Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPLIANCE REVIEW OF LOWELL GENERAL HOSPITAL'S METHUEN DIALYSIS FACILITY

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February 2014
A-01-12-00517

Office of Inspector General

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EXECUTIVE SUMMARY

Lowell General Hospital's Methuen Dialysis Facility did not always comply with Medicare billing requirements for selected services and did not make quality information fully available to patients.

WHY WE DID THIS REVIEW

In calendar year (CY) 2011, Medicare and beneficiaries paid approximately $10 billion for dialysis services under a bundled end-stage renal disease (ESRD) prospective payment system (PPS) that went into effect January 1, 2011. Compliance with Medicare billing requirements ensures proper payment for dialysis services under the ESRD PPS. The Centers for Medicare & Medicaid Services (CMS) relies on ESRD Medicare claims data to develop new and adjust existing payment systems and to monitor payment systems and the implementation of policies. We conducted this review because providers (dialysis facilities and other entities providing ESRD-related services) may not have been fully aware of, or may not have established controls to comply with, Medicare requirements for billing dialysis services under the ESRD PPS. We selected a hospital-based dialysis facility with a variety of treatment modalities, beneficiary characteristics, and billing scenarios with a potential risk for billing errors for a comprehensive review of 10 judgmentally selected beneficiary-months.

The objective of this review was to determine whether Lowell General Hospital Merrimack Valley – Methuen (the Dialysis Facility) complied with Medicare requirements for the 10 beneficiary-months in our review.

BACKGROUND

Effective January 1, 2011, Medicare pays dialysis facilities for ESRD services on a bundled per-treatment basis; among other things, it adjusts for geographic differences in area wage and the characteristics of patients and facilities. With the implementation of the ESRD PPS, all ESRD-related services and supplies furnished to a beneficiary must be billed by the dialysis facility. A dialysis facility is responsible for reimbursing other entities that provide ESRD-related services to its patients. Furthermore, CMS requires dialysis facilities to include information on their claims that is used to determine payment and to monitor safety and quality of care. CMS implemented the ESRD Quality Initiative Program (QIP) to score dialysis facilities on the quality of care provided to ESRD patients. CMS provides dialysis facilities with certificates containing their performance scores and other information that facilities must display prominently in a patient area.

The Dialysis Facility is a hospital-based dialysis facility in Methuen, Massachusetts. Lowell General Hospital (the Hospital) owns and operates the Dialysis Facility. Medicare paid the Dialysis Facility $2,344,017 for dialysis services provided to 122 ESRD beneficiaries in CY 2011.

WHAT WE FOUND

Based on the results of our review of 10 judgmentally sampled beneficiary-months, the Dialysis Facility did not always comply with Medicare billing requirements for ESRD PPS claims. The Dialysis Facility billed for treatments not furnished, did not comply with consolidated billing requirements, and did not accurately record required information on its claims used to compute the patient-level adjustment to the ESRD PPS per treatment base rate. These findings were associated with four of the beneficiary-months but did not result in a material financial impact. Furthermore, nine of the beneficiary-months had inaccurate claim information, which hinders CMS's efforts to monitor the ESRD program. Prior to our review, the Dialysis Facility did not furnish documentation to the MAC to support the use of the Hospital's higher wage index. In addition, the Dialysis Facility did not comply with the ESRD QIP requirement to post its entire Certificate of Dialysis Facility Performance. These errors occurred primarily because the Dialysis Facility did not have adequate controls to comply with certain Medicare requirements for the 10 beneficiary-months.

WHAT WE RECOMMEND

We recommend that the Hospital:

- establish controls to prevent duplicate billing of dialysis treatments,
- establish controls to ensure compliance with consolidated billing requirements,
- strengthen controls to ensure that required information is accurately recorded on the ESRD claims in accordance with Medicare billing requirements,
- establish controls to ensure that, if a new dialysis facility is opened or acquired, the appropriate wage index is applied to the new facility's claims, and
- ensure that all parts of the Certificate of Dialysis Facility Performance are prominently displayed to provide quality of care information to patients.

