



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

CIN: A-01-00-00554

February 16, 2001

Mr. Stephen L. Abbott
President and Chief Executive Officer
Cape Cod Hospital
88 Lewis Bay Road
Hyannis, MA 02601

Dear Mr. Abbott:

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

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231. Office of Inspector General, Office of Audit Services' reports are made available to members of the 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-01-00-00554 in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Armstrong".

Michael J. Armstrong
Regional Inspector General
For Audit Services

Page 2 - Mr. Stephen L. Abbott

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 AT CAPE COD HOSPITAL
FOR FISCAL YEAR ENDING
SEPTEMBER 30, 1998**



**February 2001
A-01-00-00554**

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:

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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.

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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.

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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 “[e]ach 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 hospital’s pharmacy department provides medications to outpatients receiving services throughout the hospital, including, in part, the Hematology/Oncology, Surgery, and Emergency Departments. Claims are submitted for services rendered and are reimbursed on an interim basis based on submitted charges. At year-end, 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, CCH submitted for reimbursement about \$2.1 million in charges for outpatient pharmacy claims of \$50 or more. 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 118 claims totaling \$170,943 with Revenue Charge Code (RCC) 250 and 28 claims totaling \$117,488 with RCC 636. We found no questionable charges in the 28 RCC 636 claims we reviewed. Our analysis of the 118 RCC 250 claims showed that \$87,937 of these charges did not meet the Medicare requirements for reimbursement.

Specifically, we noted that:

- ▶ \$84,310 in charges for Epoetin (EPO) treatments was determined in the medical claims review by the Fiscal Intermediary (FI) to have been incorrectly reimbursed,
- ▶ \$3,126 was billed for medications not properly supported by medical records,
- ▶ \$354 was billed for self-administered drugs not reimbursable by Medicare, and
- ▶ \$147 was billed to Medicare in error due to clerical errors.

We noted that CCH did not have or follow existing procedures for the proper billing of outpatient pharmacy services. Based on the statistical sample, we estimated that CCH had overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$188,989.

Recommendations

We recommend that CCH 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 \$188,989 to the CCH's FY 1998 Medicare cost report.

The Hospital, in its response dated February 2, 2001, believed that (1) Medicare regulations provide little guidance, and (2) the OIG should have emphasized that more than 40% of the alleged overpayment arises from medical care provided to one patient. The Hospital stated that our report "...should be revised to take account of the deficiencies...and the alleged overpayments should be reduced accordingly...." The Hospital also stated that it "...has taken great strides to address the operational deficiencies noted in the Report and, as part of its existing corporate compliance program, has conducted training sessions for many of the affected employees on the pharmacy documentation issues identified by the auditors." We commend the Hospital's corrective action measures, but believe that our final audit determinations are correct. The basis for our position is discussed starting on page 6 of this report.

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 Hematology/Oncology, Surgery, and Emergency Departments. These costs are reimbursed through the hospital's Medicare cost report.

Medicare requirements under 42 Code of Federal Regulations (CFR) Section 482.24(c) state that for benefits to be paid, "...[t]he 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 Section 410.29, with specific 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 Section 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...."

CCH is an acute care facility located in Hyannis, Massachusetts. During its FY 1998, CCH submitted for Medicare reimbursement 3,070 claims for outpatient pharmacy services of \$50 and more valued at about \$2.1 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 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 FY 1998 to identify 3,070 RCC 250 and 636 outpatient pharmacy claims of \$50 and more valuing \$2,107,839;
- ▶ employed a stratified random sampling approach consisting of two strata for each RCC. Stratum 1 consisted of a random sample of 100 outpatient pharmacy claims valued from \$50 to \$4,999. Stratum 2 consisted of all 18 outpatient pharmacy claims for RCC 250 and all 15 claims for RCC 636 in the population of claims \$5,000 or more;
- ▶ performed detailed audit testing on the billing and medical records for all 118 outpatient pharmacy claims for RCC 250. For RCC 636, we discontinued our review after finding no questionable charges for all 15 claims valued at \$5,000 or more and for 13 of our random sample of 100 claims;
- ▶ utilized the FI's medical review staff to review selected cases; and
- ▶ used a variable appraisal program to estimate the dollar impact of improper payments in the total population.

