

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE
OUTPATIENT BILLING FOR
SELECTED DRUGS AT
ESSENTIA HEALTH DULUTH**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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**Lori A. Ahlstrand
Regional Inspector General**

August 2012
A-09-12-02021

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services administers the program.

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains detail regarding each provided service (called a line item in this report). Providers should use the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and report units of service as the number of times that a service or procedure was performed or, if the HCPCS code is associated with a drug, the number of units administered.

Essentia Health Duluth (Essentia) is an acute-care hospital located in Duluth, Minnesota. Based on data analysis, we reviewed \$1,261,769 in Medicare payments to Essentia for 131 line items for injections of selected drugs that Essentia billed to Medicare during our audit period (January 1, 2008, through April 30, 2011). These line items consisted of injections for baclofen, infliximab, trastuzumab, rituximab, bortezomib, immune globulin, bevacizumab, epoetin alfa, and paclitaxel.

OBJECTIVE

Our objective was to determine whether Essentia billed Medicare for injections of selected drugs in accordance with Federal requirements.

SUMMARY OF FINDINGS

For 87 of the 131 line items reviewed, Essentia did not bill Medicare in accordance with Federal requirements. Specifically, Essentia billed the incorrect number of units of service. As a result, Essentia received overpayments totaling \$865,291. Essentia attributed the overpayments to billing system and clerical errors.

RECOMMENDATIONS

We recommend that Essentia:

- refund to the Medicare fiscal intermediary \$865,291 in identified overpayments and
- ensure compliance with Medicare billing requirements.

ESSENTIA HEALTH DULUTH COMMENTS

In written comments on our draft report, Essentia concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. Essentia's comments are included in their entirety as the Appendix.

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INTRODUCTION

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Medicare Requirements for Outpatient Claims

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains detail regarding each provided service (called a line item in this report). Providers should use the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and report units of service as the number of times that a service or procedure was performed or, if the HCPCS code is associated with a drug, the number of units administered.¹

Selected Drugs

The drugs we reviewed in this audit were baclofen, infliximab, trastuzumab, rituximab, bortezomib, immune globulin, bevacizumab, epoetin alfa, and paclitaxel.

Baclofen

Baclofen is an injectable drug used both as a muscle relaxer and to treat muscle symptoms caused by multiple sclerosis, including spasm, pain, and stiffness. Medicare requires providers to bill one service unit for each 10-milligram injection of baclofen. The HCPCS code for this drug is J0475 and is described as “Injection, baclofen, 10 [milligrams].”

Infliximab

Infliximab is an injectable drug used to treat rheumatoid and psoriatic arthritis, ulcerative colitis, Crohn’s disease, and ankylosing spondylitis. Medicare requires providers to bill one service unit for each 10-milligram injection of infliximab. The HCPCS code for this drug is J1745 and is described as “Injection, infliximab, 10 [milligrams].”

Trastuzumab

Trastuzumab is an injectable drug used to treat breast cancer that has progressed after treatment with other chemotherapy. Medicare requires providers to bill one service unit for each 10-milligram injection of trastuzumab. The HCPCS code for this drug is J9355 and is described as “Injection, trastuzumab, 10 [milligrams].”

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

Rituximab

Rituximab is an injectable drug used to treat non-Hodgkin's lymphoma, chronic lymphocytic leukemia, and symptoms of adult rheumatoid arthritis. Medicare requires providers to bill one service unit for each 100-milligram injection of rituximab. The HCPCS code for this drug is J9310 and is described as "Injection, rituximab, 100 [milligrams]."

Bortezomib

Bortezomib is an injectable drug used to treat multiple myeloma and mantle cell lymphoma. Medicare requires providers to bill one service unit for each 0.1-milligram injection of bortezomib. The HCPCS code for this drug is J9041 and is described as "Injection, bortezomib, 0.1 [milligrams]."

Immune Globulin

Immune globulin is an injectable drug used to treat primary immune deficiency conditions (e.g., chronic inflammatory demyelinating polyneuropathy). Medicare requires providers to bill one service unit for each 500-milligram injection of immune globulin. The HCPCS code for this drug is J1566 and is described as "Injection, immune globulin, intravenous, lyophilized (e.g. powder), not otherwise specified, 500 [milligrams]."

Bevacizumab

Bevacizumab is an injectable drug used to treat a certain type of brain tumor as well as cancers of the kidney, lung, colon, and rectum. Medicare requires providers to bill one service unit for each 10-milligram injection of bevacizumab. The HCPCS code for this drug is J9035 and is described as "Injection, bevacizumab, 10 [milligrams]."

Epoetin Alfa

Epoetin alfa is an injectable drug used to treat anemia. Medicare requires providers to bill one service unit for each 1,000 units of epoetin alfa. The HCPCS code for this drug is J0885 and is described as "Injection, epoetin alfa (for non-esrd [end-stage renal disease] use), 1000 units."

