

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**COMPLIANCE REVIEW OF  
WOBURN DIALYSIS**

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# ***Office of Inspector General***

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## EXECUTIVE SUMMARY

*Woburn Dialysis did not always comply with Medicare billing requirements for selected end-stage renal disease prospective payment system claims.*

### 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 an independent 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 Woburn Dialysis 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. In addition, a dialysis facility that CMS has certified to provide services to patients that dialyze in their homes must review patients' self-monitoring data and maintain it in the patients' medical records.

Woburn Dialysis is an independent dialysis facility in Woburn, Massachusetts. DaVita, Inc. (DaVita), owns and operates Woburn Dialysis. Medicare paid Woburn Dialysis \$1,364,620 for dialysis services provided to 74 ESRD beneficiaries in CY 2011.

## **WHAT WE FOUND**

Woburn Dialysis did not always comply with Medicare billing requirements for ESRD PPS claims for the 10 judgmentally sampled beneficiary-months in our review. Specifically, Woburn Dialysis:

- did not bill claims in accordance with Medicare requirements (nine beneficiary-months),
- submitted claims with inaccurate information (nine beneficiary-months),
- submitted multiple claims for repetitive dialysis services (three beneficiary-months), and
- did not ensure that home patients fully and accurately document self-monitoring data and did not always maintain this data in the medical records (three beneficiary-months).

These findings were associated with eight of the beneficiary-months but did not result in a material financial impact. Furthermore, inaccurate claims and improper submission of multiple claims may have hindered CMS's efforts to monitor the ESRD program. In addition, incomplete and missing patient self-monitoring data did not ensure home dialysis patients followed their plan of care and that only completed treatments were billed to Medicare. These errors occurred primarily because Woburn Dialysis did not have adequate controls to comply with certain Medicare requirements for the 10 beneficiary-months.

## **WHAT WE RECOMMEND**

We recommend that Woburn Dialysis:

- work with Winchester Hospital to identify and refund to Medicare for all separately billed ESRD-related laboratory services subject to consolidated billing requirements,
- 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,
- strengthen controls to ensure compliance with monthly billing requirements for repetitive services,
- educate home dialysis patients on how to record and report health status information, and
- maintain home dialysis self-monitoring data in the medical records.

## **WOBURN DIALYSIS COMMENTS AND OUR RESPONSE**

In written comments on our draft report, Woburn Dialysis concurred with our first, fifth, and sixth recommendations, partially concurred with our second recommendation, and did not express concurrence or nonconcurrence with our third and fourth recommendations. Woburn Dialysis described the corrective actions it had taken or plans to take for all recommendations except for certain findings related to our second recommendation.

Woburn Dialysis concurred with our second recommendation regarding consolidated billing requirements with respect to the laboratory tests separately billed by Winchester Hospital; however, Woburn Dialysis stated that the services separately billed by DaVita's laboratory were billed appropriately because the diagnosis codes provided by the nephrologist were not ESRD-related. Woburn Dialysis also stated that it is unable to determine whether other providers submitted claims for ESRD-related services and supplies that are subject to consolidated billing requirements. We maintain that these services were ESRD-related and that Woburn Dialysis should establish controls to ensure full compliance with consolidated billing requirements.

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## 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 an independent 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.

### OBJECTIVE

Our objective was to determine whether Woburn Dialysis 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.<sup>1</sup>

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<sup>1</sup> *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 30.1.B; *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 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. Dialysis facilities are required to develop a plan of care and provide the prescribed dose of dialysis for each patient.<sup>2</sup>

A dialysis facility can be hospital-based or independent. There were approximately 5,700 outpatient dialysis facilities in the United States in CY 2011. Independent facilities provided beneficiaries with approximately 94 percent of dialysis treatments in CY 2011. A small number of for-profit companies own the majority of dialysis facilities.

