



DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
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JUN 04 2001

CIN: A-01-00-00555

Mr. John Day
President and Chief Executive Officer
Southcoast Health System
101 Page Street
New Bedford, Massachusetts 02740

Dear Mr. Day:

Enclosed are two copies of the U.S. Department of Health and Human Services, Office of Inspector General, Office of Audit Services' report entitled, "Review of Outpatient Pharmacy Services Provided By Southcoast Hospital Group for Fiscal Year Ending September 30, 1998." A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

Final determination 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, Office of Inspector General, Office of Audit Services reports 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 Common Identification Number A-01-00-00555 in all correspondence relating to this report.

Sincerely yours,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:

Mr. George Jacobs, II
Regional Administrator
Health Care Financing Administration - Region I
U.S. Department of Health and Human Services
Room 2325, JFK Federal Building
Boston, Massachusetts 02203

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF OUTPATIENT PHARMACY
SERVICES PROVIDED BY
SOUTHCOAST HOSPITALS GROUP
FOR FISCAL YEAR ENDING
SEPTEMBER 30, 1998**



**JUNE 2001
A-01-00-00555**

Office of Inspector General

<http://www.hhs.gov/oig/>

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EXECUTIVE SUMMARY

Background

The Medicare program reimburses acute care hospitals for the reasonable costs associated with providing outpatient pharmacy services. Medicare requirements define outpatient services as "Each examination, consultation or treatment received by an outpatient in any service department of a hospital...." Medicare further requires that charges reflect reasonable costs and services provided be supported by medical records. These records must contain sufficient documentation to justify the treatment provided. Acute care hospital costs for such services are comprised of the costs of medications along with the facility costs for providing these medications to patients. The Southcoast Hospitals Group (SHG) pharmacy departments provide medications to outpatients receiving services throughout its facilities, including, in part, the Oncology, Surgery, and Emergency Departments. Claims are submitted for services rendered and are reimbursed on an interim basis based on submitted charges. At year end, SHG submits a cost report to the Medicare fiscal intermediary (FI) for final reimbursement.

Objective

The objective of our review was to determine whether outpatient pharmacy services were billed for and reimbursed in accordance with Medicare regulations.

Summary of Findings

In Fiscal Year (FY) 1998, SHG submitted for reimbursement approximately \$1.1 million in charges for outpatient pharmacy services. Our audit focused on those charges of \$50 or more, representing about \$964,000. To determine whether controls were in place to ensure compliance with Medicare regulations, we reviewed the medical and billing records for a sample of 114 claims totaling \$149,160. Our analysis showed that \$5,872 in outpatient pharmacy charges did not meet Medicare criteria for reimbursement. Specifically, we noted that SHG had erroneously billed Medicare for:

- ◇ \$2,465 in medications used under conditions not covered by Medicare, and
- ◇ \$3,407 in medications not properly supported by medical records.

In addition, we also reviewed the reasonableness of \$80,609 in unallowable, self-administered medications identified by SHG during its own internal review of pharmacy charges. This data was provided to us for review during our audit. We concurred with SHG's self-disclosure and identified an additional \$6,365 in unallowable, self-administered medications. Accordingly, we concluded that \$86,974 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

We noted that SHG did not establish or follow existing procedures for the proper billing of outpatient pharmacy services. Based, in part, on a statistical sample, we estimate that SHG had

overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$112,030.

Recommendations

We recommend that SHG strengthen its procedures to ensure that charges for pharmacy services are covered and properly documented in accordance with Medicare regulations. We will provide the results of our review to Associated Hospital Services, the Medicare FI, so that it can apply the adjustment of \$112,030 to SHG's FY 1998 Medicare cost report.

The SHG, in its response dated May 18, 2001, concurred with our recommendations and indicated that it has implemented procedures to ensure that services are charged in accordance with Medicare regulations. The SHG stated that it will work with the FI in processing the appropriate adjustment to its cost report.

