JAN 3 1 2002

CIN: A-01-01-00550

Mr. Stephen 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 (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) audit entitled “Review of Medicare Transitional Pass-Through Payments Made Under the Hospital Outpatient Prospective Payment System for Drugs, Biologicals, and Medical Devices at Cape Cod Hospital for the Period August 1, 2000 through June 30, 2001.” 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), OIG, OAS reports issued are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)
To facilitate identification, please refer to Common Identification Number A-01-01-00550 in all correspondence related to this report.

Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Roger Perez
Acting Regional Administrator
Centers for Medicare and Medicaid Services – Region I
Room 2325
J.F.K. Federal Building
Boston, Massachusetts 02203
REVIEW OF MEDICARE TRANSITIONAL PASS-THROUGH PAYMENTS MADE UNDER THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM FOR DRUGS, BIOLOGICALS, AND MEDICAL DEVICES AT CAPE COD HOSPITAL FOR THE PERIOD AUGUST 1, 2000 THROUGH JUNE 30, 2001

JANET REHNQUIST
Inspector General

JANUARY 2002
A-01-01-00550
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

**Office of Audit Services**

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

**Office of Evaluation and Inspections**

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

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.
JAN 31 2002

CIN: A-01-01-00550

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

Dear Mr. Abbott:

This report provides the results of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services’ (OAS) audit entitled “Review of Medicare Transitional Pass-Through Payments Made Under the Hospital Outpatient Prospective Payment System for Drugs, Biologicals, and Medical Devices at Cape Cod Hospital for the Period August 1, 2000 through June 30, 2001.” A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

The objective of our review was to determine whether transitional pass-through payments for drugs, biologicals, and medical devices were reimbursed in accordance with Medicare laws and regulations.

Generally, we found that the hospital was reimbursed for pass-through drugs, biologicals, and medical devices in accordance with Medicare laws and regulations. However, we did identify isolated billing issues dealing with the submission of charges for pass-through devices, units billed for pass-through drugs and incorrect coding that need to be corrected. We recommend that Cape Cod Hospital (CCH) strengthen its existing controls to ensure that pass-through payments are billed correctly.

In response to our draft report, CCH agreed with our findings and identified what steps they have taken, and plan to take, to improve controls over pass-through billing.

BACKGROUND

In August 2000, the Centers for Medicare and Medicaid Services (CMS) implemented the new prospective payment system for hospital outpatient services (OPPS). The Balanced Budget Act of 1997 amended section 1833(t) of the Social Security Act (the Act) authorizing the implementation of OPPS. The Congress enacted major changes to OPPS in 1999 under the
provides for temporary additional payments or “transitional pass-through payments” for certain innovative medical devices, drugs and biologicals for Medicare beneficiaries. The Congress intended these items to be available to Medicare beneficiaries, even if the price for these new and innovative items exceeded Medicare’s regular scheduled OPPS payment amount. As a result, beginning in August 2000, when OPPS was implemented, Medicare began paying for qualified transitional pass-through items above and beyond OPPS payment rates. For drugs and biologicals, the pass-through payment is the amount by which 95 percent of the average wholesale price exceeds the applicable fee schedule amount associated with the drug or biological. For devices, the pass-through payment equals the amount by which the hospital’s charges, adjusted to cost, exceeds the OPPS payment rate associated with the device.

The CCH is a 218 bed community hospital located in Hyannis, Massachusetts.

OBJECTIVE, SCOPE AND METHODOLOGY

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine whether transitional pass-through payments for drugs, biologicals, and medical devices were reimbursed in accordance with Medicare laws and regulations. Based on our analysis of the CMS National Claims History file, we judgmentally selected CCH for review. To accomplish our objective we:

• Used the CMS National Claims History file to identify pass-through payments made to the hospital.

• Generated a stratified statistical sample of 100 pass-through payments for drugs, biologicals, or medical devices with dates of service between August 1, 2000 and June 30, 2001. Our sample included 70 payments for drugs and biologicals and 30 payments for medical devices.

• Reviewed applicable CMS Program Memoranda to determine the eligibility of sample drugs, biologicals and medical devices.

• Obtained an understanding of the hospital’s billing process through meetings with hospital personnel.

• Reviewed the hospital’s itemized bills, Medicare UB-92 claim forms, Med A Paid Claim Detail screens and pharmacy documents to ensure the sample items were billed appropriately and paid correctly by Medicare.

Our review was based on billing records. We did not review medical records to verify that sample items were actually provided and were medically necessary and appropriate.

We limited our consideration of the internal control structure to those controls concerning the accumulation of charges, creation of outpatient bills and submission of Medicare claims because the objective of our review did not require an understanding or assessment of the complete
internal control structure at the hospital.

We conducted our review at CCH in Hyannis, Massachusetts during the period September through October 2001. On December 27, 2001 we provided CCH with a copy of our draft report. Their written comments are included as an appendix to this report.

