must be furnished as an integral, although incidental part of a physician’s professional service in the course of diagnosis or treatment of an illness or injury. That is, during any course of treatment rendered by auxiliary personnel, a 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 Horton, we were unable to identify the physician professional services to which the cardiac rehabilitation services were provided “incident to.” Horton had addressed this requirement by merely implementing procedures that provided that a medical director review patient records one day per week, evaluate each patient’s progress and exercise prescription, and update referring physicians as necessary. There were no procedures developed to provide that the medical director personally see patients to assess their progress and update treatment plans, as required by Medicare.

Medicare reimbursed Horton $21,755 for cardiac rehabilitation services provided to 55 beneficiaries during CY 2001. Our analysis of the medical and billing records of 30 sampled beneficiaries who received 615 services totaling $11,678 during CY 2001, showed that Horton claimed outpatient cardiac rehabilitation services appropriately, except as follows:

- $1,615 for 84 services provided to four beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. The documented diagnoses were not covered for Medicare outpatient cardiac rehabilitation reimbursement, and thus the beneficiary was ineligible for the services.

- $1,614 for 84 services provided to five beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. However, the documented diagnoses were also covered for Medicare outpatient cardiac rehabilitation reimbursement (a diagnoses miscoding issue only).

- $1,379 for 72 services provided to two beneficiaries for whom the physician and/or hospital medical records may not have supported the stable angina pectoris diagnoses that established eligibility for the cardiac rehabilitation program.

- $491 for 26 services provided to twenty-six beneficiaries that are not allowable for outpatient cardiac rehabilitation reimbursement.

The Medicare payments are part of a larger statistical sample. As such, these questionable services 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 Horton’s internal controls and oversight procedures. Existing controls did not ensure that diagnoses were properly coded, that beneficiaries had Medicare covered diagnoses for cardiac rehabilitation supported by the medical records, and that services were allowable for reimbursement under Medicare.

Our determinations regarding Medicare covered diagnoses were based solely on our review of the medical record documentation. The medical records have not been reviewed by Medicare fiscal intermediary (FI) staff. We believe that the Medicare FI, Empire Medicare Services, should determine appropriate recovery action.

RECOMMENDATIONS

We recommend that Horton:

- Work with the Medicare FI to ensure that Horton’s outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare coverage requirement for direct physician supervision and for services provided “incident to” a physician’s professional services.

- Work with the Medicare FI to establish the amount of repayment liability for services that did not meet criteria for Medicare reimbursement.

- Strengthen internal controls and oversight activities to ensure that diagnoses are properly coded, that services billed to Medicare are for covered diagnoses only and allowable for reimbursement under Medicare, and that medical record documentation is maintained to support covered diagnoses.

AUDITEE COMMENTS

Horton disagreed with each of our findings on direct physician supervision, services provided “incident to” a physician’s professional services, covered diagnoses, and billing errors. However, Horton agreed with our recommendation to work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program operates in accordance with the Medicare coverage requirements for physician supervision and for services provided “incident to” a physician’s professional services. Horton also agreed to ensure that appropriate written documentation to support Medicare cardiac rehabilitation services is maintained and included in the patient’s medical record, and that coding is based on appropriate documentation of supporting diagnoses.

With respect to physician supervision, Horton officials cited the Medicare Hospital Manual, §230.4A, which provides that “the physician supervision requirement is generally assumed to be met where the services are performed on the hospital premises,” and stated their belief that the supervision requirement has been met. Concerning the “incident to” requirements, Horton officials simply stated their belief that their program
conforms to Medicare requirements. Horton officials also indicated that their records support the stable angina pectoris diagnoses that established eligibility for two sampled beneficiaries, and that their procedure for performing and billing new patient evaluations meets applicable requirements.

Horton’s comments are summarized at the end of the Results of Review section of the report and are presented in their entirety as Appendix B.

**OIG RESPONSES**

Regarding direct physician supervision, the Coverage Issues Manual, §35-25(A), more specifically requires that the services of nonphysician personnel be furnished under the direct supervision of a physician. We could not conclude that the Hospital’s reliance on nearby physicians or emergency personnel met the direct supervision requirement specific to cardiac rehabilitation programs.