Paclitaxel

Paclitaxel is an injectable drug used to treat certain types of cancer (e.g., ovarian cancer and AIDS-related Kaposi's sarcoma). Medicare requires providers to bill one service unit for each 30-milligram injection of paclitaxel. The HCPCS code for this drug is J9265 and is described as "Injection, paclitaxel, 30 [milligrams]."

Essentia Health Duluth

Essentia Health Duluth (Essentia) is an acute-care hospital located in Duluth, Minnesota. Essentia's claims are processed and paid by Noridian Administrative Services, LLC (Noridian), the Medicare Part A fiscal intermediary.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Essentia billed Medicare for injections of selected drugs in accordance with Federal requirements.

Scope

We reviewed \$1,261,769 in Medicare payments to Essentia for 131 line items that we selected as potentially at risk for billing errors during our audit period (January 1, 2008, through April 30, 2011). These line items consisted of:

- 78 line items for baclofen totaling \$890,124,
- 36 line items for infliximab totaling \$272,608,²
- 2 line items for trastuzumab totaling \$31,565,
- 3 line items for rituximab totaling \$21,511,
- 8 line items for bortezomib totaling \$16,809,³
- 1 line item for immune globulin totaling \$13,307,
- 1 line item for bevacizumab totaling \$12,564,
- 1 line item for epoetin alfa totaling \$2,452, and
- 1 line item for paclitaxel totaling \$829.

We identified these payments through data analysis.

We did not review Essentia's internal controls applicable to the 131 line items because our objective did not require an understanding of controls over the submission of claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained

² For the 36 line items for infliximab, Essentia billed Medicare in accordance with Federal requirements.

³ For the eight line items for bortezomib, Essentia billed Medicare in accordance with Federal requirements.

from the National Claims History file for our audit period, but we did not assess the completeness of the file.

Our fieldwork included contacting Essentia, located in Duluth, Minnesota.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify paid Medicare claims for baclofen, infliximab, trastuzumab, rituximab, bortezomib, immune globulin, bevacizumab, epoetin alfa, and paclitaxel during our audit period;
- used computer matching, data mining, and analysis techniques to identify line items potentially at risk for noncompliance with Medicare billing requirements;
- identified 131 line items totaling \$1,261,769 that Medicare paid to Essentia;
- contacted Essentia to determine whether the information conveyed in the selected line items was correct and, if not, why the information was incorrect;
- reviewed documentation that Essentia furnished to verify whether each selected line item was billed correctly;
- calculated overpayments using corrected payment information processed by Noridian; and
- discussed the results of our review with Essentia.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

For 87 of the 131 line items reviewed, Essentia did not bill Medicare in accordance with Federal requirements. Specifically, Essentia billed the incorrect number of units of service. As a result, Essentia received overpayments totaling \$865,291. Essentia attributed the overpayments to billing system and clerical errors.

FEDERAL REQUIREMENTS

Section 9343(g) of the Omnibus Budget Reconciliation Act of 1986, P.L. No. 99-509, requires hospitals to report claims for outpatient services using HCPCS codes.

Section 1833(e) of the Act states: “No payment shall be made to any provider of services ... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider ... for the period with respect to which the amounts are being paid”

CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 4, section 20.4, states: “The definition of service units ... is the number of times the service or procedure being reported was performed.”

The Manual, chapter 17, section 90.2.A, states: “It is ... of great importance that hospitals billing for [drugs] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug ... that was used in the care of the patient.” If the provider is billing for a drug, according to chapter 17, section 70, of the Manual, “[w]here HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4”

Chapter 1, section 80.3.2.2, of the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately.”

INCORRECT BILLING

For 87 line items reviewed, Essentia billed Medicare for the incorrect number of units of service:

- For the 78 line items for baclofen, Essentia billed the incorrect number of units of service. Rather than billing from 2 to 8 service units, Essentia billed from 16 to 80 service units. The incorrect billing resulted in overpayments totaling \$802,239.
- For the two line items for trastuzumab, Essentia billed the incorrect number of units of service. Rather than billing 15 and 38 service units, Essentia billed 154 and 381 service units, respectively. The incorrect billing resulted in overpayments totaling \$28,899.
- For the three line items for rituximab, Essentia billed the incorrect number of units of service. Rather than billing from 6 to 8 service units, Essentia billed 14 service units for 2 line items and 16 service units for the remaining line item. The incorrect billing resulted in overpayments totaling \$12,285.
- For the one line item for immune globulin, Essentia billed the incorrect number of units of service. Rather than billing 48 service units, Essentia billed 481 service units. The incorrect billing resulted in an overpayment of \$12,161.