Our fieldwork was performed in August and September of 2000 at the CCH in Hyannis, Massachusetts.

The Hospital's response to our draft report is appended to this report (see APPENDIX B) and is addressed on pages 6 through 7.

FINDINGS AND RECOMMENDATIONS

In FY 1998, the Hospital submitted for reimbursement about \$2.1 million in charges for outpatient pharmacy services in claims of \$50 or more. We reviewed the medical and billing records for 118 claims totaling \$170,943 with RCC 250 and 28 claims totaling \$117,488 with RCC 636. We found no questionable charges in the 28 RCC 636 claims we reviewed. Analysis of the 118 RCC 250 claims disclosed that \$87,937 of these charges did not meet the Medicare criteria for reimbursement. Based, in part, on a statistical sample,¹ we estimate that CCH had

¹ A stratified sampling approach for each RCC was used for this review. Stratum 1 consisted of a randomly selected sample of 100 claims from the population of outpatient pharmacy claims for RCC 250 in the population of claims \$50 to \$4,999. Extrapolation to the population was applied only to Stratum 1.

overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$188,989. Findings from our review of the tested 118 claims are described in detail below and in the APPENDIX A.

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

We reviewed the billing and medical records for all 18 outpatient pharmacy claims of \$5,000 and more valued at \$131,648. Many of these services pertained to chemotherapy treatments and the administration of EPO. Our results showed that CCH should not have billed for \$77,018 in EPO treatments.

EPO Treatments

We found that CCH did not have policies and procedures in place to preclude the billing of unallowable outpatient EPO treatments to the Medicare program. The Medicare Hospital Manual, Section 230.4 Outpatient Therapeutic Services, states that:

“...[t]he FDA approved labeling for EPO states that it is indicated in the treatment of anemia induced by the drug zidovudine..., anemia associated with chronic renal failure, and anemia induced by chemotherapy in patients with non-myeloid malignancies.”

We submitted to the FI for medical review 11 claims. Medical review personnel identified \$77,018 in unallowable charges for EPO treatments because at the time of the treatment, the multiple myeloma condition did not meet the requirements for the EPO. Specifically, the patient had not received chemotherapy treatment in over three years and CCH did not provide sufficient medical documentation demonstrating that EPO was necessary or appropriate for the patient's condition.

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

We randomly selected a sample of 100 outpatient pharmacy claims valued at \$39,295. Our review of the billing and medical records identified 35 claims valued at \$10,919 that did not meet requirements for Medicare reimbursement as described below:

- ▶ \$7,292 for EPO treatments,
- ▶ \$3,126 for pharmacy services insufficiently documented,
- ▶ \$354 for non-covered self-administered medications, and
- ▶ \$147 in billing errors.

EPO Treatments

We found that CCH did not have policies and procedures in place to preclude the billing of unallowable EPO treatments for hospital outpatients to the Medicare program. In addition to Section 230.4 of the Medicare Hospital Manual, Section 3112.4 of the Medicare Intermediary Manual states that EPO is an approved treatment of anemia associated with chronic renal failure for patients with a hematocrit less than 30 percent.

The FI reviewed and reversed their reimbursement of nine claims with \$7,292 of EPO charges, because the patient with chronic renal failure had not met the requirement that anemia was associated with chemotherapy or the hematocrit was greater than 30 percent.

Pharmacy Services Insufficiently Documented

We disclosed a weakness in CCH's system of internal controls regarding the medical documentation supporting its outpatient pharmacy charges. Specifically, our review of the statistical sample of claims found that four claims totaling \$3,126 in charges were ineligible for Medicare reimbursement because such services were not sufficiently supported by CCH's medical records.

Title 42 CFR, Section 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."