For services provided “incident to” a physician’s professional services, §35-25 of the Coverage Issues Manual specifically requires that each patient be under the care of a physician, while §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 and the patient’s progress and, where necessary, to change the treatment regimen. We found no evidence of any hospital physician treating or assessing the beneficiaries during their participation in the cardiac rehabilitation program.

With respect to the stable angina diagnoses, our review of the medical records indicated that the beneficiaries did not continue to experience angina symptoms post procedure through completion of their Phase II cardiac rehabilitation program. Consequently, we could not conclude that these two beneficiaries met the requirements of the Coverage Issues Manual (the medical records have not been reviewed by FI staff). Regarding new patient evaluations conducted by nonphysician personnel, the medical records indicated that such services were not performed in conjunction with rehabilitation sessions, as required by Medicare guidelines.
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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 & Medicaid Services (CMS). CMS currently covers Phase II outpatient cardiac rehabilitation programs conducted in specialized, freestanding cardiac rehabilitation clinics and in outpatient hospital departments under the “incident to” benefit (§1861(s)(2)(A) of the Act).

Medicare coverage policy for cardiac rehabilitation services is found in §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. Under 42 Code of Federal Regulations §482.24(b), the hospital must maintain a medical record for each inpatient and outpatient. 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. According to the Intermediary Manual, §3112.4, the physician supervision requirement is generally assumed to be met where the outpatient 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 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 Medicare FI for Orange Regional Medical Center – Horton Campus (Horton) is Empire Medicare Services. For Calendar Year (CY) 2001, Horton provided outpatient cardiac rehabilitation services to 55 Medicare beneficiaries and received $21,755 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 Horton for outpatient cardiac rehabilitation services. Specifically, we determined whether:

- Horton’s policies and procedures reflected Medicare cardiac rehabilitation coverage requirements for direct physician supervision, “incident to” services, and Medicare covered diagnoses.
Payments to Horton 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.

**Scope and Methodology**

To accomplish our audit objectives, we:

- Reviewed Horton’s current policies and procedures and interviewed staff to gain an understanding of Horton’s management of its outpatient cardiac rehabilitation program and the billing procedures for cardiac rehabilitation services.

- Compared Horton’s current policies and procedures for outpatient cardiac rehabilitation to national Medicare coverage requirements and identified any differences.

- Documented how Horton’s staff provided direct physician supervision for cardiac rehabilitation services and verified that Horton’s cardiac rehabilitation program personnel were qualified in accordance with Medicare requirements.

- Verified the availability of advanced cardiac life support equipment in the cardiac rehabilitation exercise area.

- For a sample of 30 beneficiaries, reviewed all Medicare paid claims for cardiac rehabilitation services provided by Horton during CY 2001.

- For each sampled beneficiary, compared reimbursement data and lines of service to Horton’s outpatient cardiac rehabilitation service documentation.

- Reviewed the medical records maintained by the cardiac rehabilitation program to determine whether services were provided “incident to” a physician’s professional service.

- Verified the accuracy of the diagnoses identified on the Medicare claims to each beneficiary’s inpatient medical record, physician referral and supporting medical records, and Horton’s outpatient cardiac rehabilitation documentation. The Medicare FI medical review staff did not review the medical records.

- Verified that Medicare did not reimburse Horton beyond the maximum number of services allowed.

Our audit was conducted in accordance with generally accepted government auditing standards. In accordance with the intent of CMS’s request for a nationwide analysis, we determined the extent to which providers were currently complying with existing
Medicare coverage requirements. We performed fieldwork during March 2003 at the Orange Regional Medical Center – Horton Campus, Middletown, New York.

RESULTS OF REVIEW

According to the Intermediary Manual, §3112.4, the physician supervision requirement is generally assumed to be met for outpatient cardiac rehabilitation services provided on hospital premises. Although Horton’s cardiac exercise room is physically located within the Cardiac Department of the hospital, and an attending physician, present on the floor at all times, could respond to emergencies 24 hours per day, seven days per week, there was no one physician specifically designated to directly supervise the cardiac rehabilitation program.

According to the Intermediary Manual, §3112.4, to be covered under the “incident to” benefit in an outpatient hospital department, services must be furnished as an integral, although incidental part of a physician’s professional service in the course of diagnosis or treatment of an illness or injury. While Horton implemented procedures that provided that a medical director review medical record documentation, there were no procedures developed to provide that the medical director personally sees patients to assess their progress and update treatment plans, as required by the “incident to” Medicare requirements.

