DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

June 5, 2001

CIN: A-01-01-00505

Gary Gottlieb, MD
President, North Shore Medical Center
81 Highland Avenue
Salem, Massachusetts 01970

Dear Dr. Gottlieb:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' report entitled "Review of Outpatient Pharmacy Services Provided by Salem Hospital for Fiscal Year Ending September 30, 1999." A copy of this report will be forwarded to the action official noted below for his/her review and any action deemed necessary.

Final determination as to the actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the 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 public to the extent information contained therein is not subject to exemption in the Act. (See 45 CFR Part 5)

To facilitate identification, please refer to Common Identification Number A-01-01-00505 in all correspondence relating to this report.

Sincerely yours,

Michael J. Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:

Mr. George F. 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 OUTPUTPATIENT PHARMACY SERVICES PROVIDED BY SALEM HOSPITAL FOR FISCAL YEAR ENDING SEPTEMBER 30, 1999

SEPTEMBER 2001
A-01-01-00505

Office of Inspector General

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

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:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

Background

The Medicare program reimburses acute care hospitals for 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 that services provided be supported by medical records. These records must contain sufficient documentation to justify the treatment provided. Hospital costs for such services are comprised of the costs of medications and the facility costs for providing these medications to patients. The Hospital's pharmacy department provides medications to outpatients receiving services throughout the Hospital. Claims are submitted for services rendered and reimbursed on an interim basis based on submitted charges. At year end the hospital 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) 1999, Salem Hospital (Hospital) submitted for reimbursement about $3.1 million in charges for outpatient pharmacy services through revenue codes (RC) 250 (pharmacy) and 636 (drugs requiring detail coding.) Our audit focused on those charges of $50 or more, representing $1,472,936 in RC 250 and $1,560,125 in RC 636. To determine whether controls were in place to ensure compliance with Medicare regulations, we reviewed the medical and billing records for a sample of 135 claims charged through RC 250, and 123 claims charged through RC 636, totaling $441,709 and $702,817 respectively. Our analysis showed $58,686 in charges from the RC 250 sample and $20,419 in charges from the RC 636 sample did not meet Medicare criteria for reimbursement. Specifically, we found that the hospital had erroneously billed Medicare for:

- $57,040 in charges through RC 250 and $20,419 in charges through RC 636 for medication not properly supported by medical records.

- $1,646 in charges through RC 250 for medications not reimbursable by Medicare.

We noted that the Hospital did not establish or consistently follow existing procedures for the proper billing and record keeping of outpatient pharmacy services. Based, in part, on a statistical sample, we estimate that at least $106,609 in FY 1999 Medicare outpatient pharmacy charges by the Hospital were not eligible for reimbursement.

Recommendation

We recommend that the Hospital strengthen its procedures to ensure that charges for outpatient pharmacy services are covered and properly documented in accordance with Medicare regulations. We will provide the results of our review to Associated Hospital Service, the Medicare FI, so that it can apply the appropriate adjustment of $106,609 to the Hospital's FY 1999 Medicare Cost Report.

The Hospital, in its response dated May 29, 2001, concurred with our recommendation and noted that it has already begun to take corrective action to ensure that charges for pharmacy services are covered and properly documented in accordance with Medicare regulations. The Hospital's response is attached to the final report in APPENDIX C.

TABLE OF CONTENTS

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. Salem Hospital's (Hospital) pharmacy department provides medications to outpatients receiving services throughout the Hospital. These costs are reimbursed through the Hospital'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 specific exceptions, that Medicare 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) erythropoietin (EPO), (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.

The Hospital is a 255 bed acute care facility located in Salem, Massachusetts. During Fiscal Year (FY) 1999, the Hospital submitted for Medicare reimbursement 5,377 claims for outpatient pharmacy services valued at about $3.1 million.

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 1999.

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 the Hospital.

To accomplish our objective, we:

- Reviewed criteria related to outpatient pharmacy services.

- Interviewed appropriate Hospital staff concerning internal controls over Medicare claims submission.

- Used the Provider Statistical and Reimbursement Report provided by the fiscal intermediary (FI) for the Hospital's FY 1999 to identify 4,496 charges through revenue code (RC) 250 (pharmacy) totaling $1,502,956 and 881 charges through RC 636 (drugs requiring detail coding) totaling $1,564,704. We limited our testing to those claims of $50 or more, the population of which was 1,202 claims, valued at $1,472,936, charged through RC 250 and 409 claims, valued at $1,560,125, charged through RC 636.

- Employed a stratified random sampling approach consisting of two samples, each with two strata. For RC 250, stratum one consisted of a random sample of 100 outpatient pharmacy claims valued from $50 to $6,999 and stratum two consisted of all 35 outpatient pharmacy charges in the population valued at $7,000 or more. For RC 636, stratum one consisted of a random sample of 100 outpatient pharmacy claims valued from $50 to $9,999 and stratum two consisted of all 23 outpatient pharmacy claims in the population valued at $10,000 or more.

- Performed audit testing on the billing and medical records for all 258 claims selected.