RESULTS OF REVIEW

Medicare reimbursed the hospital $122,419 for our statistical selection of 100 sample items -- $42,504 for the 70 pass-through drugs and $79,915 for the 30 pass-through medical devices. Generally, we found that the hospital was reimbursed for pass-through drugs, biologicals, and medical devices in accordance with Medicare laws and regulations. However, we did identify isolated billing issues dealing with the submission of charges for pass-through devices, units billed for pass-through drugs and incorrect coding that need to be corrected. These issues could result in both overbilling and underbilling of pass-through items by CCH.

Charges for Pass-Through Devices Included Charges for Other Medical Supplies

In three instances, CCH did not break out charges for other medical supplies from charges associated with devices eligible for transitional pass-through payments on its Medicare claim forms.

For example, billed charges for an eligible defibrillator pacemaker included defibrillator pads. Defibrillator pads are not eligible for transitional pass-through payments and their associated charges should not have been included with the charges for the eligible device.

Reimbursement for medical supplies that are not eligible for transitional pass-through payments are packaged into the Ambulatory Payment Classification (APC) payment for the associated procedure or service. Because CCH did not break out other medical supply charges, for which payment is packaged into the APC rate, these charges were inappropriately included in the transitional payment amount for the eligible devices.

Pass-Through Drugs Incorrectly Billed

For several of the drugs reviewed, the number of units billed to Medicare did not agree with the number of units dispensed according to the hospital’s pharmacy records. For example, according to CMS Program Memorandum, Transmittal A-00-42, issued July 26, 2000, each 10 milligram dose of Etoposide should be billed using 1 unit of HCFA Common Procedure Coding System (HCPCS) code J9181. In one case we reviewed, the hospital billed Medicare for 10 units, or 100 milligrams, of Etoposide; however, pharmacy records indicate that 190 milligrams, or 19 units, of the drug were dispensed.
Incorrect Coding

A pacemaker system includes a pulse generator containing electronics, a battery and one or more electrodes (leads). According to hospital officials, CCH does not perform the placement or removal of pacemaker electrodes on an outpatient basis. The hospital maintains the correct HCPCS codes for the procedures related to one of our sample items were 33213, Insertion or replacement of dual chamber pacemaker pulse generator only, and 33233, Removal of permanent pacemaker pulse generator. However, we found CCH used HCPCS code 33208, Insertion or replacement of permanent pacemaker with transvenous electrodes(s); atrial and ventricular.

In addition, our review of hospital invoices found that CCH billed for eligible dual chamber pacemakers when single chamber pacemakers were provided to two Medicare beneficiaries.

Although CCH billed for dual chamber pacemakers when invoices indicate that single chamber devices were provided, the single chamber pacemakers were eligible for transitional pass-through payments. Despite the fact that that hospital did appear to provide eligible devices, the use of incorrect HCPCS codes impacts the integrity of the data CMS may use to make future decisions regarding the reimbursement of transitional pass-through devices.

RECOMMENDATIONS

We believe the issues discussed above present opportunities for the hospital to further enhance its existing controls related to the accumulation of charges, creation of outpatient bills and submission of Medicare claims. Specifically, we recommend CCH:

- Strengthen its controls over the billing process to ensure that charges for pass-through devices do not include charges for other medical supplies and pacemaker procedures and eligible pass-through items are correctly coded.

- Review billing for transitional pass-through drugs to verify that billed units are proper.

AUDITEE COMMENTS

The CCH agreed with our findings and recommendations. The full text of the hospital’s comments are included as the APPENDIX to this report.

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.

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Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Roger Perez
Acting Regional Administrator
Centers for Medicare and Medicaid Services – Region I
Room 2325
J.F.K. Federal Building
Boston, Massachusetts 02203
APPENDIX
Michael J. Armstrong  
Regional Inspector General for Audit Services  
Region I  
John F. Kennedy Federal Building  
Room 2425  
Boston, MA 02203  

Dear Mr. Armstrong:  

Cape Cod Hospital ("CCH") has reviewed the findings set out in Report #A-01-01-00550 (the "Report"). CCH makes every effort to report all of its services in accordance with established Medicare requirements and published guidelines. With respect to pass-through medications and devices, the late passage of the OPPS regulations and the constant changes in reimbursement status and/or eligibility make ongoing monitoring and compliance extremely difficult. Periodic training has been and will continue to be provided to all relevant CCH employees and professional staff to ensure that they remain aware of the applicable Medicare reporting requirements. Additionally, CCH will endeavor to strengthen its internal controls in the billing processes for pass-through medications and devices. With respect to CCH's under billing of Etoposide (a pass-through medication), CCH has corrected the billing software which gave rise to the under-reporting of unit doses and is grateful to the government auditors for pointing out this lost revenue.

Very truly yours,

[Signature]

Stephen J. Guimond  
Senior Vice President & CFO

SJG: cah  
via: certified mail

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