LOWELL GENERAL HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital concurred with most of our findings and recommendations. However, it disagreed that it billed for treatments not furnished. We maintain that the Dialysis Facility did not have the information necessary to determine the services were performed.

The Hospital also described the corrective actions it has taken and stated that Fresenius Medical Care acquired the Dialysis Facility as of September 1, 2013.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS REVIEW

In calendar year (CY) 2011, Medicare and beneficiaries paid approximately $10 billion for dialysis services under a bundled end-stage renal disease (ESRD) prospective payment system (PPS) that went into effect January 1, 2011. Compliance with Medicare billing requirements ensures proper payment for dialysis services under the ESRD PPS. The Centers for Medicare & Medicaid Services (CMS) relies on Medicare claims data to develop new and adjust existing payment systems and to monitor payment systems and the implementation of policies. We conducted this review because providers (dialysis facilities and other entities providing ESRD-related services) may not have been fully aware of, or may not have established controls to comply with, Medicare requirements for billing dialysis services under the ESRD PPS. We selected a hospital-based facility with a variety of treatment modalities, beneficiary characteristics, and billing scenarios with a potential risk for billing errors for a comprehensive review of 10 judgmentally selected beneficiary-months.

OBJECTIVE

Our objective was to determine whether Lowell General Hospital Merrimack Valley – Methuen (the Dialysis Facility) complied with Medicare requirements for the 10 beneficiary-months in our review.

BACKGROUND

Medicare, which is administered by CMS, provides health insurance coverage to eligible beneficiaries with ESRD under Title XVIII of the Social Security Act (the Act). Chronic kidney disease causes reduced kidney function. ESRD, the last stage in chronic kidney disease, is permanent kidney failure that requires a regular course of maintenance dialysis or a kidney transplant.

Dialysis Treatments

Dialysis replaces the function of the kidneys by removing waste and excess water from the body. There are two types of dialysis treatments: hemodialysis and peritoneal dialysis. In hemodialysis, an artificial kidney is used to remove waste and excess fluid from blood. Hemodialysis is typically furnished three times a week in 3- to 5-hour sessions. In peritoneal dialysis, blood is cleaned inside the abdomen (the peritoneal cavity). Peritoneal dialysis is furnished continuously, rather than as individual sessions.

Medicare covers three dialysis treatments per week. CMS considers each hemodialysis treatment to be a single dialysis treatment. CMS equates 1 week (7 days) of peritoneal dialysis to three dialysis treatments.[1]

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[1] *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 11, § 30.1.B; CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 80.4.

Dialysis Facilities

Dialysis facilities provide outpatient dialysis treatments to ESRD patients. Beneficiaries may receive dialysis either at a Medicare-certified dialysis facility or at home. A dialysis facility can be either a hospital-based or independent facility. There were approximately 5,700 outpatient dialysis facilities in the United States in CY 2011. Hospital-based facilities provided beneficiaries with approximately 6 percent of dialysis treatments in CY 2011.

Lowell General Hospital Merrimack Valley – Methuen

The Dialysis Facility is a hospital-based dialysis facility in Methuen, Massachusetts. Lowell General Hospital (the Hospital) owns and operates the Dialysis Facility. The Hospital also owns and operates a second hospital-based dialysis facility in Lowell, Massachusetts.[2] Medicare paid the Dialysis Facility $2,344,017 for dialysis services provided to 122 ESRD beneficiaries in CY 2011. The Dialysis Facility has 19 stations and operates 16 hours a day, 6 days a week.

NHIC, Corp., is the Medicare administrative contractor (MAC) for the Dialysis Facility.

Medicare Billing Requirements for Dialysis Services

ESRD services are subject to the monthly billing requirements for repetitive services.[3] Dialysis facilities submit a monthly claim for each beneficiary to a MAC, which contracts with CMS to process and pay Medicare claims. The claims must be completed accurately in order for the MAC to process them correctly and promptly.[4]

CMS requires dialysis facilities to include information on their claims that is used to determine payment and to monitor safety and quality of care. For example, dialysis facilities are required to report hemoglobin or hematocrit levels for their beneficiaries receiving erythropoiesis-stimulating agents (ESAs) on their Medicare claims for payment.[5]

Changes to the End-Stage Renal Disease Payment System

Before January 1, 2011, Medicare used a single payment rate to reimburse dialysis facilities for the costs of dialysis treatments and certain routine drugs, laboratory tests, and supplies. In addition, dialysis facilities could receive payments for separately billable injectable drugs and

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[2] Effective July 1, 2012, Lowell General Hospital and Saints Medical Center merged to combine formally as Lowell General Hospital. During our audit period, Saints Medical Center owned and operated the two dialysis facilities. Subsequently, effective September 1, 2013, Fresenius Medical Care acquired Lowell General Hospital's dialysis facilities.

