



Office of Audit Services  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203  
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March 9, 2001

CIN: A-01-00-00549

Michael Rosenblatt, M.D.  
President  
Beth Israel Deaconess Medical Center  
330 Brookline Avenue  
Boston, MA 02215

Dear Dr. Rosenblatt:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' (OAS) report entitled "Review of Outpatient Pharmacy Services Provided by the Beth Israel Deaconess Medical Center for Fiscal Year Ending September 30, 1998." 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 (Public Law 90-23), OIG, OAS reports issued to the Department's grantees and contractors are made available, if requested, to members of the press and general public to the extent information contained therein is not subject to the exemptions in the Act which the Department chooses to exercise (45 CFR Part 5). To facilitate identification, please refer to Common Identification Number A-01-00-00549 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink that reads "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  
OUTPATIENT PHARMACY SERVICES  
PROVIDED BY THE BETH ISRAEL  
DEACONESS MEDICAL CENTER  
FOR FISCAL YEAR ENDING  
SEPTEMBER 30, 1998**



**March 2001  
A-01-00-00549**

# ***Office of Inspector General***

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## **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 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) 1998, the Beth Israel Deaconess Medical Center (Hospital) submitted for reimbursement about \$3.6 million in charges for outpatient pharmacy services through revenue codes (RC) 250 and 636. Our audit focused on those charges of \$50 or more, representing \$1,761,336 in RC 250 and \$1,779,415 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 122 claims charged through RC 636, totaling \$292,187 and \$254,088 respectively. Our analysis showed \$48,559 in charges from the RC 250 sample and \$28,296 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:

- \$46,179 in charges through RC 250 and \$28,296 in charges through RC 636 for medication not properly supported by medical records.
- \$2,380 in charges through RC 250 for medications not reimbursable by Medicare.

We noted that the Hospital did not establish or 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 \$221,905 in FY 1998 Medicare outpatient pharmacy charges by the Hospital were not eligible for reimbursement.

In addition, we identified a total of 19 claims, with charges totaling \$41,391 that had incomplete physicians' orders or incomplete evidence of the administration of medication. 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.

### **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 Services of Maine, the Medicare FI, so that it can apply the appropriate adjustment of \$221,905 to the Hospital's FY 1998 Medicare Cost Report.

The Hospital, in its response dated February 28, 2001, concurred with our recommendation and agreed 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

	<b>Page</b>
<b>INTRODUCTION</b>	<b>1</b>
<b>BACKGROUND</b>	<b>1</b>
<b>OBJECTIVE, SCOPE AND METHODOLOGY</b>	<b>1</b>
<b>FINDINGS AND RECOMENDATION</b>	<b>2</b>
<b>PHARMACY SERVICES NOT SUFFICIENTLY DOCUEMNTED</b>	<b>3</b>
<b>PHARMACY SERVICES NOT COVERED BY MEDICARE</b>	<b>4</b>
<b>CONCLUSION</b>	<b>4</b>
<b>RECOMMENDATION</b>	<b>5</b>
<b>AUDITEE RESPONSE</b>	<b>5</b>
<b>OTHER MATTERS</b>	<b>5</b>
<b>APPENDIX A – STATISTICAL SAMPLING METHODOLOGY REVENUE CODE 250</b>	
<b>APPENDIX B – STATISTICAL SAMPLING METHODOLOGY REVENUE CODE 636</b>	
<b>APPENDIX C – THE AUDITEE’S RESPONSE TO THE DRAFT REPORT</b>	

## **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 Beth Israel Deaconess Medical Center'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 591 bed acute care facility located in Boston, Massachusetts. During Fiscal Year (FY) 1998, the Hospital submitted for Medicare reimbursement 14,871 claims for outpatient pharmacy services valued at about \$3.6 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 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 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 FI for the Hospital's FY 1998 to identify 8,195 charges through revenue code (RC) 250 totaling \$1,818,819 and 6,676 charges through RC 636 totaling \$1,809,669. We limited our testing to those claims of \$50 or more, the population of which was 2,665 claims, valued at \$1,761,336, charged through RC 250 and 2,101 claims, valued at \$1,779,415, 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 \$5,499 and stratum two consisted of all 35 outpatient pharmacy claims in the population valued at \$5,500 or more. For RC 636, stratum one consisted of a random sample of 100 outpatient pharmacy claims valued from \$50 to \$6,699 and stratum two consisted of all 22 outpatient pharmacy claims in the population valued at 6,700 or more.
- Performed audit testing on the billing and medical records for all 257 claims selected.
- Utilized the Fiscal Intermediary's (FI) medical review staff to review selected cases.
- Used a variable appraisal program to estimate the dollar impact of improper payments in the \$50 to \$5,499 (RC 250) and the \$50 to \$6,699 (RC 636) strata.

Our fieldwork was performed from June through October of 2000 at the Hospital in Boston, Massachusetts.

The Hospital's response to our draft report is appended to this report (see APPENDIX C).