During CY 2001, Medicare reimbursed Horton $21,755 for cardiac rehabilitation services claimed for 55 beneficiaries with diagnoses allowable under the Medicare coverage policy found in §35-25 of the Coverage Issues Manual. Our analysis of the medical and billing records of 30 sampled beneficiaries who received 615 services totaling $11,678 during CY 2001, showed that Horton claimed outpatient cardiac rehabilitation services appropriately, except as follows:

- $1,615 for 84 services provided to four beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. The documented diagnoses were not covered for Medicare outpatient cardiac rehabilitation reimbursement, and thus the beneficiary was ineligible for the services.

- $1,614 for 84 services provided to five beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. However, the documented diagnoses were also covered for Medicare outpatient cardiac rehabilitation reimbursement (a diagnoses miscoding issue only).

- $1,379 for 72 services provided to two beneficiaries for whom the physician and/or hospital medical records may not have supported the stable angina pectoris diagnoses that established eligibility for the cardiac rehabilitation program.
$491 for 26 services provided to twenty-six beneficiaries that are not allowable for outpatient cardiac rehabilitation reimbursement.

We attribute these questionable services to weaknesses in Horton’s internal controls and oversight procedures. Existing controls did not ensure that diagnoses were properly coded, that beneficiaries had Medicare covered diagnoses for cardiac rehabilitation supported by the medical records, and that services were allowable for reimbursement under Medicare.

The findings from our review of Medicare outpatient cardiac rehabilitation services are described in detail below.

**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 program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself, provided the contractor does not determine that the physician is too remote from the patients' exercise area to be considered immediately available and accessible. The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises.

On a day-to-day basis, Horton’s cardiac rehabilitation program was staffed and run by registered nurses and an exercise physiologist. A clinical coordinator, who was a registered nurse, was responsible for the day-to-day supervision of the cardiac rehabilitation area. There was no one physician specifically designated to directly supervise the program and there was no documentation maintained in the cardiac rehabilitation program’s medical records to support physician supervision during exercise sessions.

The cardiac exercise room is physically located within the Cardiac Department of the hospital, and an attending physician, present on the floor at all times, could respond to emergencies 24 hours per day, seven days per week. In addition, Horton’s written policies include procedures for managing emergency situations.

Although physician supervision is assumed to be met in an outpatient hospital department, we believe that Horton should work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program specifically conforms to the 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 regimen.

According to Horton’s policies and procedures, each patient referred to the outpatient cardiac rehabilitation program attended an initial assessment session conducted by an exercise physiologist and a registered nurse. This session included, 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 initial assessment, an individualized plan of care for exercise training, which addressed the cardiac risk factor, educational and counseling plan, psychosocial plan, discharge plan, and outcome measurement plan, was developed. Thereafter, the exercise physiologist and registered nurses performed ongoing assessments prior to each exercise session. These assessments included a determination based on new onset of signs/symptoms, blood pressure, and heart rate and rhythm. Based on these ongoing assessments, the cardiac rehabilitation staff contacted referring physicians, when necessary.

Horton implemented policies and procedures by which a medical director would periodically review patient records, generally one day per week, evaluate each patient’s progress and exercise prescription, and update referring physicians as necessary. There were no procedures developed, however, to provide that the medical director personally sees patients to assess their progress and update treatment plans.

We believe that Horton should work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program conforms to the “incident to” requirements.

MEDICARE COVERED DIAGNOSES AND CLAIMS REVIEW

According to §35-25 of the Coverage Issues Manual, rehabilitation services are 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. This was further clarified by the FI’s Local Medical Review Policy, which provided that covered diagnoses for outpatient cardiac rehabilitation services are (1) acute myocardial infarction within 12 months of entry into the cardiac rehabilitation program, (2) coronary artery bypass
graft surgery within six months of entry into the program, and (3) angina wherein the patient has had a positive pre-entry stress test within six months of starting the program.