- For the one line item for bevacizumab, Essentia billed the incorrect number of units of service. Rather than billing 120 service units, Essentia billed 240 service units. The incorrect billing resulted in an overpayment of \$6,721.
- For the one line item for epoetin alfa, Essentia billed the incorrect number of units of service. Rather than billing 30 service units, Essentia billed 331 service units. The incorrect billing resulted in an overpayment of \$2,230.
- For the one line item for paclitaxel, Essentia billed the incorrect number of units of service. Rather than billing 12 service units, Essentia billed 136 service units. The incorrect billing resulted in an overpayment of \$756.

In total, Essentia received overpayments of \$865,291. Essentia attributed the overpayments to billing system and clerical errors.

RECOMMENDATIONS

We recommend that Essentia:

- refund to the Medicare fiscal intermediary \$865,291 in identified overpayments and
- ensure compliance with Medicare billing requirements.

ESSENTIA HEALTH DULUTH COMMENTS

In written comments on our draft report, Essentia concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. Essentia's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: ESSENTIA HEALTH DULUTH COMMENTS



June 1, 2012

Via Certified Mail & the HHS/OIG Delivery Server Submission

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services, Region IX
90-7th Street, Suite 3-650
San Francisco, CA 94103

Re: Essentia Health Duluth
Provider Number 240019
Report Number: A-09-12-02021

Dear Ms. Ahlstrand:

Essentia Health Duluth ("Essentia") appreciates the opportunity to respond to the Department of Health and Human Services, Office of Inspector General (OIG) draft report titled "Review of Medicare Outpatient Billing for Selected Drugs at Essentia Health Duluth."

The draft report recommends that Essentia refund to Medicare the identified overpayments and ensure compliance with Medicare billing requirements. Essentia concurs with these recommendations, has already refunded the identified overpayments, and has taken steps to prevent similar billing system and clerical errors from occurring in the future.

Background

On May 17, 2011, Essentia received a letter from the OIG's Office of Audit Services (OAS) requesting a self review of 124 specified line items. As noted in the draft report, OAS selected the line items for review after determining that the line items were "potentially at risk for billing errors" during the audit period January 1, 2008 through April 30, 2011.

Essentia conducted the requested self-review and submitted its results to OAS on June 6, 2011. Later, on July 14, 2011 Essentia received a request by the OAS to self-review an additional 7 specified line items. Essentia conducted this self-review and provided the results of the additional review on July 26, 2011.

Concurrence with the Report's Recommendations

The conclusions reached in the OIG draft report are consistent with the conclusions reached by Essentia through its management of the requested self-reviews. The draft report makes two recommendations, with which Essentia concurs, as discussed more fully below.

Recommendation 1: "refund to the Medicare fiscal intermediary \$865,291 in identified overpayments."

During the self-review process, Essentia refunded the identified overpayments associated with 87 of the 131 reviewed line items through the normal claims correction process. Essentia provided OAS with documentation to verify the refunds for all line items.

Due to the findings above, Essentia initiated a self-review of additional claims for the selected drugs to ensure accurate billing. Steps have been taken to identify, review and refund any additional overpayments discovered to ensure billing in accordance with Federal requirements.

Recommendation 2: "ensure compliance with Medicare billing requirements."

Essentia concurs with this recommendation. Since the time period covered by this review, Essentia has continued its efforts to educate employees about the use of HCPCS codes and the use of our information technology systems to assist with efforts to ensure proper unit billing.

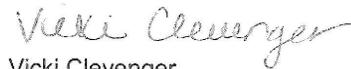
Specifically, it was determined that a system set up between our pharmacy and billing systems resulted in the erroneous reporting of drug units for selected drugs. Essentia converted to a new billing system on July 31, 2010. After the conversion, Essentia monitored 100% of pre-billed claims for injections of selected drugs for a period of time. In addition, Essentia implemented billing system edits to identify claims with unlikely drug units for review and correction as needed.

In addition, Essentia completes regularly scheduled internal compliance reviews of its billing practices and provides concurrent education and feedback. The Organizational Integrity & Compliance Department will include a review of outpatient billing for drugs in a future work plan.

Conclusion

Essentia is committed to making a healthy difference in the lives of our patients through excellence in clinical care and operations. To support this commitment, Essentia maintains an active and comprehensive Organizational Integrity & Compliance program, and is committed to the prevention, detection and correction of compliance issues, including coding and billing matters. Essentia believes it has made the necessary payment adjustments related to this review, and has taken steps to ensure compliance with Medicare billing requirements related to this review. We appreciate your assistance in this matter, and your support of our compliance efforts.

Sincerely,



Vicki Clevenger

Vice President, Compliance & Audit/Chief Compliance Officer

Essentia Health

Organizational Integrity & Compliance | MCL 203

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