## **Home Dialysis**

A dialysis facility that CMS has certified to provide services to patients, who dialyze in their homes, must ensure that its services are equivalent to services provided within a dialysis facility.<sup>3</sup> Dialysis facilities train patients to self-monitor their health status and to record self-monitoring data daily, including dialysis treatment data, weight, blood pressure, and medications administered.<sup>4</sup> Dialysis facilities must review the patients self-monitoring data at least every 2 months and maintain it in the patients' medical records.<sup>5</sup>

## **Woburn Dialysis**

Woburn Dialysis is an independent dialysis facility in Woburn, Massachusetts. DaVita, Inc. (DaVita), owns and operates Woburn Dialysis. As of September 30, 2013, DaVita operated or provided administrative services at 2,042 outpatient dialysis centers located in the United States serving approximately 166,000 patients.<sup>6</sup> Medicare paid Woburn Dialysis \$1,364,620 for dialysis services provided to 74 ESRD beneficiaries in CY 2011. Woburn Dialysis has 17 stations and operates 11 hours a day, 6 days a week. Woburn Dialysis also furnishes home peritoneal dialysis services.

Cahaba Government Benefit Administrators, LLC, is the Medicare administrative contractor (MAC) for Woburn Dialysis.

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<sup>2</sup> 42 CFR § 494.90.

<sup>3</sup> 42 CFR § 494.100.

<sup>4</sup> *ESRD Basic Technical Surveyor Interpretive Guidance*, pp. 229-231 (October 3, 2008) at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpbgmguidance.pdf>. Last accessed October 15, 2013.

<sup>5</sup> 42 CFR §§ 494.100(b)(2) and 494.100(b)(3).

<sup>6</sup> About DaVita: <http://www.davita.com/about>. Last accessed November 18, 2013.

## **Laboratory Services Furnished to Woburn Dialysis Patients**

Woburn Dialysis generally uses DaVita's laboratory for laboratory services furnished to its patients, but there are various circumstances, such as the urgency of receiving the test results, when it sends blood specimens to Winchester Hospital's laboratory. Under an agreement between DVA Healthcare of Massachusetts, Inc. (which is a subsidiary of DaVita, Inc.), and Winchester Hospital, Winchester Hospital is required to bill DaVita directly for all laboratory services performed by Winchester Hospital for specimens drawn at Woburn Dialysis. The agreement required Woburn Dialysis to use Winchester Hospital's laboratory requisition forms and indicate that the specimens originated from Woburn Dialysis.<sup>7</sup>

## **Medicare Billing Requirements for Dialysis Services**

ESRD services are subject to the monthly billing requirements for repetitive services.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup>

## **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 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. Oral equivalents of ESRD related injectable drugs are included in the ESRD PPS.<sup>11</sup> However, oral-only ESRD-related drugs are excluded from the ESRD PPS until January 1, 2016.<sup>12</sup>

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<sup>7</sup> The agreement between DVA Healthcare of Massachusetts, Inc., and Winchester Hospital also applied to all laboratory services performed by Winchester Hospital for specimens drawn at Wellington Circle Dialysis.

<sup>8</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 50.3.

<sup>9</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 1, § 80.3.2.2.

<sup>10</sup> "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 (CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 60.4.2).

<sup>11</sup> 75 Fed. Reg. 49030, 49036 (August 12, 2010).

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.<sup>13</sup> 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<sup>14</sup> 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.

### **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).<sup>15</sup> 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.<sup>16</sup>

### **Consolidated Billing**

The ESRD PPS includes a consolidated billing requirement for services included in the bundled payment rate, including for example ESRD-related laboratory services and certain drugs. 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."<sup>17</sup> The AY modifier serves as an attestation that the service was not used for the treatment of ESRD.<sup>18</sup>

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<sup>12</sup> American Taxpayer Relief Act of 2012, § 632(b).

<sup>13</sup> 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. Woburn Dialysis elected to be reimbursed 100 percent by the bundled ESRD PPS.

<sup>14</sup> In each CY, a cash deductible must be satisfied before payment is made under Medicare Part B.

<sup>15</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 20.1.

<sup>16</sup> *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 60.A.3.