According to §35-25(E) of the Coverage Issues Manual, in order for a visit to be reimbursable, at least one Group 1 service must be performed. A Group 1 service may consist of continuous ECG telemetric monitoring during exercise; ECG rhythm strip with interpretation and physician's revision of exercise prescription; and limited examination for physician follow-up to adjust medication or other treatment changes. Not all the services need be performed at each visit. A hospital may also be reimbursed for a Group 2 service, such as a new patient evaluation or stress test. However, a Group 2 service conducted by nonphysician personnel must be performed in conjunction with a rehabilitation session.

During CY 2001, Medicare reimbursed Horton $21,755 for cardiac rehabilitation services claimed for 55 beneficiaries with diagnoses allowable under the Medicare coverage policy found in §35-25 of the Coverage Issues Manual. Our analysis of the medical and billing records of 30 sampled beneficiaries who received 615 services totaling $11,678 during CY 2001, showed that Horton claimed outpatient cardiac rehabilitation services appropriately, except as follows:

- $1,615 for 84 services provided to four beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. The documented diagnoses were not covered for Medicare outpatient cardiac rehabilitation reimbursement, and thus the beneficiary was ineligible for the services. This occurred because Horton had established procedures by which claims would be coded using the diagnoses listed on physician referral forms. In these instances, the referral forms differed from the appropriate diagnoses contained in the medical record documentation.

- $1,614 for 84 services provided to five beneficiaries for whom physician and/or hospital and medical records supported diagnoses that differed from the claimed diagnoses. However, the documented diagnoses were covered for Medicare outpatient cardiac rehabilitation reimbursement (a diagnoses miscoding issue only). This occurred because Horton had established procedures by which claims would be coded using the diagnoses listed on physician referral forms. In these instances, the referral forms differed from the appropriate diagnoses contained in the medical record documentation.

- $1,379 for 72 services provided to two beneficiaries for whom the medical records may not have supported the stable angina pectoris diagnoses that established eligibility for the cardiac rehabilitation program. Since the outpatient cardiac rehabilitation service documentation in both cases did not indicate whether the stable angina pectoris symptoms continued to exist post-procedure, cardiac catheterization, we reviewed inpatient medical records, as well as the medical records of the referring physicians. The medical records, which covered dates of service from the inpatient stay through completion of the Phase II cardiac...
rehabilitation program, did not appear to indicate that the two beneficiaries continued to experience stable angina pectoris symptoms post-cardiac catheterization, and through their completion of the Phase II program.

- $491 for 26 services provided to twenty-six beneficiaries that are not allowable for outpatient cardiac rehabilitation reimbursement. For each of the 26 beneficiaries, Horton was reimbursed for a new patient evaluation conducted by nonphysician personnel. These services were not performed in conjunction with a rehabilitation session. Horton cardiac rehabilitation staff misinterpreted the Medicare requirements for Group 2 services.

We attribute these questionable services to weaknesses of existing controls to ensure that the patients had Medicare covered diagnoses supported by medical records, and to misinterpretation of the Medicare requirements for Group 2 services.

Medical personnel have not yet validated our conclusions, particularly those regarding Medicare covered diagnoses. Therefore, we believe that the Medicare FI should determine whether the claims discussed in this report are allowable and whether recovery action is needed.

The questionable services and Medicare payments are part of a larger statistical sample and will be included in the multi-state projection of outpatient cardiac rehabilitation service claims not meeting Medicare coverage requirements.

A summary of questionable services is contained in Appendix A of this report.

**RECOMMENDATIONS**

We recommend that Horton:

- Work with the Medicare FI to ensure that Horton’s outpatient cardiac rehabilitation program is being conducted in accordance with the Medicare requirements for direct physician supervision and for services provided “incident to” a physician’s professional services.

- Work with the Medicare FI to establish the amount of repayment liability for services that did not meet criteria for Medicare reimbursement.

- Strengthen internal controls and oversight activities to ensure that diagnoses are properly coded, that services billed to Medicare are for covered diagnoses only and allowable for reimbursement under Medicare, and that medical record documentation is maintained to support covered diagnoses.
AUDITEE COMMENTS AND OIG RESPONSES

Horton, in its response dated November 12, 2003 (see Appendix B), disagreed with each of our findings on direct physician supervision, services provided “incident to” a physician’s professional services, covered diagnoses, and billing errors. However, Horton agreed with our recommendation to work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program operates in accordance with the Medicare coverage requirements for physician supervision and for services provided “incident to” a physician’s professional services. Horton also agreed to ensure that appropriate written documentation to support Medicare cardiac rehabilitation services is maintained and included in the patient’s medical record, and that coding is based on appropriate documentation of supporting diagnoses.