- 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 $6,999 (RC 250) stratum. The variable appraisal program was not used to extrapolate the $50 to $9,999 (RC 636) stratum because of the small number of errors found in that stratum.

Our fieldwork was performed from November 2000 through February 2001 at the Hospital in Salem, Massachusetts.

FINDINGS AND RECOMMENDATIONS

In FY 1999, the Hospital submitted for reimbursement about $3 million in charges for outpatient pharmacy services in claims of $50 or more through RCs 250 and 636. We reviewed the medical and billing records for 135 claims charged through RC 250 totaling $441,709 and 123 claims charged to RC 636 totaling $702,817. Our analysis disclosed that $79,105 did not meet the Medicare criteria for reimbursement. Based, in part, on a statistical sample, we estimate that at least $106,609 in FY 1999 Medicare outpatient pharmacy charges by the Hospital were not eligible for reimbursement. Specifically, we found that: (1) pharmacy services were not sufficiently documented and (2) unallowable medications were billed to Medicare. Findings from our review of the sampled claims are described in detail below and in the APPENDICES.

PHARMACY SERVICES NOT SUFFICIENTLY DOCUMENTED

Our audit disclosed a need for improvement in the Hospital's system of internal controls regarding the medical record documentation supporting its outpatient pharmacy charges. Our review of sampled claims from RCs 250 and 636 disclosed a total of $77,459 in Medicare charges reviewed were ineligible for Medicare reimbursement because such services were not sufficiently supported in the Hospital's medical records. In support of the charges examined, the Hospital provided us with patient medical record charts, detailed listings of medications administered to patients, and billing information of services provided.

Revenue Code 250

We reviewed the billing and medical record documentation for a randomly selected sample of 100 outpatient pharmacy claims, between $50 to $6,999, totaling $78,001. We determined that 15 claims had charges totaling $3,817 that did not meet requirements for Medicare reimbursement.

We also reviewed all 35 claims of outpatient pharmacy charges that were greater than or equal to $7,000, totaling $363,708. We determined that 11 claims had charges totaling $53,223 that did not meet requirements for Medicare reimbursement.

Revenue Code 636

We reviewed the billing and medical record documentation for a randomly selected sample of 100 outpatient pharmacy claims, between $50 to $9,999, totaling $347,296 and found no errors.

We also reviewed all 23 claims of outpatient pharmacy charges that were greater than or equal to $10,000, totaling $355,521. We determined that 6 claims had charges totaling $20,419 that did not meet requirements for Medicare reimbursement.

The type of errors we identified included: (1) no evidence of medication being administered, (2) no evidence of physicians' order and (3) billing errors.

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."

PHARMACY SERVICES NOT COVERED BY MEDICARE

We found that the Hospital did not have policies and procedures in place to preclude the billing of $1,646 of unallowable self-administered medications for hospital outpatients to the Medicare program. Our review of the billing and medical record documentation for the random sample of 100 outpatient pharmacy claims for RC 250 identified 24 claims in which self-administered medication totaling $1,646 was improperly billed to Medicare. Our review of the billing and medical record documentation for 35 RC 250 outpatient pharmacy claims with value greater than or equal to $7,000 and for 23 RC 636 outpatient pharmacy claims with value greater than or equal to $10,000 identified no errors. Examples of billing for self-administered medications included patients' day-to-day prescriptions, and over-the-counter medications supplied to the patients during their period of treatment at the Hospital.

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, (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.

CONCLUSION

For FY 1999, the Hospital submitted for Medicare reimbursement approximately $3 million in charges for outpatient pharmacy services of $50 or more under RCs 250 and 636. As a result of our audit, we determined that a total of $106,609 should not have been billed to the Medicare program, as shown below:

Revenue Code	Stratum 1 (Projected)	Stratum 2	Total
250	$32,967	$53,223	$ 86,190
636	$ -0-	$20,419	$ 20,419
Total	$32,967	$73,642	**$106,609**

Details of our sample appraisal for stratum 1 can be found in APPENDICES A and B.

RECOMMENDATION

We recommend that the Hospital 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 Service, the Medicare FI, so that it can apply the appropriate adjustment of $106,609 to the Hospital's FY 1999 Medicare Cost Report.

AUDITEE RESPONSE AND OIG COMMENTS

The Hospital, in its response dated May 29, 2001, concurred with our recommendations and noted that it has already begun to take corrective action to ensure that charges for pharmacy services are covered and properly documented in accordance with Medicare regulations. The Hospital Corporate Compliance Department has established an Improvement Team composed of representatives from Administrative, Clinical, Financial and Operational departments to develop an education and training plan to take immediate corrective action. In addition, the Hospital Compliance Department plans to be proactively monitoring and auditing outpatient pharmacy charges in the future to ensure that Medicare regulations are adhered to. We commend the Hospital's proactive efforts to correct the issues identified during the course of our review. The Hospital's response is attached to this report in APPENDIX C.