## **FINDINGS AND RECOMMENDATION**

In FY 1998, the Hospital submitted for reimbursement about \$3.6 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 \$292,187 and 122 claims charged to RC 636 totaling \$254,088. Our analysis disclosed that \$76,855 did not meet the Medicare criteria for reimbursement. Based, in part, on a statistical sample, we estimate that at least \$221,905 in FY 1998 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 weakness in the Hospital's system of internal controls regarding the medical record documentation supporting its outpatient pharmacy charges. Our review of sampled claims from RC 250 and 636 disclosed a total of \$74,475 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 \$5,499, totaling \$60,213. We determined that 26 claims had charges totaling \$4,714 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 \$5,500, totaling \$231,974. We determined that 10 claims had charges totaling \$41,465 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 \$6,699, totaling \$107,400. We determined that 21 claims had charges totaling \$8,259 that did not meet requirements for Medicare reimbursement.

We also reviewed all 22 claims of outpatient pharmacy charges that were greater than or equal to \$6,700, totaling \$146,688. We determined that 3 claims had charges totaling \$20,037 that did not meet requirements for Medicare reimbursements.

The type of errors we identified included: 1) no evidence of medication being administered; 2) no evidence of physicians' order; 3) no identification of specific medications that were charged to Medicare; and 4) missing 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."

## PHARMACY SERVICES NOT COVERED BY MEDICARE

We found that the Hospital did not have policies and procedures in place to preclude the billing 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 16 claims in which self-administered medication totaling \$2,312 was improperly billed to Medicare. Examples of billing for self-administered medications included patients' day-to-day prescription, and over-the-counter medications supplied to the patients during their period of treatment at the Hospital. We also found charges described as take home medication on the Hospitals detail bills.

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.

In addition, we identified one claim, charged to RC 250, totaling \$68, for tubing and a solution that was used in conjunction with a medication that was not approved by the Food and Drug Administration. The investigational medication was not billed to Medicare. According to the FI, if Medicare does not cover a service or medication provided to a patient, then anything associated with it is also not covered by Medicare.

## CONCLUSION

For FY 1998, the Hospital submitted for Medicare reimbursement approximately \$3.5 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 \$221,905 should not have been billed to the Medicare program, as shown below:

Revenue Code	Stratum 1 (Projected)	Stratum 2	Total
250	\$87,380	\$41,465	\$128,845
636	\$73,023	\$20,037	\$93,060
<b>Total</b>	<b>\$160,403</b>	<b>\$61,502</b>	<b>\$221,905</b>

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 Services of Maine, the Medicare FI, so that it can apply the appropriate adjustment of \$221,905 to the Hospital's FY 1998 Medicare Cost Report.

## **AUDITEE RESPONSE**

The Hospital, in its response dated February 28, 2001, concurred with our recommendation and agreed 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.

## **OTHER MATTERS**

We identified a total of 19 claims, with charges totaling \$41,391 that had incomplete physicians' orders or incomplete evidence of the administration of medication. For example, several physicians' orders were undated or did not indicate the duration of the order. In addition, medical records often 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 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**

**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) 1998. We identified 2,665 claims valued at \$1,761,336. 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 \$5,499. Stratum 2 consisted of all 35 outpatient pharmacy claims of \$5,500 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 35 of the 100 randomly selected claims, \$7,094 of the \$60,213 sampled charges did not meet Medicare criteria for reimbursement. Extrapolating the results of our statistical sample for this stratum over the population of 2,630 claims with \$1,529,361 in charges and using standard statistical methods, we are 95 percent confident that the Hospital billed at least \$87,380 in error for FY 1998. 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 \$5,499	100	35	\$7,094	\$186,574	\$87,380	\$285,768

**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) 1998. We identified 2,101 claims valued at \$1,779,415. 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 \$6,699. Stratum 2 consisted of all 22 outpatient pharmacy claims of \$6,700 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 21 of the 100 randomly selected claims, \$8,259 of the \$107,399 sampled charges did not meet Medicare criteria for reimbursement. Extrapolating the results of our statistical sample for this stratum over the population of 2,079 claims with \$1,632,727 in charges and using standard statistical methods, we are 95 percent confident that the Hospital billed at least \$73,023 in error for FY 1998. 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 \$6,699	100	21	\$8,259	\$171,708	\$73,023	\$270,392

## APPENDIX C



**BETH ISRAEL DEACONESS  
MEDICAL CENTER**

A member of CAREGROUP



A major teaching hospital  
of Harvard Medical School

Michael Rosenblatt, MD  
President

February 28, 2001

George R. Minot Professor  
of Medicine  
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Michael J Armstrong  
Regional Inspector General for Audit Services  
Office of Audit Services  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203

Dear Mr. Armstrong:

Thank you for your report entitled, "*Office of the Inspector General (OIG) Draft Report: Review of Outpatient Pharmacy Services Provided by the Beth Israel Deaconess Medical Center for Fiscal Year Ending September 30, 1998,*" (CIN: A-01-00-00549), which outlined the results of your audit involving a review of outpatient pharmacy services. We understand the findings and recommendation that were contained in the report. The Medical Center is strengthening its procedures to ensure that charges for pharmacy services are covered and properly documented in accordance with Medicare regulations.

Sincerely yours,

Michael Rosenblatt, M.D.  
President  
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