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INTRODUCTION

BACKGROUND

The Medicare program reimburses acute care hospitals for the reasonable costs associated with providing outpatient pharmacy services. Hospital costs for such services are comprised of the costs of medications along with the facility costs for providing these medications to patients. The SHG's pharmacy department provides medications to outpatients receiving services throughout the facility, including, in part, the Oncology, Surgery, and Emergency Departments. These costs are reimbursed through the SHG's Medicare cost report.

Medicare requirements under 42 Code of Federal Regulations (CFR) §482.24(c) state that for benefits to be paid, "...The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services."

For coverage of pharmacy services provided to hospital outpatients, Medicare requirements state, under 42 CFR §410.29, with certain exceptions, that Medicare does not pay for "any drug or biological that can be self-administered." In certain cases, Medicare requirements limit coverage of medications to purposes approved by the Food and Drug Administration (FDA). For the coverage of the drug Epoetin (EPO), the Medicare Hospital Manual §230.4(B)(4) states that, "...The FDA approved labeling for EPO states that it is indicated in the treatment of anemia induced by the drug zidovudine (commonly called AZT), anemia associated with chronic renal failure, and anemia induced by chemotherapy in patients with non-myeloid malignancies. EPO is covered for these indications when it is furnished incident to a physician's service..."

The SHG is comprised of three nonprofit community hospitals in Massachusetts - Charlton Memorial Hospital in Fall River, St. Luke's Hospital in New Bedford, and Tobey Hospital in Wareham. The hospitals have been united since 1996 as part of Southcoast Health System and they presently are licensed for 630 acute medical/surgical beds. During its FY 1998, SHG submitted for Medicare reimbursement 14,337 claims, valued at about \$1.1 million, for outpatient pharmacy services under revenue center code 250.

OBJECTIVES, SCOPE AND METHODOLOGY

Our review was made in accordance with generally accepted government auditing standards. The objective of our review was to determine whether outpatient pharmacy services were billed for and reimbursed in accordance with Medicare regulations. Our review included services provided during FY 1998.

We limited consideration of the internal control structure to those controls concerning claims submission because the objective of our review did not require an understanding or assessment of the complete internal control structure at SHG.

To accomplish our objective, we:

- ◇ reviewed criteria related to outpatient pharmacy services,
- ◇ interviewed appropriate SHG staff concerning internal controls over Medicare claims submission,
- ◇ used the Provider Statistical and Reimbursement Report provided by the FI for SHG's FY 1998 to identify 14,337 outpatient pharmacy claims, totaling \$1,121,739 from revenue center codes 250, 255, and 258. We limited our testing to those claims of \$50 or more, the population of which was 2,163 claims valued at \$964,432.
- ◇ employed a stratified random sampling approach consisting of two strata. Stratum 1 consisted of a random sample of 100 outpatient pharmacy claims valued from \$50 to \$4,999. Stratum 2 consisted of all 14 outpatient pharmacy claims in the population valued at \$5,000 or more,
- ◇ performed detailed audit testing on the billing and medical records for the 114 claims selected in the sample,
- ◇ utilized the FI's medical review staff to review selected cases,
- ◇ used a variable appraisal program to estimate the dollar impact of improper payments in the \$50 to \$4,999 stratum, and,
- ◇ reviewed the reasonableness of \$80,609 in unallowable, self-administered medications identified by SHG and provided to us during our audit.

Our field work was performed during August and September of 2000 at SHG's St. Luke's Hospital campus in New Bedford, Massachusetts.

The SHG response to our draft report is appended to this report (see APPENDIX B).

FINDINGS AND RECOMMENDATIONS

In FY 1998, SHG submitted for reimbursement about \$1,121,739 in charges for outpatient pharmacy services. We reviewed the medical and billing records for 114 selected claims totaling \$149,160. Our analysis showed that \$5,872 in outpatient pharmacy charges did not meet Medicare criteria for reimbursement.

