



SEP 27 2001

Office of Audit Services
Region I
John F. Kennedy Federal Building
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CIN: A-01-01-00507

Mr. Elwin Bresette
Chief Financial Officer
Lawrence and Memorial Hospital
365 Montauk Avenue
New London, CT 06320

Dear Mr. Bresette:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' (OIG/OAS) report entitled, "Review of Outpatient Pharmacy Services Provided by the Lawrence and Memorial Hospital for Fiscal Year Ending September 30, 1999." 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 to be 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 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-01-01-00507 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:

Judith Berek, Regional Administrator
Centers for Medicare and Medicaid Services – Region II
U.S. Department of Health and Human Services
26 Federal Plaza, Room 3811
New York, New York 10278-0063

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF OUTPATIENT PHARMACY
SERVICES PROVIDED BY
LAWRENCE AND MEMORIAL
HOSPITAL
FOR FISCAL YEAR 1999**



SEPTEMBER 2001

A-01-01-00507

Office of Inspector General

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

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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 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 Lawrence and Memorial Hospital’s (Hospital) 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. Our review covered the fiscal year October 1, 1998 to September 30, 1999 (FY 1999).

Summary of Findings

In FY 99, the Hospital submitted for reimbursement about \$822,995 in charges for outpatient pharmacy services through revenue charge codes (RCC) 250-259 (pharmacy) and 636 (drugs requiring detail coding). Our audit focused on outpatient pharmacy services of \$50 or more valued at \$557,508 and outpatient drug charges of \$700 or more valued at \$121,290. To determine whether controls were in place to ensure compliance with Medicare regulations, we reviewed the medical and billing records for a two strata sample of 112 pharmacy claims totaling \$48,825 and 44 drug claims totaling \$121,290. For the 44 drug claims we found that charges were made in accordance with Medicare regulations. However, our analysis of the 112 pharmacy claims showed that \$9,313 did not meet the Medicare criteria for reimbursement.

Specifically, we noted that:

- \$1,687 in radiology related pharmacy charges, were not covered.
- \$7,626 in other pharmacy charges, were not properly supported by medical records.

We noted that the Hospital did not have or follow existing procedures for the proper billing and record keeping of outpatient pharmacy services. Based, in part, on our statistical sample, we estimated that the Hospital billed at least \$41,210 in pharmacy charges that did not meet the Medicare criteria for reimbursement.

Recommendations

We recommend that the Hospital strengthen its procedures to ensure that only covered charges for outpatient pharmacy services are billed to Medicare. Further, the Hospital should ensure that these covered charges are properly billed, documented, and coded in accordance with Medicare regulations. We will provide the results of our review to Empire Medical Services in Syracuse, New York, the Medicare FI, so that it can apply the appropriate adjustment of \$41,210 to the Hospital's FY 1999 Medicare 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 Hospital's pharmacy department provides medications to outpatients receiving services throughout the Hospital, including, in part, the Hospital's Cancer Center, and its Surgery and Emergency Departments. 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.

Medicare also reimburses providers for the use of contrast material as part of radiology procedures. This contrast material is classified as ionic or non-ionic. According to the Medicare Hospital Manual, §443(3)(g), reimbursement of non-ionic, also referred to as low osmolar contrast material, is allowed only in the following situations: (1) in all intrahectal injections, or (2) in intravenous and intra-arterial injections when the patient has had a previous adverse reaction to the contrast material, a history of asthma or allergy, significant cardiac dysfunction, severe debilitation, or sickle cell disease.

The Hospital is an acute care facility located in New London, Connecticut. During its FY 1999, the Hospital submitted for Medicare reimbursement about \$823,000 in charges for outpatient pharmacy charges under RCCs 250-259 and 636. Of this, \$678,798 was for services of \$50 or more.

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 FI for FY 1999 to identify the Hospital's submitted RCC 250-259 charges totaling \$651,190 and RCC 636 charges totaling \$171,805. For RCC 250-259, we limited our testing to those claims of \$50 or more, the population of which was 2,886 claims, valued at \$557,508. For RCC 636, we limited our testing to those claims with drug charges of \$700 or more valued at \$121,290.
- Employed a stratified random sampling approach consisting of two strata for RCC 250-259. Stratum one consisted of a random sample of 100 outpatient pharmacy claims valued from \$50 to \$999, and stratum two consisted of all 12 outpatient pharmacy claims in the population valued at \$1,000 or more.
- Performed detailed audit testing on the billing and medical records for all 112 outpatient pharmacy claims for RCC 250-259 and for all 44 outpatient drug claims valued at \$700 or more under RCC 636.
- 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 \$999 strata of the RCC 250-259 sample.

Our fieldwork was performed from October of 2000 through March of 2001 at the Hospital in New London, Connecticut.