[3] *Medicare Claims Processing Manual*, Pub. 100-04, ch. 8, §50.3.

[4] *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, §80.3.2.2.

[5] "National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities," *Medicare Claims Processing Manual*, Transmittal 751 (Change Request 4135; November 10, 2005). Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 60.4.2).

nonroutine laboratory tests. These separately billable services represented about 40 percent of total Medicare payments per dialysis treatment.

Effective January 1, 2011, the ESRD PPS combined the single payment rate and separate reimbursements for dialysis services into a bundled per-treatment base rate. The CY 2011 base rate for a dialysis treatment was $230. Medicare adjusts the base rate for geographic factors and the characteristics of patients and facilities to determine the per-treatment payment to dialysis facilities.[6] In addition, dialysis facilities that treat beneficiaries with unusually high resource requirements, measured through the utilization of specific services, are entitled to additional payments beyond the otherwise applicable PPS payment amounts. After a beneficiary's Part B deductible[7] has been met, Medicare reimburses dialysis facilities 80 percent of the base rate and all applicable adjustments for each dialysis treatment furnished. Beneficiaries are responsible for the remaining 20 percent.

Facility-Level Adjustment for Geographic Differences in Area Wage Levels

The ESRD PPS includes a facility-level adjustment that reflects geographic differences in area wage levels. Medicare adjusts the labor-related share of the ESRD PPS base rate using the wage index in which the ESRD facility is geographically located.[8] Prior to January 1, 2006, CMS used Metropolitan Statistical Areas (MSAs) to determine the wage index. The Dialysis Facility and the Hospital were located in the same MSA. CMS replaced MSAs with Core-Based Statistical Areas (CBSAs).[9] Under the new CBSA code structure the Dialysis Facility and Hospital are located in different CBSAs.

Patient-Level Adjustment for Case-Mix Variability

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients to account for case-mix variability. The adult case-mix adjusters include body surface area (BSA) and low body mass index (BMI).[10] Both measures are strong predictors of variation in costs and are closely associated with the duration and intensity of dialysis necessary to achieve a therapeutic dialysis target for ESRD patients. Medicare computes the BSA and BMI using patient height and weight data that dialysis facilities record on their claims.[11]

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[6] CMS offered dialysis facilities the option to elect to be reimbursed 100 percent by the bundled ESRD PPS and required facilities to make this election by November 1, 2010. Approximately 87 percent of dialysis facilities elected this option. CMS uses a blended payment rate composed of the old and the new payment system phased in during a 4-year transition period to reimburse each dialysis treatment to facilities that did not elect the bundled ESRD PPS payment.

[7] In each CY, a cash deductible must be satisfied before payment is made under Medicare Part B.

[8] 75 Fed. Reg. 49200 (Aug. 12, 2010).

[9] 70 Fed. Reg. 70167-70170 (Nov. 21, 2005).

[10] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 20.1.

[11] *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 11, § 60.A.3.

Consolidated Billing

The ESRD PPS includes a consolidated billing requirement for services included in the bundled payment rate. With the implementation of the ESRD PPS, all ESRD-related services must be billed by the dialysis facility and are no longer separately payable when furnished by a provider other than the dialysis facility. When an ESRD-related service is billed by an outside supplier or provider, the claim will be rejected or denied to prevent duplicate payment. In the event that a service is furnished for reasons other than the treatment of ESRD, the dialysis facility (or outside supplier or provider) may submit a claim for separate payment using modifier "AY."[12] The AY modifier serves as an attestation that the service was not used for the treatment of ESRD.[13]