A summary of Horton’s comments as well as the OIG responses to those comments is detailed below.

Auditee Comments on Direct Physician Supervision

With respect to physician supervision, Horton officials cited the Medicare Hospital Manual, §230.4A, which provides that “the physician supervision requirement is generally assumed to be met where the services are performed on the hospital premises,” and stated their belief that the supervision requirement has been met.

OIG Response

The Coverage Issues Manual, §35-25(A), more specifically requires that the services of nonphysician personnel be furnished under the direct supervision of a physician. We could not conclude that the Hospital’s reliance on nearby physicians or emergency personnel met the direct supervision requirement specific to cardiac rehabilitation programs.

Auditee Comments on “Incident To” Services

With respect to the “incident to” requirements, Horton officials simply stated their belief that their program conforms to Medicare requirements.

OIG Response

§35-25 of the Coverage Issues Manual specifically requires that each patient be under the care of a physician, while §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 and the patient’s progress and, where necessary, to change the treatment regimen. We found no evidence of any hospital physician treating or assessing the beneficiaries during their participation in the cardiac rehabilitation program.
Auditee Comments On Covered Diagnosis and Billing Errors

Horton officials indicated that their records support the stable angina pectoris diagnoses that established eligibility for two beneficiaries, and that their procedure for performing and billing new patient evaluations meets applicable requirements.

OIG Response

With respect to the stable angina diagnoses, our review of the medical records indicated that the beneficiaries did not continue to experience angina symptoms post procedure through completion of their Phase II cardiac rehabilitation program\(^1\). Consequently, we could not conclude that these two beneficiaries met the requirements of the Coverage Issues Manual. Regarding new patient evaluations conducted by nonphysician personnel, the medical records indicated that such services were not performed in conjunction with rehabilitation sessions, as required by Medicare guidelines.

\(^1\) FI staff has not yet reviewed the medical records.
VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Timothy J. Hogan  
Regional Inspector General for Audit Services  
Orange Regional Medical Center - Horton Campus  
Office of Audit Services  
Region II  
Jacob K. Javits Federal Building  
26 Federal Plaza  
Rm 3900A  
New York, New York  
10278

Re  Orange Regional Medical Center - Horton Campus  
Report No. A-02-03-01013

November 12, 2003

Dear Mr. Hogan:

This letter is provided in response to the draft report of the Office of the Inspector General ("OIG") dated October 15, 2003, entitled "Review of Outpatient Cardiac Rehabilitation Services at Orange Regional Medical Center - Horton Campus." Set forth below are each of the OIG's findings and the response of Orange Regional Medical Center - Horton Campus ("ORMC-Horton Campus").

1. OIG REVIEW AREA: Physician Involvement in Outpatient Cardiac Rehabilitation

1(a). OIG ISSUE: Direct Physician Supervision

"Although physician supervision is assumed to be met in an outpatient hospital department, we believe that ORMC should work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program specifically conforms to the supervision requirements."

ORMC-HORTON CAMPUS RESPONSE:

ORMC - Horton’s Outpatient Cardiac Rehabilitation Program is located in the Hospital’s Cardiology Department. The Medicare Hospital Manual Section 230.4A states that "...the physician supervision requirement is generally assumed to be met where the services are performed on the hospital premises. The hospital medical staff that supervises the service need not be in the same department as the ordering physician."
ORMC-Horton believes that the supervision requirement as defined in the Medicare Hospital Manual and the applicable Local Medical Review Policy (LMRP) has been met. ORMC-Horton will, however, work with our fiscal intermediary to ensure that our cardiac rehabilitation program continues to conform to the applicable physician supervision requirements.

1(b). OIG ISSUE: "Incident To" Physician Services

"We believe that Horton should work with the Medicare FI to ensure that the outpatient cardiac rehabilitation program conforms to the 'incident to' requirements."