FINDINGS AND RECOMMENDATION

In FY 1999, the Hospital submitted for reimbursement 2,886 claims for outpatient pharmacy services of \$50 or more valued at \$557,508 and 44 claims for outpatient drug charges of \$700 or more valued at \$121,290. We reviewed the medical and billing records for 112 claims totaling \$48,825 with RCC 250-259 and 44 claims totaling \$121,290 with RCC 636. For the 44 RCC 636 claims we found that charges were made in accordance with Medicare regulations. However, our analysis of the 112 RCC 250-259 claims showed that \$1,687 in radiology related pharmacy charges and another \$7,626 in pharmacy medication charges did not meet the Medicare criteria for reimbursement. Based, in part, on our statistical sample, we estimate that the Hospital overstated its FY 1999 Medicare outpatient pharmacy charges by at least \$41,210. Findings from our review are described in detail below and in APPENDIX A.

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

We reviewed the billing and medical record documentation for a randomly selected sample of 100 outpatient pharmacy claims valued at \$18,211. We determined that \$2,119 (12 percent) did not meet requirements for Medicare reimbursement, as \$1,687 in charges were not for covered services and another \$432 were not properly supported by medical records.

Radiology Related Pharmacy Charges

Our audit disclosed a weakness in the Hospital's procedures for billing Medicare for contrast material used in its radiology procedures. Ionic material, also referred to as other than low osmolar, may be billed as part of the radiology procedure or separately under RCC 255, pharmacy incident to radiology. A more expensive non-ionic material, also referred to as low osmolar contrast material (LOCM), will also be reimbursed by Medicare, but only if certain conditions set forth in the Medicare Hospital Manual ' 443 are met. Based on our analysis of the billing and medical records for the 100 claims in our sample, we found that the Hospital had submitted 70 claims to Medicare containing charges for LOCM without documenting the conditions required to be present for Medicare reimbursement of the more expensive contrast material. Our review further showed that the Hospital received Medicare reimbursement for its LOCM because the Hospital did not bill its LOCM under RCC 636 as required.

According to ' 443(3)(g) of the Medicare Hospital Manual, Medicare only pays for LOCM when it is used in the following situations; (1) in all intrathecal injections, or (2) in intravenous and intra-arterial injections when the patient has had a previous adverse reaction to the contrast material, a history of asthma or allergy, significant cardiac dysfunction, severe debilitation, or sickle cell disease.

The Manual further states that Hospitals are required to bill LOCM under RCC 636, drugs requiring detailed coding, using specified HCPCS codes and the applicable ICD-9-CM diagnosis code to identify the existence of the medical condition which justifies the use of the more expensive LOCM. If an intrathecal procedure is not present, or one of the ICD-9-CM diagnosis codes is not present to indicate the existence of a required medical condition, the FI will deny payment for LOCM. In these instances, LOCM is not covered and should not be billed to Medicare.

For the 70 sample claims containing LOCM charges without the proper coding required for Medicare reimbursement, we subsequently researched each patient's prior medical records. We found 59 patients had a medical condition that would qualify for reimbursement of the LOCM, although such coding was not indicated on the original claim. For the remaining 11 claims totaling \$1,687 in LOCM charges, Hospital medical records did not identify any medical conditions that would warrant the use of LOCM. Therefore, these charges did not meet Medicare's criteria for reimbursement.

This situation resulted from several contributing factors. Citing concerns over patient safety, the Hospital used LOCM exclusively in all radiology procedures throughout FY 1999. As a result, the hospital no longer determined whether the more expensive LOCM was medically necessary, and therefore, stopped documenting whether the patient met any of the qualifying conditions for reimbursement of the more expensive LOCM. In addition, the hospital did not bill the LOCM under RCC 636, drugs requiring special coding and therefore the claims bypassed the FI edits to determine whether the special coding requirements for payment of LOCM were met.

As a result, we concluded that \$1,687 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Medication Charges Not Sufficiently Documented

Our review of the statistical sample of 100 claims also disclosed that \$432 in medication charges were ineligible for Medicare reimbursement because such services were not sufficiently supported in the Hospital's medical records.

Title 42 CFR ' 482.24 states that, A..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 found that the Hospital had submitted 4 claims to Medicare containing charges for outpatient pharmacy services that did not meet requirements for Medicare reimbursement. In these instances, we found that the described medication on the bill was not found or otherwise did not match the quantity documented in the patient's medical record.

As a result, we concluded that \$432 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

REVIEW OF OUTPATIENT PHARMACY CHARGES \$1,000 AND OVER

We reviewed the billing and medical record documentation for all outpatient pharmacy claims valued at \$1,000 or more. Our review of these 12 claims valued at \$30,614 showed that \$7,194 of these services did not meet requirements for Medicare reimbursement as described below.

Medication Charges Not Sufficiently Documented

Our review of the statistical sample of 100 claims disclosed that \$7,194 in charges were ineligible for Medicare reimbursement because such services were not sufficiently supported in the Hospital's medical records.