<sup>17</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §§ 10, 60.1 and 60.2.1.1.

<sup>18</sup> *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 20.2.B.1 and 20.3.E.

## 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 scores facilities 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 based on scores for performance year 2010.<sup>19</sup>

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.<sup>20</sup> In addition, medically unlikely edits<sup>21</sup> 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).<sup>22</sup> We then used the National Claims History file to identify all other CY 2011 Medicare claims submitted by any 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.

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<sup>19</sup> CMS Fact Sheet "CMS Finalizes Quality Incentive Program for Dialysis Facilities," released December 29, 2010.

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

<sup>21</sup> 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.

<sup>22</sup> 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 7 and multiplying the result by 3.

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 Woburn Dialysis. 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 Woburn Dialysis 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 \$27,346 in Medicare payments to Woburn Dialysis for 10 beneficiary-months (each beneficiary-month consisted of one or more ESRD PPS claims) with dates of service in CY 2011.

We conducted our fieldwork from April 2012 through November 2013. We also contacted 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.

The Appendix contains the details of our scope and methodology.

## **FINDINGS**

Woburn Dialysis did not always comply with Medicare billing requirements for ESRD PPS claims for the 10 judgmentally sampled beneficiary-months in our review. Specifically, Woburn Dialysis:

- did not bill claims in accordance with Medicare requirements (nine beneficiary-months),
- submitted claims with inaccurate information (nine beneficiary-months),
- submitted multiple claims for repetitive dialysis services (three beneficiary-months), and
- did not ensure that home patients fully and accurately document self-monitoring data and did not always maintain the patient self-monitoring data in the medical records (three beneficiary-months).

These findings were associated with eight of the beneficiary-months but did not result in a material financial impact. Furthermore, inaccurate claims and improper submission of multiple claims may have hindered CMS's efforts to monitor the ESRD program. In addition, incomplete and missing patient self-monitoring data did not ensure home dialysis patients followed their

plan of care and that only completed treatments were billed to Medicare. These errors occurred primarily because Woburn Dialysis did not have adequate controls to comply with certain Medicare requirements for the 10 beneficiary-months.

## **CLAIMS NOT BILLED IN ACCORDANCE WITH MEDICARE REQUIREMENTS**

CMS requires dialysis facilities to bill claims in accordance with Medicare requirements. Through our analysis of the 10 beneficiary-months in our review, we found that Woburn Dialysis did not bill claims in accordance with Medicare requirements for 9 beneficiary-months. Specifically, Woburn Dialysis did not accurately record required information on its claims that was used to compute the patient-level adjustment to the ESRD PPS per treatment base rate (seven beneficiary-months),<sup>23</sup> and Woburn Dialysis did not comply with consolidated billing requirements (seven beneficiary-months).<sup>24</sup>

### **Patient Weight Recorded on Claims Did Not Comply With Medicare Requirements**

CMS requires dialysis facilities to measure patient weight in kilograms immediately following the last dialysis session of the month and record it on the ESRD PPS claim in order for the MAC to compute the patient-level adjustments to the ESRD PPS base rate.<sup>25</sup> In addition, CMS requires dialysis facilities to submit bills monthly for repetitive ESRD services.<sup>26</sup>

Home dialysis patients are trained to weigh themselves daily. CMS requires dialysis facilities to maintain home patients' self-monitoring health status records in their medical records; therefore, dialysis facilities have the ability to record the appropriate weight on claims.

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. Furthermore, the requirement that facilities submit bills monthly for repetitive services ensures that all treatments of the same type furnished during the month are paid at the same rate.

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<sup>23</sup> The seven beneficiary-months consisted of four beneficiary-months for which Woburn Dialysis did not measure and record patient weight and height on claims correctly and three beneficiary-months for which Woburn Dialysis did not measure and record patient height on claims correctly.

<sup>24</sup> The number of beneficiary-months adds to 14 because some of the beneficiary months had more than one error. For 9 beneficiary months, 5 had both inaccurate patient-level adjustment information and did not comply with consolidated billing requirements.

