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

APR 2 4 2001

CIN:A-01-00-00547

Richard E. Pugh
President & CEO
New Milford Hospital
21 Elm Street
New Milford, Connecticut 06776

Dear Mr. Pugh:

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 the New Milford Hospital for Fiscal Year Ending September 30, 1999." A copy of this report will be forwarded to the action official noted below for her 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-01-00-00547 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
Health Care Financing Administration
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 THE NEW MILFORD HOSPITAL FOR FISCAL YEAR ENDING SEPTEMBER 30, 1999

APRIL 2001
A-01-00-00547

Office of Inspector General

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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. Hospital costs for such services include the costs of medications along with the facility costs for providing these medications to patients. The New Milford Hospital (Hospital) pharmacy department provides medications to outpatients receiving services throughout the Hospital, including, in part, the Hospital's Regional Cancer Center, and its Surgery and Emergency Departments. Claims are submitted for services rendered and are 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 the Hospital's outpatient pharmacy services were billed for and reimbursed in accordance with Medicare regulations.

Summary of Findings

In Fiscal Year (FY) 1999, the Hospital submitted for reimbursement about $1.2 million in charges for outpatient pharmacy services of $50 or more under revenue center code (RCC) 250 - Pharmacy. To determine whether controls were in place to ensure compliance with Medicare regulations, we reviewed the medical and billing records for a sample of 117 claims totaling $271,272. Our analysis showed that $43,972 of these charges did not meet Medicare criteria for reimbursement. Specifically, we noted that the Hospital had erroneously billed Medicare for:

- $29,675 in medications used under conditions not covered by Medicare,
- $13,248 in medications not properly supported by medical records, and
- $1,049 in unallowable self-administered medications.

We noted that the Hospital did not establish or follow existing procedures for the proper billing of outpatient pharmacy services. Based on a statistical sample, we estimate that the Hospital had overstated its FY 1999 Medicare outpatient pharmacy charges by at least $166,160.

Recommendations

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 Empire Medicare Services, the Medicare FI, so that it can apply the appropriate adjustment of $166,160 to the Hospital's FY 1999 Medicare cost report.

The Hospital, in its response dated April 12, 2001 (See APPENDIX B), concurred with our recommendations and indicated that it has implemented procedures to ensure that services are charged in accordance with Medicare regulations.

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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 include 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 Regional 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 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 Hospital is a 95 bed acute care facility located in New Milford, Connecticut. During its FY 1999, the Hospital submitted for Medicare reimbursement about $1.2 million in charges for outpatient pharmacy services of $50 or more 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 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 the Hospital's FY 1999 to identify 865 claims, valued at $1,152,602, for outpatient pharmacy charges of $50 or more from RCC 250.

- 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 17 outpatient pharmacy claims in the population valued at $5,000 or more,

- performed detailed audit testing on the billing and medical records for the 117 claims selected in the sample,

- utilized the FI's medical review staff to review selected claims, and

- used a variable appraisal program to estimate the dollar impact of improper payments in the $50 to $4,999 stratum.

Our field work was performed during July 2000 at the Hospital in New Milford, Connecticut.

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

FINDINGS AND RECOMMENDATIONS

In FY 1999, the Hospital submitted for reimbursement about $1.2 million in charges for outpatient pharmacy services in claims of $50 or more under RCC 250. We reviewed the medical and billing records for 117 selected claims totaling $271,272. Our analysis disclosed that $43,972 of the sampled charges did not meet the Medicare criteria for reimbursement. Based, in part, on a statistical sample, we estimate that the Hospital had overstated its FY 1999 Medicare outpatient pharmacy charges by at least $166,160. Findings from our review of the sample of 117 claims are described in detail below and in the APPENDIX A.

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 $108,339. We determined that $34,759 did not meet requirements for Medicare reimbursement as described below.

Noncovered Services

We found that the Hospital 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 25 claims which contained, in part, charges for the administration of EPO. With the assistance of the FI's medical review staff, we found that 14 of the claims for EPO services were properly billed in accordance with the above requirements. However, the FI found that medical record documentation supplied to us by the Hospital for the remaining 11 claims did not support the covered use of EPO. For example, we found one patient receiving 30,000 units of EPO every two weeks for the treatment of anemia. The medical records for the patient did not show that the patient's anemia was associated with chronic renal failure, AZT or chemotherapy induced in a non-myeloid malignancy to justify need for EPO.

As a result, we concluded that $29,675 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

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. In support of the charges examined, the Hospital provided us with patient medical record charts and detailed billing listings of medications administered to patients. Our review of a statistical sample of claims disclosed that $4,195 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 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 18 claims to Medicare containing charges for outpatient pharmacy services which were not always 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 $4,195 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Self-Administered Medications

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. 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.

Based on our analysis of the 100 claims in our sample, we found that the Hospital submitted to Medicare 15 claims containing unallowable self-administered medications totaling $889. Examples of these medications charged 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 such charges to include pain medication tablets given to patients following outpatient surgery.

As a result, we concluded that $889 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 17 claims valued at $162,933 showed that $9,213 of these services did not meet requirements for Medicare reimbursement as described below.

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. In support of the charges examined, the Hospital provided us with patient medical record charts and detailed listings of medications administered to patients. Our review disclosed that $9,053 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 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 17 claims in our sample. Based on our analysis, we found that the Hospital had submitted 12 claims to Medicare containing charges for outpatient pharmacy services which were not always 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 $9,053 in outpatient pharmacy charges did not meet Medicare's criteria for reimbursement.

Other Errors

Our review of the 17 outpatient pharmacy claims valued at $5,000 or more also showed that the Hospital had included $160 in self-administered medications contained in four claims. Such errors reflect similar instances described previously in this report.