We also reviewed the reasonableness of \$80,609 in unallowable, self-administered medications identified by SHG during its own internal review of pharmacy charges. This data was provided

to us for review during our audit. We concurred with SHG's self-disclosure and identified an additional \$6,365 in unallowable, self-administered medications. As a result, we concluded that \$86,974 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Our analysis disclosed that a total of \$92,846 in outpatient pharmacy charges did not meet Medicare criteria for reimbursement. Based, in part, on a statistical sample, we estimate that SHG had overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$112,030. Findings from our review are described in detail below and in APPENDIX A.

IDENTIFICATION OF UNALLOWABLE, SELF-ADMINISTERED MEDICATIONS

At the time of our audit, SHG presented us with detailed listings showing all medications it had billed to Medicare during FY 1998 including its identification of \$80,609 in unallowable, self-administered medications. We concurred with SHG's self-disclosure and identified an additional \$6,365 in unallowable, self-administered medications.

We found that SHG did not have policies and procedures in place to preclude the billing of unallowable, self-administered medications for hospital outpatients to the Medicare program. Under 42 CFR §410.29, Medicare Part B, with specific exceptions, does not pay for, "...any drug or biological that can be self-administered." The Medicare Hospital Manual §422, identifies these exceptions as; (1) drugs and biologicals which must be put directly into an item of durable medical equipment or a prosthetic device, (2) blood clotting factors, (3) drugs used in immunosuppressive therapy, (4) EPO, in accordance with FDA approved labeling, (5) certain oral anti-cancer drugs and their associated antiemetics, and (6) insulin that is administered in an emergency situation to a patient in a diabetic coma.

Medications included in SHG's disclosure included various prescription and non-prescription medications. In addition to SHG's self-disclosure, we identified another \$6,365 in unallowable, self-administered medications. Of this amount, \$2,785 was attributed to routine insulin injections and \$3,580 was classified by SHG as "Pharmacy Variable" consisting of assorted self-administered medications. The SHG agreed to add these charges to its self-disclosure.

We commend SHG's efforts in identifying the above unallowable charges and concur with its results. Accordingly, we concluded that \$86,974 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

REVIEW OF OUTPATIENT PHARMACY CHARGES \$50 TO \$4,999

We reviewed the billing and medical record documentation for a randomly selected sample of 100 outpatient pharmacy claims valued at \$44,925. We determined that \$4,006 did not meet requirements for Medicare reimbursement as described below.

Noncovered Services

We found that SHG did not have procedures in place to preclude Medicare billing for the drug EPO when used for purposes other than the FDA's approved labeling. The Medicare Hospital Manual §230.4(B)(4) states that, "...The FDA approved labeling for EPO states that it is indicated in the treatment of anemia induced by the drug zidovudine (commonly called AZT), anemia associated with chronic renal failure, and anemia induced by chemotherapy in patients with non-myeloid malignancies. EPO is covered for these indications when it is furnished incident to a physician's service..."

We examined the billing and medical records for the 100 claims in our sample. We identified 18 claims which contained, in part, charges for the administration of EPO. With the assistance of the FI's medical review staff, we found that 15 of the claims for EPO services were billed in accordance with the above requirements. However, the FI found that medical record documentation supplied to us by SHG for the remaining 3 claims, valued at \$2,465, did not support the covered use of EPO. For example, we found one patient whose principal diagnosis was Chronic Renal Insufficiency.

Based on the above, we concluded that \$2,465 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Pharmacy Services Not Sufficiently Documented

Our audit disclosed a weakness in SHG's system of internal controls regarding the medical record documentation supporting its outpatient pharmacy charges. In support of the charges examined, SHG provided us with patient medical record charts and detailed listings of medications administered to patients. Our review of a statistical sample of claims disclosed that \$1,541 in charges were ineligible for Medicare reimbursement because such services were not sufficiently supported in SHG's medical records.

Title 42 CFR, §482.24 states that, "...A medical record must be maintained for every individual evaluated or treated in the hospital...The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services."