Quality Incentive Program

The ESRD Quality Incentive Program (QIP) is designed to improve patient outcomes by establishing payment incentives for dialysis facilities to meet performance standards. CMS establishes quality of care measures for each calendar year performance period and facilities are scored on each measure. Dialysis facilities that do not meet or exceed the highest possible total score for a performance period will have their Medicare payments for dialysis services furnished during the corresponding payment year reduced on a sliding scale, with a maximum 2 percent reduction applied to any facility. Reductions apply to payments made after January 1, 2012 (payment year 2012), based on scores for performance year 2010. For each payment year, CMS provides dialysis facilities with certificates containing their performance scores and other information. These certificates must be prominently displayed in a patient area of the facility.[14]

CMS established two quality measures for the CY 2011 performance period: (1) an anemia management measure that assesses the percentage of patients with a hemoglobin level greater than 12 g/dL (for which a lower percentage indicates better performance on the measure) and (2) a hemodialysis adequacy measure, which assesses the percentage of patients with a urea reduction ratio (URR) of at least 65 percent (for which a higher percentage indicates better performance on the measure). The hemoglobin and URR readings that dialysis facilities reported on their CY 2011 claims were used to determine payment year 2013 performance scores.

Medicare Oversight of Erythropoiesis-Stimulating Agents

CMS established a monitoring policy, which reduces Medicare payments for ESAs when a beneficiary's hemoglobin or hematocrit exceeds a threshold under certain circumstances.[15] In

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[12] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, §§ 10, 60.1 and 60.2.1.1.

[13] *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 11, § § 20.2.B.1 and 20.3.E.

[14] CMS Fact Sheet, "CMS Finalizes Quality Incentive Program for Dialysis Facilities," released December 29, 2010.

[15] "Modification to the National Monitoring Policy for Erythropoietic Stimulating Agents for End-Stage Renal Disease Patients Treated in Renal Dialysis Facilities," *Medicare Claims Processing Manual*, Transmittal 1307 (Change Request 5700; July 20, 2007).

addition, medically unlikely edits[16] identify claims that bill for quantities of ESAs in excess of maximum dosage amounts and return these claims to providers for correction before processing for payment.

HOW WE CONDUCTED THIS REVIEW

We used CMS's National Claims History file to identify CY 2011 dialysis treatments reimbursed under the ESRD PPS and grouped those treatments by beneficiary and calendar month (beneficiary-month).[17] We then used the National Claims History file to identify all other CY 2011 Medicare claims submitted by other providers for those beneficiary-months. Using medical and billing records, we reviewed a judgmental sample of 10 beneficiary-months to determine whether the claims complied with Medicare requirements for billing dialysis services. We selected the beneficiary-months to obtain a variety of treatment modalities, beneficiary characteristics, and billing scenarios with the potential risk for billing errors for review. All beneficiaries selected for review were adult patients. We limited our review of internal controls to those applicable to billing procedures and medical record documentation for ESRD PPS services furnished by the Dialysis Facility. Our objective did not require that we determine whether the services billed were medically necessary. This report does not represent an overall assessment of all claims submitted by the Dialysis Facility for Medicare reimbursement. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

Our audit covered $23,091 in Medicare payments to the Dialysis Facility for 10 beneficiary-months (each beneficiary-month consisted on one ESRD PPS claim) with dates of service in CY 2011.

We conducted our fieldwork at the Dialysis Facility from April through August 2012. We also contacted NHIC, Corp.,[18] and CMS officials.

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 objectives.

Appendix A contains the details of our scope and methodology.

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[16] Medically unlikely edits identify claims before they are processed by CMS for payment that have ESAs in excess of the maximum dosages and return these claims to providers for correction.

[17] Each hemodialysis treatment was considered a single dialysis treatment. We converted peritoneal dialysis to dialysis treatments by dividing the number of days peritoneal dialysis was billed during a beneficiary-month by seven and multiplying the result by three.

[18] NHIC, Corp., is the MAC responsible for processing and paying Medicare claims submitted by the Dialysis Facility.