<sup>25</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 50.3 and *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 60.A.3.

<sup>26</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §50.3.

For four beneficiary-months,<sup>27</sup> Woburn Dialysis did not measure and record patient weight on claims in accordance with Medicare requirements. Rather, Woburn Dialysis generally recorded a patient's most recent weight measured in the facility on, or prior to, the last date in each claim's billing period, which was not the date of the last dialysis session of the month. In addition, Woburn Dialysis recorded a patient's weight on one claim in pounds instead of kilograms.

For three of the beneficiary-months, errors occurred because Woburn Dialysis typically recorded the weight measured during a home patient's most recent monthly facility visit. The monthly clinic visits for home patients can occur anytime during the month.

For one of the beneficiary-month, errors occurred because Woburn Dialysis submitted a new claim whenever there was a change in the type of dialysis service furnished rather than waiting until the end of the month to submit one claim for each type of service. Woburn Dialysis generally recorded the patient's most recent weight measured in the facility on, or prior to, the last date in the claim billing period.

Furthermore, DaVita's billing system did not have controls in place to ensure that the weight recorded on its claims were reasonable. For example, for one beneficiary-month, Woburn Dialysis submitted a claim for a patient with an incorrect weight measurement that was approximately more than double the weight measurement that Woburn Dialysis submitted on previous claims for this patient.

Because patients' weights were not measured and recorded in accordance with Medicare requirements, Woburn Dialysis received net overpayments of \$842 for the four beneficiary-months. Furthermore, the beneficiaries' copayments were overstated by a net \$211.

### **Patient Height Recorded on Claims Did Not Comply With Medicare Requirements**

CMS requires dialysis facilities to measure beneficiary height in centimeters during the last dialysis session of the month and record it on the ESRD PPS claim in order for the MAC to compute the patient level adjustments to the ESRD PPS base rate.<sup>28</sup> People typically lose about 1 centimeter (0.4 inches) of height every 10 years after age 40 and even more after age 70 because of aging changes in the bones, muscles, and joints. In total, people may lose 2.54 to 7.62 centimeters (1 to 3 inches) in height as they age.<sup>29</sup> Therefore, more frequent measurements

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<sup>27</sup> The number of beneficiary-months does not add to four because one beneficiary-month had both in-facility and home dialysis services.

<sup>28</sup> *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 60.A.3. In addition, CMS issued guidance that height should be measure for the initial billing period and may be assessed periodically, as reasonable or if the facility notes any changes in the patient (*Medicare Learning Network, MNL Matters Article number SE0511 "MMA – End Stage Renal Disease Composite Payment Rate System changes"*).

<sup>29</sup> "Aging changes in body shape: MedlinePlus Medical Encyclopedia" at <http://www.nlm.nih.gov/medlineplus/ency/article/003998.htm>. Last accessed October 15, 2013.

of height documented in the medical records provides assurance that the height recorded on the claim and used to calculate the ESRD PPS payment is accurate.

For five beneficiary-months, Woburn Dialysis recorded a height on the claims that was measured more than a year before the last dialysis session of the month in the claim billing period. On average approximately 3.5 years elapsed since the patients were admitted to the facility and the beneficiary-month selected. One patient was admitted to Woburn Dialysis 8 years before the beneficiary-month selected; therefore, the patient's height recorded on the claim was measured as much as 8 years prior to the beneficiary-month. Beneficiaries in our sample ranged from 48 years old to 87 years old, with an average age of about 72 years old.