ORMC-HORTON CAMPUS RESPONSE:

ORMC-Horton believes that its cardiac rehabilitation program conforms to the "incident to" requirements. ORMC-Horton will work with its fiscal intermediary to ensure its continued compliance with the "incident to" requirements.

2. OIG REVIEW AREA: Medicare Covered Diagnoses and Claims Review

2(a). OIG ISSUE:

"[Services were provided] to four beneficiaries for whom physician and/or hospital medical records supported diagnoses that differed from the claimed diagnoses. The documented diagnoses were not covered for Medicare outpatient cardiac rehabilitation reimbursement, and thus the beneficiary was ineligible for the services. This occurred because Horton had established procedures by which claims would be coded by using the diagnosis listed on the physician referral form. In these instances, the referral form differed from the appropriate diagnoses contained in the medical record documentation."

ORMC-HORTON CAMPUS RESPONSE:

ORMC-Horton's procedures for assuring accuracy in documentation and billing have been reviewed and strengthened. ORMC-Horton will work with its fiscal intermediary to ensure that appropriate medical record documentation continues to be maintained to support billing and appropriate coding for outpatient cardiac rehabilitation services under Medicare.

2(b). OIG ISSUE:

"[Services were] provided to five beneficiaries for whom physician and/or hospital and medical records supported diagnoses that differed from the claimed diagnoses. However, the documented diagnoses were covered for Medicare outpatient cardiac rehabilitation reimbursement (a diagnoses miscoding issue only). This occurred because Horton had established procedures by which claims would be coded by using the diagnoses listed on
the physician referral forms. In these instances, the referral form differed from the appropriate diagnoses contained in the medical record documentation."

**ORMC-HORTON CAMPUS RESPONSE:**

ORMC-Horton's records contain documentation of appropriate diagnoses to support the outpatient cardiac rehabilitation services provided. ORMC-Horton will work with its fiscal intermediary to ensure that appropriate medical record documentation continues to be maintained to support billing and appropriate coding for outpatient cardiac rehabilitation services under Medicare.

2(c). **OIG ISSUE:**

"[Services were] provided for two beneficiaries for whom the medical records may not have supported the stable angina pectoris diagnoses that established eligibility for the cardiac rehabilitation program. Since the outpatient cardiac rehabilitation service documentation in both cases did not indicate whether the stable angina pectoris symptoms continued to exist post-procedure, cardiac catheterization, we reviewed inpatient medical records, as well as the medical records of the referring physicians. The medical records, which covered dates of service from the inpatient stay through completion of the Phase II cardiac rehabilitation program, did not appear to indicate that the two beneficiaries continued to experience stable angina pectoris symptoms post-cardiac catheterization, and through their completion of the Phase II program."

**ORMC-HORTON CAMPUS RESPONSE:**

ORMC-Horton's records contain documentation of appropriate diagnoses to support the outpatient cardiac rehabilitation services provided. ORMC-Horton will work with its fiscal intermediary to ensure that appropriate medical record documentation continues to be maintained to support billing for outpatient cardiac rehabilitation services under Medicare.

2(d). **OIG ISSUE:**

"[...ORMC-Horton] was reimbursed for new patient evaluation[s] conducted by non-physician personnel. These services were not performed in conjunction with a rehabilitation session. Horton cardiac rehabilitation staff misinterpreted the Medicare requirements for Group 2 services."

**ORMC-HORTON CAMPUS RESPONSE:**

ORMC-Horton believes its procedure for performing and billing new patient evaluations meets the requirements of the applicable Medicare manuals and the LMRP, and is in conformity with the industry standard. ORMC-Horton will work with its fiscal intermediary to ensure that it continues to comply with all Medicare billing requirements.
SUMMARY RESPONSE TO RECOMMENDATIONS:

ORMC-Horton will work directly with its fiscal intermediary to ensure that the outpatient cardiac rehabilitation program continues to operate in accordance with the Medicare coverage requirements for physician supervision and for services provided "incident to" a physician's professional services.

* ORMC-Horton will continue to ensure that appropriate written documentation to support Medicare cardiac rehabilitation services is maintained and included in the patient's medical record, and that coding is based on appropriate documentation of supporting diagnoses.

If you have any further questions or concerns, please call at any time.

Sincerely,

Robert Wolleben
Executive Vice President/COO