Self-Administered Medications

We found that CCH did not have policies and procedures in place to preclude the billing of unallowable self-administered medications for hospital outpatients to the Medicare program. We reviewed the medical and billing records of the 100 randomly selected claims containing outpatient pharmacy charges and identified \$354 in self-administered medications from 20 claims. 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. Medicare Part B requirements under 42 CFR Section 410.29 disallow payments for self-administered medications.

Billing Errors

We also found that procedures were not in place to assure that all claims submitted to Medicare for reimbursement accurately reflected the services rendered to the patient, resulting in \$147 in billing errors. Specifically, one claim valued at \$70 was never administered. The patient's medication record indicated that the medication was not administered on the date specified on the billing.

The Medicare Hospital Manual Section 400(G) requires providers to “[b]ill only for services provided.” The CCH attributed this overpayment to a failure in their pharmacy disbursing system to credit an account after a drug is withdrawn from the system and not administered to a patient on account of a “no show” or other reason.

Further, in the FI's review of claims, three claims with \$77 of overcharges were adjusted because CCH had originally submitted the claims under RCC 250 rather than RCC 636. This resulted in the FI reimbursing the CCH 80 percent of the reasonable charges instead of \$10 per 1,000 units administered.

CONCLUSION

In FY 1998, CCH submitted for Medicare reimbursement \$2.1 million in charges for outpatient pharmacy claims of \$50 or more. We reviewed the medical and billing records for a sample of 118 claims totaling \$170,943 with RCC 250. We noted that CCH did not have or follow existing procedures for the proper billing of outpatient pharmacy services. Based on a statistical sample, we estimated that CCH had overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$188,989. Our results are summarized below.

For stratum 1 (claims from \$50 to \$4,999), 35 of the 100 randomly selected claims did not meet Medicare reimbursement requirements. Extrapolating the results of the statistical sample for this stratum over the population and using standard statistical methods, we are 95 percent confident that CCH billed at least \$111,971 in error for FY 1998. We attained our estimate by using a single stage sample appraisal program.

For stratum 2 (\$5,000 and over), 10 of the 18 claims did not meet Medicare reimbursement requirements.

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

RECOMMENDATIONS

We recommend that CCH strengthen its procedures to ensure that charges for outpatient pharmacy services are reimbursable by Medicare and properly documented in accordance with Medicare regulations. Specifically, for outpatient services, CCH should preclude the billing to the Medicare program of unallowable self-administered medications and EPO treatments. CCH should also submit all charges for outpatient services using the correct revenue codes, that accurately reflect the services rendered to patients, and maintain sufficient support in CCH's medical records of each patient. We will provide the results of our review to Associated Hospital Service, the Medicare Fiscal Intermediary, so that it can apply the appropriate adjustment of \$188,989 to CCH's FY 1998 Medicare cost report.

AUDITEE RESPONSE AND OIG COMMENTS

The Hospital, in its response dated February 2, 2001, believed that (1) Medicare regulations provide little guidance, and (2) the OIG should have emphasized that more than 40% of the alleged overpayment arises from medical care provided to one patient. The Hospital stated that our report "...should be revised to take account of the deficiencies...and the alleged overpayments should be reduced accordingly..." The Hospital also stated that it "...has taken great strides to address the operational deficiencies noted in the Report and, as part of its existing corporate compliance program, has conducted training sessions for many of the affected employees on the pharmacy documentation issues identified by the auditors." We commend the Hospital's corrective action measures, but believe that our final audit determinations are correct. We have summarized the Hospital's response below and have provided our comments.

Auditee Reponse Regarding Medicare Regulations Providing Little Guidance

The Hospital stated that its utmost concern "...has always been to ensure that its patients receive the outpatient pharmacy services they need..." The Hospital relies on "the clinical judgment of its clinicians to provide CCH patients with appropriate pharmaceuticals and pharmacological therapies..." The Hospital's billing personnel then "endeavor to bill for those services in keeping with Medicare regulations and guidelines..." The Hospital contends, however, that those regulations and guidelines are of no help in defining self-administered medications and in specifically listing such medications. The Hospital states that "...Medicare has never been able to agree on what drugs and/or biologicals are truly 'self-administered' and in what contexts..." The Hospital requests that OIG issue an instruction to CCH's fiscal intermediary to provide all Massachusetts hospital providers with a definitive list of self-administered medications that will "contain all drugs, specify dosages and modes of administration, and note under what clinical circumstances each such drug/biologic will not be deemed to be 'self-administered'..."