We examined the billing and medical records for the 100 claims in our sample. Based on our analysis, we identified:

- ◇ \$1,059 in charges for medications for which no supporting medical record was found, and
- ◇ \$482 in charges for medications for which the quantity of medication administered did not reflect the quantity billed to Medicare.

As a result, we concluded that \$1,541 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

REVIEW OF OUTPATIENT PHARMACY CHARGES \$5,000 AND OVER

We reviewed the billing and medical record documentation for all outpatient pharmacy claims valued at \$5,000 or more. Our review of these 14 claims valued at \$104,235 showed that \$1,866 of these services did not meet requirements for Medicare reimbursement as described below.

Pharmacy Services Not Sufficiently Documented

Our audit disclosed a weakness in SHG's system of internal controls regarding the medical record documentation supporting its outpatient pharmacy charges. Title 42 CFR, §482.24 states that, "...A medical record must be maintained for every individual evaluated or treated in the hospital...The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services."

In support of the charges examined, SHG provided us with patient medical record charts and detailed listings of medications administered to patients. Our analysis showed that SHG submitted four claims containing \$1,866 in medication charges which were billed to Medicare but lacked evidence of administration. Foremost herein was one claim containing \$1,747 in undocumented charges. This claim involved the billing to Medicare of 36 grams of Intravenous Immunoglobulin but medical record documentation showed only the administration of 34 grams.

As a result, we identified \$1,866 in outpatient pharmacy charges which did not meet Medicare's criteria for reimbursement.

Conclusion

For FY 1998, SHG submitted for Medicare reimbursement \$964,432 in charges for outpatient pharmacy services of \$50 or more. As a result of our audit, we determined that a total of at least \$112,030 should not have been billed to the Medicare program as summarized below.

The SHG disclosed \$80,609 in unallowable, self-administered medications at the time of our audit and concurred with an additional \$6,365.

For stratum 1, consisting of a population of \$860,197 in charges ranging from \$50 to \$4,999, we randomly sampled 100 claims with charges amounting to \$44,925 and found \$4,006 in charges unallowable for Medicare reimbursement. Extrapolating the results of the statistical sample for this stratum over the population using standard statistical methods, we are 95 percent confident that SHG billed at least \$23,190 in error for FY 1998. We attained our estimate by using a

variable sample appraisal program.

For stratum 2, consisting of the entire 14 claims with charges of \$5,000 and over, we found that, of the \$104,235 charged, \$1,866 should not have been billed to the Medicare program.

Details of our sample appraisal can be found in APPENDIX A.

Recommendations

We recommend that SHG strengthen its procedures to ensure that charges for pharmacy services are covered and properly documented in accordance with Medicare regulations. We will provide the results of our review to Associated Hospital Services, the Medicare FI, so that it can apply the \$112,030 adjustment to SHG's FY 1998 Medicare cost report.

Auditee Response

The SHG, in its response dated May 18, 2001 (See APPENDIX B), concurred with our recommendations. The SHG indicated that it had developed computer controls to preclude billing for unallowable self-administered medications, implemented new guidelines and procedural controls to ensure accurate billing for EPO, and provided staff training on maintaining proper medical record documentation. In addition, SHG has provided the FI with an adjustment to its FY 1998 cost report to remove charges for the identified self-administered medications and will work with the FI to process the remaining adjustments to the cost report.

APPENDICES

**REVIEW OF
OUTPATIENT PHARMACY SERVICES PROVIDED BY THE
SOUTHCOAST HOSPITALS GROUP**

STATISTICAL SAMPLE INFORMATION

Our population consisted of outpatient pharmacy claims valued at \$50 or more and with dates of service during SHG's FY 1998. Our sample consisted of two strata; claims with charges ranging from \$50 to \$4,999 (Stratum 1), and claims with charges of \$5,000 or more (Stratum 2).