Title 42 CFR ' 482.24 states that, A..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 12 claims in our sample. Based on our analysis, we found that the Hospital had submitted 4 claims to Medicare containing charges for outpatient pharmacy services, which were not adequately supported in the patients=medical records. In these instances, we found that the described medication on the bill was not found or otherwise did not match the quantity documented in the patient's medical record.

As a result, we concluded that \$7,194 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Conclusion

For FY 1999, the Hospital submitted for Medicare reimbursement about \$557,508 in charges for outpatient pharmacy services of \$50 or more under RCC 250-259 and \$121,290 in charges for outpatient drugs of \$700 or more under RCC 636. As a result of our audit, we determined that at least \$41,210 should not have been billed to the Medicare program as summarized below.

For stratum 1, consisting of a population of \$526,894 in charges ranging from \$50 to \$999, we randomly sampled \$18,211 and found \$2,119 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 the Hospital billed for at least \$34,016 in error for FY 1999. We attained our estimates by using a variable sample appraisal program.

For stratum 2, consisting of the entire 12 claims with charges of \$1,000 and over, we found that, of the \$30,614 charged, \$7,194 should not have been billed to the Medicare program.

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

Recommendations

We recommended that the Hospital strengthen its procedures to ensure that only charges for covered pharmacy services were billed to Medicare. Further, the Hospital should ensure that these covered charges are properly billed, documented, and coded in accordance with Medicare regulations. We will provide the results of our review to the FI, Empire Medicare Services, so that it can apply the appropriate adjustment of \$41,210 to the Hospital's FY 1999 Medicare cost report.

Auditee Response

The Hospital, in its response dated September 17, 2001 (see Appendix B), concurred with our recommendations. The Hospital indicated that it has instituted a patient questionnaire, to be completed prior to administering contrast material, in order to determine whether the patient has a medical condition that would qualify them for Medicare reimbursement of the more expensive LOCM. In addition, the Hospital performed a compliance training of all employees which emphasized the importance of documenting services provided in the medical record. The Hospital also stated its intention to fully comply with the FI to process the proper adjustment to the FY 1999 cost report.

APPENDICIES

**REVIEW OF
OUTPATIENT PHARMACY SERVICES PROVIDED BY THE
LAWRENCE & MEMORIAL HOSPITAL**

STATISTICAL SAMPLE INFORMATION

Our population consisted of outpatient pharmacy claims valued at \$50 or more and with dates of service during the Hospital's FY 1999. Our sample consisted of two strata; claims with charges ranging from \$50 to \$999 (Stratum 1), and claims with charges of \$1,000 or more (Stratum 2).

	<u>Stratum 1</u>	<u>Stratum 2</u>
Population		
Items	2,874 Claims	12 Claims
Dollars	\$526,894	\$30,614
Sample ¹		
Items	100 Claims	12 Claims
Dollars	\$18,211	\$30,614
Errors		
Items	15 Claims	4 Claims
Dollars	\$ 2,119	\$7,194

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

Point Estimate: \$60,904
Lower Limit: \$34,016
Upper Limit: \$87,793

SUMMARY OF TOTAL ERRORS

Stratum 1	\$34,016
Stratum 2	<u>\$ 7,194</u>
Total	<u>\$41,210</u>

¹ Projection of sample results was applied only to Stratum 1. All 12 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 miscoding errors is between \$34,016 and \$87,793. Accordingly, we are 95 percent confident that the dollar value of errors is \$34,016 or more.



LAWRENCE & MEMORIAL HOSPITAL

365 Montauk Avenue, New London, CT 06320 (860) 442-0711

September 17, 2001

CIN: A-01-01-00507

Mr. Michael Armstrong
Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Audit Services, Region I
John F. Kennedy Federal Building
Boston, MA 02203

Dear Mr. Armstrong:

The Hospital has reviewed a draft copy of the report pertaining to "Review of Outpatient Pharmacy Services Provided by the Lawrence & Memorial Hospital for Fiscal Year Ending September 30, 1999" and concurs with your results.

RADIOLOGY RELATED PHARMACY CHARGES The Hospital has made an institutional decision to use low osmolar contrast material on all patients treated. This decision was made based on clinical data that this type of contrast has the least amount of adverse reactions. As a result to your findings related to radiology pharmacy charges, the hospital has instituted a patient questionnaire prior to administering contrast. This questionnaire will determine whether the patient has a medical condition that is covered to administer low osmolar contrast material for Medicare reimbursement purposes. If the Medicare patient does not have a history of or a current condition that is covered, no billing will occur.

MEDICARE CHARGES NOT SUFFICIENTLY DOCUMENTED The Hospital did a compliance training of all employees emphasizing the importance of documentation of services provided, be included in the medical record.

It is our intention to fully comply with the Fiscal Intermediary, Empire Medicare Services for FY 1999 audit, to make the adjustment on the cost report.

Should you have any questions regarding this document, do not hesitate to contact Tina DiCioccio or myself.

Sincerely,



Elwin Bresette
Chief Financial Officer

cc: Cindy Kane
Donna Blakely
Fran Ulschak