OIG Comments

We believe that existing criteria pertaining to the noncoverage of self-administered medications under Medicare Part B is adequate. Many of the self-administered medications we found were patients' day-to-day prescriptions and over-the-counter medications supplied to the patients during their period of treatment at the Hospital.

Auditee Response Regarding the Two Billing Errors Identified

The Hospital stated that our report emphasized the dollar value of the \$77,018 in alleged overpayments for the review of outpatient pharmacy charges of \$5,000 and over, but minimizes the fact that eleven of these claims, accounting for more than 40% of the alleged overpayment, pertained to chemotherapy treatments and the administration of Epoetin for a single patient. The Hospital attached to their written response a signed statement of the physician who cared for this patient prior to her death in 1998, describing the patient's underlying medical conditions they believe substantiates that the patient did benefit from the Epoetin treatments and that they were

provided for conditions covered by Medicare. The Hospital stated "...[i]t is unclear how much of the patient's underlying medical documentation the auditors actually reviewed in preparing the Report-- and CCH hopes that with the accompanying submission of the signed statement from [the physician], the disallowance on these 11 claims will be reversed."

OIG Comments

We recognize that the 11 disallowed claims identified in our audit report represent over 40% of the alleged overpayment in the stratum of outpatient pharmacy charges of \$5,000 and over, and pertained to chemotherapy treatments and the administration of EPO for a single patient.

To confirm whether these claims should be disallowed, we submitted copies of supporting medical documents from the patient's file to the FI for medical review. Medical review personnel reviewed the documents and deemed the \$77,018 in charges for EPO treatments as unallowable. Specifically, the patient had not received chemotherapy treatment in over three years and CCH did not provide sufficient medical documentation to demonstrate that EPO was necessary or appropriate for the patient's condition. Accordingly, our final report recommends that CCH make a financial adjustment of \$77,018.

[CCH's response to our draft report included a statement prepared by the physician subsequent to the issuance of our draft report. We did not attach this statement to this report because it contains personal information about the patient and about the physician. However, we have furnished a copy of the physician's statement to the FI.]

APPENDICES

**ESTIMATE OF OUTPATIENT PHARMACY CHARGES
NOT ELIGIBLE FOR MEDICARE REIMBURSEMENT**

To obtain our population for variable sampling, we identified all outpatient pharmacy claims \$50 and more with Revenue Charge Code 250 from the Provider Statistical and Reimbursement Report provided by the Fiscal Intermediary for Cape Cod Hospital (CCH) in Fiscal Year (FY) 1998. We identified 2,008 claims valued at \$1,033,031. 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 \$4,999. Stratum 2 consisted of all 18 outpatient pharmacy claims in the population of claims \$5,000 and more.

Our review disclosed that in 35 of the 100 randomly selected claims, \$10,919 of the \$39,295 sampled charges did not meet Medicare criteria for reimbursement. Extrapolating the results of our statistical sample for this stratum over the population of 1,990 claims with \$901,383 in charges and using standard statistical methods, we are 95 percent confident that CCH billed at least \$111,971 in error for FY 1998. The table below summarizes our statistical projections for these results. When the estimated \$111,971 overcharge is combined with the \$77,018 of the \$131,648 overcharge in the 10 of 18 claims for \$5,000 and over, the total CCH overcharge for outpatient pharmacy services in FY 1998 is \$188,989.

Outpatient Pharmacy Overcharged	Sample Errors	Point Estimate	90% Confidence Interval	
			Lower Limit	Upper Limit
Number of Claims \$50 to \$4,999	35			
Amount \$50 to \$4,999	\$10,919	\$217,293	\$111,971	\$322,615

EXHIBIT A

Exhibit A of Cape Cod Hospital's response to the draft report has been excluded to protect patient confidentiality.

