

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE
TRANSITIONAL PASS-THROUGH
PAYMENTS MADE UNDER THE
HOSPITAL OUTPATIENT PROSPECTIVE
PAYMENT SYSTEM FOR DRUGS,
BIOLOGICALS, AND MEDICAL
DEVICES AT LEHIGH VALLEY
HOSPITAL**



**JANET REHNQUIST
INSPECTOR GENERAL**

**JANUARY 2002
A-03-01-0023**



DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OFFICE OF AUDIT SERVICES
150 S. INDEPENDENCE MALL WEST
SUITE 316
PHILADELPHIA, PENNSYLVANIA 19106-3499

January 22, 2002

Our Reference: Common Identification Number A-03-01-00023

Dr. Elliot Sussman, CEO
Lehigh Valley Hospital
1200 South Cedar Crest Boulevard
Allentown, Pennsylvania 18105

Dear Dr. Sussman:

This final report presents the results of our review of Medicare Transitional Pass-Through Payments Made Under the Hospital Outpatient Prospective Payment System for Drugs, Biologicals, and Medical Devices at Lehigh Valley Hospital (LVH) for the period August 1, 2000 to June 30, 2001. 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 review of payments to LVH for 100 sampled items, we found, with minor exceptions, that LVH complied with Medicare laws and regulations for billing transitional pass-through drugs, biologicals and medical devices. These minor exceptions had an insignificant effect on the overall Medicare reimbursement.

In a written response to our draft report, LVH concurred with our findings and agreed to take the necessary actions to implement our recommendation. The full text of LVH's response is included with this report as an Appendix.

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 Balanced Budget Refinement Act adding Section 1833(t)(6) to the Act. Section 1833(t)(6) 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 prices for these new and innovative items exceeded Medicare's regular scheduled OPPS payment amounts. 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 LVH, a part of the Lehigh Valley Health Network, is one of the largest teaching facilities in Pennsylvania. The LVH is recognized as a leading regional source in its key clinical areas: cancer treatment, cardiovascular medicine, mental health, neurosciences, pediatrics, surgery services, trauma, women's health, perinatal care, kidney transplantation and burn treatment. The hospital is an advanced acute care facility with more than 800 patient beds in operation on three sites.

OBJECTIVE SCOPE AND METHODOLOGY

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

To accomplish our objective we:

- ❖ Used CMS's National Claims History File to identify pass-through payments made to LVH;
- ❖ Generated a stratified random sample of services based on status code ("G" Current Drugs or Biologicals, "J" New Drugs and Biologicals, and "H" Devices) each of which represented one line item of service from a paid hospital claim;
- ❖ Reviewed the itemized bill, Medicare claim (UB-92) and remittance advice to determine if each sample item was billed appropriately and paid correctly by Medicare;
- ❖ Obtained an understanding of the hospital's billing process through meetings with hospital personnel; and
- ❖ Reviewed applicable Federal registers and CMS Program Memoranda to determine the eligibility of devices for pass-through payment.

Our review was conducted in accordance with generally accepted government auditing standards. Since the objective of our review did not require an understanding or assessment of the complete internal control structure at LVH, we limited our review to

obtaining an understanding of the controls concerning the accumulation of charges, creation of outpatient bills and submission of Medicare claims.

We conducted our review during September and October 2001 at LVH's administrative offices in Bethlehem, Pennsylvania.

RESULTS OF REVIEW

We determined that LVH generally was reimbursed for pass-through drugs, biologicals and medical devices in compliance with Medicare laws and regulations. However, we did note a few minor billing errors. Medicare reimbursed LVH \$57,327 for the 100 sample items, \$43,514 for 70 drugs/biologicals and \$13,813 for 30 medical devices.

We identified four instances where the quantity of a drug billed Medicare did not agree with the quantity actually dispensed per the patient's daily encounter form. These discrepancies occurred in converting the amount of the drug dispensed to the amount billed and resulted in both over and underpayments. We discussed these differences with LVH officials who agreed with our conclusions.

The LVH incorrectly billed Procedure code C1057 three times. Included in the amounts billed were three items: a Stereotactic Breast Biopsy clip, which was an approved device, and a Stereotactic Probe and a Probe Guide which were not approved as pass-through devices and should not have been billed as a pass-through item. We discussed these items with LVH officials who agreed with our conclusions and stated that they have taken action to adjust the claims and strengthen billing controls.

CONCLUSION AND RECOMMENDATION

For the most part, the drugs, biologicals and devices in our sample were eligible for reimbursement as pass-through items. We also found that, with the exception of some minor billing errors, LVH billed and was reimbursed for these pass-through items in accordance with Medicare rules and regulations.

To prevent such errors from occurring in the future, we recommend that LVH use the results of our audit to stress to its employees the need to use correct data in generating Medicare claims.

LVH'S RESPONSE

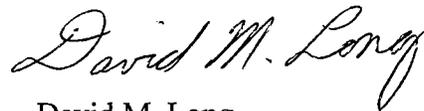
In a written response to our draft report, LVH concurred with our findings and agreed to take the necessary actions to implement our recommendation. The full text of LVH's response is included with this report as an Appendix.

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 the information contained therein is not subject to exemptions in the Act. (See CFR 45 Part 5).

To facilitate identification, please refer to Common Identification Number A-03-01-00023 in all correspondence relating to this report

Sincerely yours,



David M. Long
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Steven McAdoo, Acting Regional Administrator
Centers for Medicare and Medicaid Services, Region III
Public Ledger Building, Suite 216
150 S. Independence Mall West
Philadelphia, Pennsylvania 19106-3499

LEHIGH VALLEY
HOSPITAL AND
HEALTH NETWORK

January 8, 2002

Mr. David Long
Regional Inspector General for Audit Services
150 South Independence Mall West, Suite 316
Philadelphia, PA 19106-3499

RE: Common ID Number A-03-01-00023

Dear Mr. Long:

Dr. Sussman has referred to me your December 14, 2001 letter concerning your offices review of Medicare Transitional Pass-Through Payments under Hospital Outpatient PPS at Lehigh Valley Hospital.

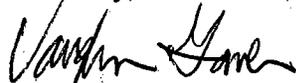
Our response to the conclusion and recommendation found in the draft report attached to your letter is as follows:

LVH Patient Accounting and Pharmacy staff have reviewed the charge description master and made changes that will make it easier for staff doing the pharmacy charging to bill the correct number of units. This review has also served to increase staff awareness of the importance of charging for the correct number of units. The final audit report will be shared with Patient Accounting and Pharmacy management and staff to further stress the importance of correct billing.

The charge description master has been adjusted to bill only the Stereotatic Breast Biopsy clip as a pass-through item using CPT code C1057. The Probe and the Guide are no longer billed using a pass-through CPT code.

We understand this response will be incorporated into the final audit report. Thank you for the opportunity to respond. I would like to add that your audit staff was professional and mindful of my staff's regular duties during the course of the audit. I commend them for their work.

Sincerely,


Vaughn Gower