FINDINGS

Based on the results of our review of 10 judgmentally sampled beneficiary-months, the Dialysis Facility did not always comply with Medicare billing requirements for ESRD PPS claims. The Dialysis Facility billed for treatments not furnished, did not comply with consolidated billing requirements, and did not accurately record required information on its claims used to compute the patient-level adjustment to the ESRD PPS per treatment base rate. These findings were associated with four of the beneficiary-months but did not result in a material financial impact. Furthermore, nine of the beneficiary-months had inaccurate claim information, which hinders CMS's efforts to monitor the ESRD program. Prior to our review, the Dialysis Facility did not furnish documentation to the MAC to support the use of the Hospital's higher wage index. In addition, the Dialysis Facility did not comply with the ESRD QIP requirement to post its entire Certificate of Dialysis Facility Performance. These errors occurred primarily because the Dialysis Facility did not have adequate controls to comply with certain Medicare requirements for the 10 beneficiary-months.

CLAIMS NOT BILLED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Billing for Treatments Not Furnished

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Social Security Act (the Act), § 1862(a)(1)(A)). In addition, payments may not be made to any provider of services or other person without information necessary to determine the amount due the provider (the Act, § 1833(e)).

For one beneficiary-month, the Dialysis Facility billed and was reimbursed for two treatments that were not performed. On September 6 and 13, 2011, a home peritoneal dialysis patient had hemodialysis treatments at the Hospital's other dialysis facility instead of performing the dialysis at home. The Hospital's other dialysis facility billed Medicare for the hemodialysis services.[19] Since the peritoneal and hemodialysis treatments were billed under different Medicare provider numbers, the Hospital's billing department did not adjust the number of peritoneal dialysis treatments billed to Medicare accordingly. Dialysis Facility officials attributed this error to inadequate controls to prevent the duplicate billing of dialysis treatments. There was no material financial impact for this finding.

Separate Payments for Services Did Not Comply With Consolidated Billing Requirements

MACs make payments to dialysis facilities for all ESRD-related services and supplies furnished to a beneficiary through the ESRD PPS. Dialysis facilities are responsible for reimbursing other

[19] We did not review the claim submitted by the Hospital's other dialysis facility to determine whether the total number of treatments billed to and reimbursed by Medicare for this beneficiary in September 2011 was medically justified.

entities that provide ESRD-related services to its patients.[20] Medicare made the following duplicate payments for ESRD-related services that were billed by other providers and suppliers.

Intravenous Infusion

For one beneficiary-month, a home peritoneal dialysis patient required the intravenous infusion of an ESRD-related drug. The patient chose to go to the Hospital for the infusion because it was more convenient, according to Dialysis Facility staff. The Dialysis Facility was not aware they should notify other providers to bill the Dialysis Facility for ESRD-related service. There was no material financial impact for this finding.

Drugs

For one beneficiary-month, the patient's nephrologist prescribed a local anesthetic cream used for access management that the patient had filled at their local pharmacy using the Medicare Part D prescription drug benefit. The Dialysis Facility and the ordering nephrologist were not aware that the cream was included in the ESRD PPS. There was no material financial impact for this finding.

Claims Data Used to Make Patient-Level Adjustments Did Not Comply With Medicare Requirements

CMS requires dialysis facilities to measure weight in kilograms immediately following the last dialysis session of the month and record it on the ESRD PPS claim.[21] The patient's weight is required on the claim in order to compute the patient level adjustments to the ESRD PPS base rate.[22] Because a dialysis patient's weight fluctuates throughout the month, the requirement that the facility record the patient's weight, measured immediately following the last dialysis session of the month, on the claim ensures that the MAC reimburses all facilities for treatments consistently.

For three beneficiary-months, the Dialysis Facility furnished beneficiaries with home peritoneal dialysis services. The Dialysis Facility did not record the patients' weight measured immediately following the last dialysis session of the month on the claims for these beneficiaries. For two beneficiary-months, the Dialysis Facility recorded the weight measured during the patients' monthly facility visits on its claims. The monthly clinic visits for home patients can occur anytime during the month. The Dialysis Facility stated that obtaining the weight from the last dialysis session of the month from patients' home records in a timely manner would be a challenge. Patients bring their home records in at their monthly visit, which can be several days or weeks after the end of the billing month.