However, the Exhibit will remain on file with the Office of Inspector General as part of the Hospital's official response.

CHOATE, HALL & STEWART

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February 2, 2001

BY MESSENGER DELIVERY

Mr. Michael J. Armstrong
Regional Inspector General
for Audit Services
U.S. Department of Health and Human Services
John F. Kennedy Federal Building
Boston, Massachusetts 02203

RE: CIN: A-01-00-00554
Cape Cod Hospital (Hyannis, MA)
Outpatient Pharmacy Review (FY 98)

Dear Mr. Armstrong:

We represent Cape Cod Hospital ("CCH") in connection with a review by the Office of the Inspector General (the "OIG") of certain outpatient pharmacy services provided at CCH during its fiscal year ended September 30, 1998 ("FY 98"). You recently delivered preliminary findings from that review to CCH, in a report dated January 2001 (the "Report"). As requested at the end of the Report, CCH submits the following written comments about it:

I. **GENERAL COMMENTS**

CCH disagrees with the conclusions in the Report for three principal reasons, each of which is examined separately below.

First, while the Report alleges certain deficiencies in CCH's record-keeping procedures and related internal controls, it does not refute that medically necessary outpatient pharmacy services were provided to patients at CCH throughout FY 98. These services were provided in a clinically appropriate manner and by qualified, dedicated professionals. Moreover, the Report does not mention nor even reflect the existence of the many policies, procedures and internal controls which were put in place by CCH after FY 98 but before this audit. Those initiatives would not be reflected in the patient records used by the auditors in preparing the Report due to, among other factors, the age and limited nature of the information actually reviewed by them.

Second, in billing for these pharmacy services, CCH did its best to follow regulations which often provide no guidance as to the subjects they supposedly control (such as which drugs are "self-administered" in what contexts). Any errors CCH may have made in billing the outpatient pharmacy services therefore, are understandable and certainly were inadvertent.

Third, more than 40% of the alleged overpayment arises from medical care provided to one patient. With respect to this one patient, it appears that the auditors may have failed to review all of the relevant medical records and, consequently, determined incorrectly that the relevant Epoetin treatments did not meet applicable Medicare coverage requirements. The treating physician has submitted a signed attestation about his care of this patient, including the clinical conditions giving rise to her need for Epoetin. That signed statement is appended as an exhibit to this submission and clearly substantiates the clinical appropriateness of such treatments from a Medicare coverage perspective.

II. SPECIFIC POINTS OF DISAGREEMENT

(A) The Regulations Provide Little Guidance.

CCH has tried as best it can to abide by the regulations and other instructions applicable to billing for outpatient pharmacy services. CCH's overarching concern, however, has always been to ensure that its patients receive the outpatient pharmacy services they need. CCH relies on the clinical judgment of its clinicians to provide CCH patients with appropriate pharmaceuticals and pharmacological therapies, and the Report does not refute that such care was indeed rendered throughout FY98. CCH's billing personnel then endeavor to bill for those services in keeping with Medicare regulations and guidelines. In many instances, however, those regulations and guidelines are of no help. For example, nowhere in the regulations or guidelines is there a definitive list of "self-administered" medications. In fact, Medicare has never been able to agree on what drugs and/or biologicals are truly "self-administered" and in what contexts.¹

CCH requests that as part of its final report, the OIG issue an instruction to CCH's fiscal intermediary to provide all Massachusetts hospital providers with a definitive list of self-administered medications. To be of any real value to these providers, however, the list should contain all drugs, specify dosages and modes of

¹ It is interesting to note that past Medicare commissions and/or working groups abandoned their efforts to compile a definitive list of "self-administered" medications because of, among other things, their inability to reach agreement as to which medications are/are not truly self-administered. Consequently, providers such as CCH are left with an ambiguous "we'll know it when we see it" standard.

administration, and note under what clinical circumstances each such drug/biologic will not be deemed to be "self-administered."²

(B) One Patient's Claims Comprise More than 40% of the Alleged Overpayment.