OTHER MATTERS

We identified a total of 7 claims, with charges totaling $4,202, that had incomplete physicians' orders or incomplete evidence of the administration of medication. In each instance, medical records indicated that a patient did receive medication, but did not specify the amount of medication received. Title 42 CFR, §482.24 (c) (2) (vi) requires that all records must document the following, as appropriate, including "All practitioners' orders, nursing notes, reports of treatment, medication records…." Although we are not including those errors in our estimate of overcharges, we believe that the hospital should improve its system of medical records to ensure that all physician orders are complete, with respect to dates, dosage and duration, and that medical records contain complete and specific evidence of the administration of all medications.

APPENDICES

STATISTICAL SAMPLING METHODOLOGY
REVENUE CODE 250

ESTIMATE OF OUTPATIENT PHARMACY CHARGES
NOT ELIGIBLE FOR MEDICARE REIMBURSEMENT

To obtain our population for variable sampling, we identified all outpatient pharmacy claims $50 or more charged through Revenue Code 250 in Fiscal Year (FY) 1999. We identified 1,202 claims valued at $1,472,936. From this population we 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 $6,999. Stratum 2 consisted of all 35 outpatient pharmacy claims $7,000 or more in the population. The results of our review of stratum 2 are summarized in the body of this report.

Our review of stratum 1 disclosed that in 34 of the 100 randomly selected claims, $5,463 of the $78,001 sampled charges, did not meet Medicare criteria for reimbursement. Extrapolating the results of our statistical sample for this stratum over the population of 1,167 claims with $1,109,228 in charges and using standard statistical methods, we are 95 percent confident that the Hospital billed at least $32,967 in error for FY 1999. The table below summarizes our statistical projections for these results.

Stratum 1	Claims Sampled	Claims in Error	Error Amount	Point Estimate	90 % Confidence Interval	
					Lower Limit	Upper Limit
$50 to $6,999	100	34	$5,463	$63,750	$32,967	$94,532

APPENDIX B

STATISTICAL SAMPLING METHODOLOGY
REVENUE CODE 636

ESTIMATE OF OUTPATIENT PHARMACY CHARGES
NOT ELIGIBLE FOR MEDICARE REIMBURSEMENT

To obtain our population for variable sampling, we identified all outpatient pharmacy claims $50 or more charged through Revenue Code 636 in Fiscal Year (FY) 1999. We identified 409 claims valued at $1,560,125. From this population we 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 $9,999. Stratum 2 consisted of all 23 outpatient pharmacy claims $10,000 or more in the population. The results of our review of stratum 2 are summarized in the body of this report.

Our review of stratum 1 disclosed that all of the 100 randomly selected claims totaling $347,296 met Medicare criteria for reimbursement. Since there was no error found in this stratum, there was no extrapolation performed.

APPENDIX C

THE NORTH SHORE
MEDICAL CENTER

Salem Hospital

81 Highland Avenue
Salem, Massachusetts 01970
Tel. 978 741-1200

May 29, 2001

Mr. Michael J. Armstrong
Regional Inspector General of Audit Services
Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203

Common Identification Number A-01-01-00505

Dear Mr. Armstrong:

We have reviewed the draft report entitled, "Review of Outpatient Pharmacy Services Provided by Salem Hospital for Fiscal Year Ending September 30, 1999" enclosed in your April 20, 2001 letter.

As you requested we have reviewed the draft report to ensure the validity of the facts and reasonableness of the recommendation presented. In addition, we appreciate the changes to the wording, which were discussed, and agreed upon, between William Bamerick and Brian W. Kozik. Our response to the recommendation included in the draft report is provided below, along with the agreed upon changes to the final report wording.

<u>Salem Hospital Response</u>

We agree with the recommendation to strengthen our procedures to ensure that charges for outpatient pharmacy services are covered and properly documented in accordance with Medicare regulations. The Salem Hospital Corporate Compliance Department continues to be proactive in ensuring Administrative, Clinical, Financial and Operational policies and procedures and internal controls related to physician documentation, medical record documentation and pharmacy documentation are in place and updated as necessary. As the issues identified during the review were brought to the Compliance Department's attention, an Improvement Team was formed with representatives from Administrative, Clinical, Financial and Operational departments to develop an education and training plan to take immediate corrective action. In addition to the education and training which has already occurred, the Compliance Department will be proactively monitoring and auditing Outpatient Pharmacy charges to ensure the policies and procedures and internal controls related to Medicare requirements are strictly adhered to.

I would also like to note in our response that patient care was not impacted by any of the reported findings and that the majority of documentation issues were the result of a lack of consistency in recording the service rendered on all Hospital forms. In addition, the $106,609 in outpatient pharmacy charges represent submitted charges when, in fact the actual reimbursement for those charges were approximately $46,800.

If there is any additional information you require please do not hesitate to contact me directly.

Sincerely,

Gary Gottlieb, MD MBA
President and Chief Executive Officer
The North Shore Medical Center, Inc.

cc: Gordon H. Boudrow, Jr., Chief Financial Officer, North Shore Medical Center
David Wright, Legal Counsel, North Shore Medical Center
Brian W. Kozik, Director of Compliance, North Shore Medical Center