	<u>Stratum 1</u>	<u>Stratum 2</u>
Population		
Items	2,149 Claims	14 Claims
Dollars	\$860,197	\$104,235
Sample ¹		
Items	100 Claims	14 Claims
Dollars	\$44,925	\$104,235
Errors		
Items	23 Claims	4 Claims
Dollars	\$4,006	\$1,866

**PROJECTION OF SAMPLE RESULTS²
Precision at the 90 Percent Confidence Level**

Point Estimate: \$86,075
Lower Limit: \$23,190
Upper Limit: \$148,961

SUMMARY OF TOTAL ERROR

Self-administered Medications	\$86,974
Stratum 1	\$23,190
Stratum 2	<u>\$ 1,866</u>
Total	<u>\$112,030</u>

¹ Projection of sample results was applied only to Stratum 1. All 14 claims in Stratum 2 were reviewed.

² Based on our sample appraisal methodology for Stratum 1, we are 90 percent confident that the dollar value of errors is between \$23,190 and \$148,961. Accordingly, we are 95 percent confident that the dollar value of errors is \$23,190 or more.



May 18, 2001

Michael J. Armstrong
Regional Inspector General for Audit Services
Office of Inspector General
Department of Health and Human Services
John F. Kennedy Federal Building
Boston MA 02203

RE: Review of Outpatient Pharmacy Services for Fiscal Year Ending September 30, 1998
CIN: A-01-00-00555

Dear Mr. Armstrong:

This letter is in response to your draft report on the Office of Inspector General Review of Outpatient Pharmacy Services Provided by Southcoast Hospitals Group for Fiscal Year Ending September 30, 1998.

Self-administered Medications

Last year, the Southcoast Compliance Officer initiated an internal audit of self-administered medications to assess the controls to ensure compliance with Medicare requirements. We appreciate your acknowledgement that SHG identified unallowable charges and that you concur with our results. In November 2000, Southcoast provided the Fiscal Intermediary with the adjustment to the FY 1998 cost report.

Southcoast has established computer controls in the billing system to help ensure, on a pre-billing basis, that only charges consistent with Medicare self-administered drug requirements are billed. Approximately 2,500 outpatient accounts are subjected to this screen each week. Significant education on the Medicare requirements has been provided to management, pharmacy, billing and reimbursement personnel. Additionally, the Medicare rules for self-administered drugs are addressed in hospital-wide compliance training sessions and new employee orientations.

■ *Uniting for our community*

CHARLTON MEMORIAL HOSPITAL
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Fall River, Massachusetts 02720
Telephone (508) 679-7555

Michael J. Armstrong
May 18, 2001
Page 2

Noncovered Services (EPO)

Last year, Southcoast established a multi-departmental team to examine the EPO ordering, dispensing, administration, documentation and billing processes. The team members include pharmacists, nurses, billers, and compliance auditors. New guidelines and procedural controls have been developed to ensure accurate billing of EPO. Southcoast continues to monitor changes in Medicare coverage of EPO and will update policies and procedures as needed.

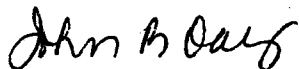
In February 2001, the OIG completed a review of selected Southcoast EPO claims submitted to Medicare during 1999, and the results reflect an accuracy rate of 98.4%.

Services Not Sufficiently Documented

Since 1999, the compliance office of Southcoast has provided compliance education and training to thousands of employees, and medical record documentation is a major focus. Medical record completeness, legibility, and timeliness are emphasized in the training. Compliance staff work closely with clinic personnel to ensure understanding of special documentation requirements of Medicare, particularly medication administration.

Southcoast will cooperate with Associated Hospital Service, the Medicare FI, and process the outstanding stratum 1 and 2 adjustments of \$25,056 to the FY 1998 Medicare cost report.

Sincerely,



John B. Day
President and Chief Executive Officer
Southcoast Health System

Cc: Frank Byrne, Director of Corporate Compliance
Linda Bodenmann, Compliance Officer
Stephen Davis, Esq. Office of Inspector General