Conclusion

For FY 1999, the Hospital submitted for Medicare reimbursement $1,152,602 in charges for outpatient pharmacy services of $50 or more under RCC 250. As a result of our audit, we determined that a total of at least $166,160 should not have been billed to the Medicare program as summarized below.

For stratum 1, consisting of a population of $989,669 in charges ranging from $50 to $4,999, we randomly sampled 100 claims with charges amounting to $108,339 and found $34,759 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 at least $156,947 in error for FY 1999. We attained our estimate by using a single stage sample appraisal program.

For stratum 2, consisting of the entire 17 claims with charges of $5,000 and over, we found that, of the $162,933 charged, $9,213 should not have been billed to the Medicare program.

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

Recommendations

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 the FI, Empire Medicare Services, so that it can apply the appropriate adjustment of $166,160 to the Hospital's FY 1999 Medicare cost report.

Auditee Response

The Hospital, in its response dated April 12, 2001 (See APPENDIX B), concurred with our recommendations. The Hospital also indicated that it has implemented new procedures to ensure that services are charged in accordance with Medicare regulations and has hired an internal auditor to monitor the Hospital's adherence to these procedures.

APPENDICES

APPENDIX A

REVIEW OF OUTPATIENT PHARMACY SERVICES PROVIDED BY THE NEW MILFORD 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 $4,999 (Stratum 1), and claims with charges of $5,000 or more (Stratum 2).

	Stratum 1	Stratum 2
Population		
Items	848 Claims	17 Claims
Dollars	$989,669	$162,933
Sample[1]		
Items	100 Claims	17 Claims
Dollars	$108,339	$162,933
Errors		
Items	37 Claims	14 Claims
Dollars	$34,759	$9,213

PROJECTION OF SAMPLE RESULTS[2]
Precision at the 90 Percent Confidence Level

Point Estimate: $294,755
Lower Limit: $156,947
Upper Limit: $432,562

SUMMARY OF TOTAL ERRORS

Stratum 1	$156,947
Stratum 2	9,213
Total	$166,160

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1 Projection of sample results was applied only to Stratum 1. All 17 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 $156,947 and $432,562. Accordingly, we are 95 percent confident that the dollar value of errors is $156,947 or more.

NEW MILFORD HOSPITAL
An Affiliate of Columbia-Presbyterian Medical Center

21 Elm Street New Milford, Connecticut 06776-2993
tel. 860 355 2611
www.newmilfordhospital.org

April 12, 2001

BY FAX & OVERNIGHT DELIVERY

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

Re: Common Identification Number A-01-00-00547

Dear Mr. Armstrong:

I am writing in response to your letter, which New Milford Hospital (the "Hospital") received on March 16, 2001, wherein you report to us the findings of your audit referenced as "Review of Outpatient Pharmacy Services Provided By the New Milford Hospital for Fiscal Year Ending September 30, 1999" and make recommendations with respect to the Hospital's internal compliance controls ("Audit Report"). The Hospital has reviewed the Audit Report and based upon its review, hereby agrees that the Hospital had overstated its FY 1999 Medicare outpatient pharmacy charges by at least $166,160.

In addition, we are responding to your request for the status of any action taken or contemplated in response to your recommendations. With respect to the noncovered services, we wish to state that it was never the Hospital's intention to bill the Medicare program for services which were noncovered or medically unnecessary. In all cases subject to the audit, the treating physician believed that the pharmaceutical in question was medically necessary, covered under the circumstances and in the patient's best interests. Notwithstanding, the Hospital now fully realizes the Medicare limitations of coverage and has implemented comprehensive measures to assure that claims for Epoetin are only submitted to Medicare when the Medicare coverage requirements are fully satisfied.

Specifically, the Hospital has redesigned its Medical Oncology Encounter Billing Sheet to require that before Epoetin can be dispensed by the Hospital pharmacy, the ordering physician must document on the Encounter Billing Sheet the patient's laboratory results indicating a specified range of anemia, a diagnosis which supports one of the FDA approved uses for Epoetin (i.e., anemia induced by chemotherapy in patients with non-myeloid

malignancies) and a physician certification with respect to the service being indicated. We believe that this intervention will prevent the ordering of Epoetin for noncovered Medicare services.

While we are confident that the redesigned Medical Oncology Encounter Billing Sheet will address the Epoetin coverage issue, we have taken additional corrective actions. The Hospital has purchased new "front end" software that evaluates a proposed treatment in relation to the patient's ICD-9 code(s). Therefore, if a physician were to offer Epoetin for a patient with anemia, which was not secondary to chemotherapy, the software would alert the physician that the Epoetin would not be covered by Medicare. The advantage of this software is that the physician could provide advance notice to the patient of its noncovered status prior to providing a noncovered service. The Hospital will be conducting quarterly internal audits to monitor compliance with the Medicare rules as it relates to Epoetin coverage.

With respect to the claims submitted to Medicare for "unallowable self-administered medications" for outpatients, the Hospital has discontinued classifying self-administered medications under Revenue Code 250 to avoid inadvertent billing. The Hospital now categorizes self-administered medications as Revenue Code 637, which is the revenue code for non-covered charges under Medicare.

With respect to the identified issues relating to inadequate documentation, the Hospital has engaged an external consultant to present (during the month of May) an inservice on medical documentation and Medicare coverage rules as it relates to the medical, administrative and clinical staff of the Oncology Department.

Finally, the Hospital is pleased to inform you that it has just hired an internal auditor with clinical expertise who will work with the Hospital's Corporate Compliance Officer to monitor adherence to these described corrective actions.

We hope that this has been responsive to your recommendations and assures you of our ongoing commitment to compliance with the Medicare program's rules. If you have any further questions, please do not hesitate to call.

Sincerely,

Richard E. Pugh
President & CEO