With respect to that section of the Report dealing with the auditors' review of outpatient pharmacy charges of \$5,000 and over, the Report indicates that the auditors reviewed all 18 claims from FY 98 which fell into this category (total charges of \$131,648). The Report notes that eleven of these claims (total charges of \$77,018) pertained to chemotherapy treatments and the administration of Epoetin. All eleven claims pertain to a single patient.

The auditors found that this one patient had not received chemotherapy treatment in over three years, and that CCH did not provide sufficient medical documentation to them as to the appropriateness of the patient's treatment with Epoetin. The physician who cared for this patient (prior to her death in 1998) reviewed the auditors' findings and then prepared a signed statement relative to the medical necessity of the patient's Epoetin treatments. A copy of that statement is attached as Exhibit A.

The physician's description of the patient's underlying medical conditions substantiates that she benefited from the Epoetin treatments and that they were provided for conditions covered by Medicare. Among other things, the physician confirms the patient's renal failure and anemia induced by chemotherapy (both covered conditions for Epoetin under Section 230.4 of the Medicare Hospital Manual). Moreover, he details the patient's other associated medical conditions, all of which clearly substantiate the appropriateness of treating her with Epoetin. It is unclear how much of the patient's underlying medical documentation the auditors actually reviewed in preparing the Report -- and CCH hopes that with the accompanying submission of the signed statement from the physician, the disallowance on these 11 claims will be reversed.

² For example, many cardiac patients routinely take nitroglycerin tablets to relieve their angina. Such tablets are placed under the tongue, where they are more rapidly absorbed. It is usually the patient who places the tablet under his/her own tongue, thereby self-administering the medication. In the context of a hospital's emergency room, however, where this same patient has presented (sometimes via ambulance) with severe chest pain, the patient may be given a nitroglycerin tablet by a nurse or physician -- because the patient is physically incapable of self-administering the tablet to him/herself. Under those circumstances is the nitroglycerin tablet a self-administered medication? The applicable Medicare regulations and guidelines provide no answer.

II. CONCLUSIONS

The Report should be revised to take account of the deficiencies noted above and the alleged overpayments should be reduced accordingly. CCH has taken great strides to address the operational deficiencies noted in the Report and, as part of its existing corporate compliance program, has conducted training sessions for many of the affected employees on the pharmacy documentation issues identified by the auditors. Moreover, pharmacy-related policies have been reviewed and, where indicated, revised in light of the issues noted in the Report. CCH had put many of these policies into place prior to this audit yet after the patients comprising it had been treated at CCH. The Report makes no mention of these initiatives and it is unlikely that the auditors would have identified them by way of the documents they reviewed while at CCH.

Very truly yours,

Michael G. Jones, P.C.
Michael G. Jones, P.C.

cc: Cape Cod Hospital
ex.3217333.1doc

We noted that CCH did not have or follow existing procedures for the proper billing of outpatient pharmacy services. Based on the statistical sample, we estimated that CCH had overstated its FY 1998 Medicare outpatient pharmacy charges by at least \$188,989.

Recommendations

We recommend that CCH 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 \$188,989 to the CCH's FY 1998 Medicare cost report.

The Hospital, in its response dated February 2, 2001, believed that (1) Medicare regulations provide little guidance, and (2) the OIG should have emphasized that more than 40% of the alleged overpayment arises from medical care provided to one patient. The Hospital stated that our report "...should be revised to take account of the deficiencies...and the alleged overpayments should be reduced accordingly...." The Hospital also stated that it "...has taken great strides to address the operational deficiencies noted in the Report and, as part of its existing corporate compliance program, has conducted training sessions for many of the affected employees on the pharmacy documentation issues identified by the auditors." We commend the Hospital's corrective action measures, but believe that our final audit determinations are correct. The basis for our position is discussed starting on page 6 of this report.