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[20] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 10.

[21] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 50.3 and *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 11, § 60.A.3.

[22] *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 11, § 60.A.3.

For one beneficiary-month, the beneficiary had both home peritoneal and hemodialysis treatments during the month. The Dialysis Facility submitted the home dialysis monthly claim with the weight measured before the last hemodialysis session of the month[23] rather than the weight measured immediately following the last home dialysis session of the month. There was no material financial impact for this finding.

Dialysis Facility Did Not Comply With Other Billing Requirements

Drugs and Biologicals Inappropriately Aggregated on the Claim

The dialysis facility should report any drug or biological furnished on the ESRD claim with the line item date of service and the quantity of the drug or biological furnished at the time of the visit.[24] Line item billing for drugs furnished on each date of service provides CMS with the most accurate claims information and could be used to assist CMS in future refinements to improve the accuracy and equity of ESRD payments.[25]

For eight beneficiary-months, beneficiaries were furnished drugs requiring line item billing. However, the Dialysis Facility reported the units furnished for the drugs in the aggregate on its Medicare claims. The Dialysis Facility officials stated that the Hospital's system automatically aggregated the drugs on its claims.

Most Recent Hemoglobin and Hematocrit Readings Not Report on the Claim

CMS requires dialysis facilities to report either a hemoglobin or hematocrit reading on their claims to indicate the patient's most recent reading taken before the start of the billing period.[26]

For one beneficiary-month, the Dialysis Facility did not report the most recent hemoglobin reading on its claim. This occurred because the Dialysis Facility's billing department made a clerical error. As a result, a lower hemoglobin level was reported on the claim. We acknowledge that this one error may not have had an effect on Medicare payments to the Dialysis Facility. However, inaccurate claims information that is used for ESA monitoring or QIP purposes could result in incorrect payments to dialysis facilities. Such inaccurate information also hinders CMS's efforts to monitor safety and quality.

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[23] The ESRD PPS claim for the patient's hemodialysis services were submitted by the Hospital's other dialysis facility. We did not determine whether that claim was submitted in accordance with Medicare guidelines.

[24] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, §§ 50.4 and 60.2.

[25] "Line Item Billing Requirement for End Stage Renal Disease (ESRD) Claims," *Medicare Claims Processing Manual*, Transmittal 1084 (Change Request 5039; October 26, 2006).

[26] "National Monitoring Policy for EPO and Aranesp for End Stage Renal Disease Patients Treated in Renal Dialysis Facilities," *Medicare Claims Processing Manual*, Transmittal 751 (Change Request 4135; November 10, 2005). Effective January 1, 2012, ESRD facilities are required to report hematocrit or hemoglobin levels on all ESRD claims (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 60.4.2).

Facility-Level Adjustment for Geographic Differences in Area Wage Levels Not Documented or Reviewed

The Dialysis Facility is located in a different geographical area, with a lower wage index, than the Hospital. When a hospital-based facility is located in a different geographical area than the main hospital complex, the facility must furnish financial data to the MAC that demonstrates that the wages and benefits paid to dialysis facility employees are identical those paid to hospital employees in order for the hospital's wage index to apply to the dialysis facility.[27] When CMS introduced CBSA codes as the basis for wage index factors in January 2006, the MAC automatically assigned the Hospital's wage index to the Dialysis Facility without a review of financial data and a determination that the wage scales were identical.

During our review, we brought this matter to the attention of Dialysis Facility officials and the Dialysis Facility submitted the required documentation to the MAC for review. The MAC concluded that the Dialysis Facility was currently and retroactively operating under the same salary and benefit package as the Hospital. CMS agreed that the correct wage index adjustment was being applied to the Dialysis Facility's ESRD claims.

ENTIRE CERTIFICATE OF DIALYSIS FACILITY PERFORMANCE NOT POSTED

A dialysis facility must prominently display its Certificate of Dialysis Facility Performance, which indicates the total performance score achieved, in a patient area.[28] Part 1 of the certificate identifies the facility's QIP score, and Part 2 explains the purpose of the QIP, how the facility is scored, and how patients can get additional information.

The Dialysis Facility did not post Part 2 of the 2012 Certificate of Dialysis Facility Performance in the patient waiting area. As a result, patients may not have been aware of the significance to the QIP and how to obtain additional information about it. The Dialysis Facility stated that this was an oversight and subsequently posted Part 2 of the certificate.

RECOMMENDATIONS

We recommend that the Hospital:

- establish controls to prevent duplicate billing of dialysis treatments,
- establish controls to ensure compliance with consolidated billing requirements,
- strengthen controls to ensure that required information is accurately recorded on the ESRD claims in accordance with Medicare billing requirements,
- establish controls to ensure that, if a new dialysis facility is opened or acquired, the appropriate wage index is applied to the new facility's claims, and

[27] *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 30.2.B.2.

[28] The Act, § 1881(h)(6) (C).

- ensure that all parts of the Certificate of Dialysis Facility Performance are prominently displayed to provide quality of care information to patients.

LOWELL GENERAL HOSPITAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital concurred with most of our findings and recommendations. However, it disagreed that it billed for treatments not furnished. We maintain that the Dialysis Facility did not have the information necessary to determine the services were performed.

The Hospital also described the corrective actions it has taken and stated that Fresenius Medical Care acquired the Dialysis Facility as of September 1, 2013.

The Hospital's comments are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $23,091 in Medicare payments to the Dialysis Facility for 10 beneficiary-months (each beneficiary-month consisted on one ESRD PPS claim) with dates of service in CY 2011. We judgmentally selected these beneficiary-months because of various billing characteristics and the potential risk for billing errors. We also identified all other CY 2011 Medicare claims submitted by any other provider(s) for those 10 beneficiary-months.

We conducted a comprehensive review of the ESRD PPS claims for the 10 beneficiary-months, but limited our review of the separately billed items during the beneficiary-month to those that were potentially subject to consolidated billing.

We evaluated compliance with ESRD billing requirements. The objective of our review did not require that we not use medical review to determine whether the services billed were medically necessary or whether any separately billed services were ESRD-related.

We limited our review of internal controls to those applicable to billing procedures and medical record documentation for ESRD PPS services furnished by the Dialysis Facility. We established reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

This report does not represent an overall assessment of all claims submitted by the Dialysis Facility for Medicare reimbursement.

We conducted our fieldwork at the Dialysis Facility from April through August 2012.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials;
- used CMS's National Claims History file to identify the first 11 months of CY 2011 dialysis treatments reimbursed to the Dialysis Facility under the ESRD PPS and grouped those treatments by beneficiary-months;
- identified 903 beneficiary-months with $2,116,602 in Medicare payments to the Dialysis Facility under the ESRD PPS for 115 beneficiaries from which we selected our sample;
- identified all other CY 2011 Medicare claims submitted by other providers for the 115 beneficiaries;

- selected a judgmental sample of 10 beneficiary-months to obtain a variety of treatment modalities, beneficiary characteristics, and billing scenarios with potential risk for billing errors for a detailed review;

- reviewed available data from CMS's Common Working File for the selected claims to determine whether the claims had been cancelled or adjusted;

- interviewed Dialysis Facility personnel and reviewed the Dialysis Facilities policies and procedures applicable to billing ESRD claims;

- toured the dialysis facility to gain an understanding of its operations and observe whether the QIP Certificate was properly posted;

- reviewed the itemized bills and medical record documentation provided by the Dialysis Facility to support the selected claims;

- determined whether the ESRD PPS claims submitted by the facility[29] were supported and billed correctly;

- determined whether any services subject to consolidated billing were inappropriately separately billed;

- contacted MAC about the wage index applied to the Dialysis Facility's claims;

- discussed the incorrectly billed claims with Dialysis Facility personnel to determine the underlying causes of noncompliance with Medicare requirements;

- calculated the correct payments for those claims requiring adjustments; and

- discussed the results of our review with Dialysis Facility officials.

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 objectives.

[29] Three of the beneficiary-months judgmentally selected each contained one ESRD PPS claim for home dialysis services. These home dialysis beneficiaries were patients at the Hospital's other dialysis facility. The Hospital incorrectly billed the ESRD PPS claims with the Dialysis Facility's provider number. Because the Dialysis Facility received payment for these beneficiary-months we included them in the scope of our review.

APPENDIX B: LOWELL GENERAL HOSPITAL COMMENTS

Lowell General Hospital

Complete connected care℠

December 17, 2013

Mr. David Lamir
Regional Inspector General for Audit Services
Office of Audit Services, Region 1
JFK Federal Building
15 New Sudbury Street, Room 2425
Boston, MA 02203

Report Number: A-01-12-00517

Dear Mr. Lamir:

Lowell General Hospital (LGH) appreciates the opportunity to review and provide comments on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled ***Compliance Review of Lowell General Hospital's Methuen Dialysis Facility***. LGH is committed to complying with all regulations and standards governing Federal health care programs, improving internal controls and proactively auditing and monitoring to minimize the risk of errors.

LGH's responses to the OIG's recommendations are set forth below.

OIG Recommendations;

1. establish controls to prevent duplicate billing,
2. establish controls to ensure compliance with consolidated billing requirements,
3. strengthen controls to ensure that required information is accurately recorded on the ESRD claim in accordance with Medicare billing requirements,
4. establish controls to ensure that, if a new dialysis facility is opened or acquired, the appropriate wage index is applied to the new facility's claims, and
5. ensure that all parts of the Certificate of Dialysis Facility Performance are prominently displayed to provide quality of care information to patients.

LGH Comments

1. LGH is not in concurrence with the OIG with regards to for billing for treatments not furnished. The patient received home peritoneal dialysis and hemodialysis treatment on the two days in question. Although this is an extremely rare occurrence, both services were provided to the patient. Both services are reasonable and necessary for the treatment of the illness and to improve the functionality of the patient.
2. LGH is concurring with the OIG and has taken corrective actions to assure full compliance with the consolidated billing requirements. A home peritoneal patient required an

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intravenous infusion of an ESRD-related drug and chose to go to the hospital for convenience purposes. The dialysis staff was unaware they should notify the clinic that the patient was receiving an ESRD-related service. A corrective action was taken to educate the peritoneal nurse to inform the clinic about patients receiving ESRD-related services. This action alerted the billing department to not bill separately according to Medicare billing requirements. Also, as part of the consolidating billing review, was a patient' nephrologist prescribing local anesthetic cream used for access management. The dialysis staff and the nephrologist were not aware that the cream was included in the ESRD PPS payment. Staff and physicians have been educated to this billing requirement.

3. LGH is concurring with the OIG and has taken corrective action to ensure compliance with Medicare billing requirements. The patient's weight is required on the claim in order to compute the patient level adjustments to the ESRD PPS base rate. Because the patient weight fluctuates during the month, the patient's weight should be measured immediately following the last session of the month. A corrective action has changed the process for collecting home peritoneal dialysis patient's weight. The last day of the month, the home dialysis patients are required to call the facility and state there current weight. If the dialysis staff does not receive a call from the patient, they will call the patient that day. Also with regards to other billing arrangements, line item billing for drugs and biologicals was furnished in the aggregate on Medicare claims. LGH billing department has refined its billing process to comply with line item billing per Medicare regulations.
4. LGH is concurring with the OIG to ensure that the appropriate wage index is applied to new facility's claims. Since the Methuen dialysis facility is located in a different geographical location than hospital, the provider must furnish financial documentation that demonstrates that the wages and benefits paid to dialysis employees are identical to those paid to hospital employees in order for the hospital wage index to apply to the dialysis facility. This documentation was provided to our Fiscal Intermediary and they concluded that the correct wage index was being applied to the Methuen dialysis facility. It should be noted that as of September 1, 2013, LGH's dialysis facilities have been acquired by Fresenius Medical Care.
5. LGH is concurring that all parts of the Certificate of Dialysis Facility Performance are prominently displayed to provide quality of care information to patients. The dialysis staff has taken corrective action and posted the applicable certificate immediately after the oversight was recognized.

Thank you for the opportunity to review and comment on the Draft Report. Please take our comments into consideration before the final report is issued.

Sincerely,

William F. Wyman
Corporate Compliance Officer