For two beneficiary-months, we found discrepancies between patient height recorded on the claim and the height recorded on the medical record. Specifically:

- For one beneficiary-month with dates of service in June 2011, Woburn Dialysis recorded 147.32 centimeters on the ESRD PPS claims. This was the height recorded on patient's initial assessment report dated April 5, 2011. However, the patient's height recorded on the ESRD Medical Evidence Report – Medicare Entitlement and /or Patient Registration Form (CMS-2728)<sup>30</sup> completed by the patient's prior dialysis facility and signed by the patient's physician on March 28, 2011, was 157.48 centimeters. Woburn Dialysis contacted the patient's current facility in March 2013, and the patient's height measured at 152.4 centimeters. Woburn Dialysis officials were not sure why the discrepancy occurred.
- For another beneficiary-month with dates of service in January 2011, Woburn Dialysis recorded 170.18 centimeters on the ESRD PPS claim. This was the height recorded on the patient's initial assessment report dated January 11, 2011. However, the patient's height recorded on the CMS-2728 Form signed by the patient's physician in February 2006 was 166 centimeters. Woburn Dialysis officials stated that the height of 170.18 centimeters was originally entered into DaVita's clinical software system by the patient's prior facility, which was a DaVita facility. However, in January 2011, the patient's height was changed in DaVita's clinical software system to 166 centimeters and then changed back to 170.18 centimeters in February. Woburn Dialysis was not sure why the height discrepancy occurred or why the height entered in DaVita's clinical software system in January 2011 was not the same as the height recorded on the claim. The patient is now deceased.

Woburn Dialysis staff stated that patient height is measured upon admission to the facility and reassessed if the facility notes a change in the patient's height, such as an amputation. Woburn Dialysis enters the height measured during a patient's initial assessment into DaVita's clinical software system. DaVita's billing system uses this height to populate the height on the claim.

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<sup>30</sup> Dialysis facilities are required to submit the ESRD Medical Evidence Report – Medicare Entitlement and /or Patient Registration Form to the ESRD Network Organizations within 45 days from the date a patient is diagnosed with ESRD and either receives a transplant or starts a regular course of dialysis. This form is also required if a patient loses Medicare coverage and is reapplying for Medicare benefits. The form must be retained in the patient's medical records.

We do not have assurance that the height used to calculate the ESRD PPS payment for five beneficiary-months was accurate because of the age of the documentation in the medical records to support the height of the patient. Furthermore, since we were unable to determine the actual height of patients during the last dialysis session of the two beneficiary-months, we could not calculate the effect this data would have had on Medicare payments to the facility.

An overstatement in the patient height recorded on the claim would result in an overpayment for each dialysis treatment, and an understatement in the patient height recorded on the claim would result in an underpayment for each dialysis treatment.

### **Separate Payments Did Not Comply With Consolidated Billing Requirements**

The MAC makes 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 entities that provide ESRD-related services to their patients.<sup>31</sup>

For seven beneficiary-months,<sup>32</sup> Medicare made duplicate payments for ESRD-related services that were billed by Woburn Dialysis and other providers and suppliers.

#### *Laboratory Services*

For six beneficiary-months, the patients' nephrologists ordered ESRD-related laboratory services for which 10 specimens were sent to Winchester Hospital and 2 specimens were sent to DaVita's laboratory.

These ESRD-related laboratory services were subject to consolidated billing requirements; however, Winchester Hospital and DaVita's laboratory separately billed Medicare for the services. Specifically:

- For the 10 specimens sent to Winchester Hospital, Woburn Dialysis did not use laboratory requisition forms that indicated the specimens originated from Woburn Dialysis. Therefore, Winchester Hospital staff was unaware that the laboratory services were subjected to the agreement and billed Medicare for laboratory services instead of billing DaVita. When the MAC rejected the claims for these services, Winchester Hospital resubmitted the claims for these services with an incorrect "AY" modifier because the requisition forms did not state that the laboratory test was ESRD-related. Winchester Hospital did not contact the ordering physician or Woburn Dialysis to determine why services were denied.
- For the two specimens sent to DaVita's laboratory, DaVita separately billed the services to Medicare with an "AY" modifier because the patients' nephrologists ordered the test

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<sup>31</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 10.

<sup>32</sup> The number of beneficiary-months does not add to seven because one beneficiary-month had both ESRD-related laboratory services and drugs separately billed to Medicare during the month.

with a diagnosis code that DaVita did not consider to be ESRD-related. However, the patients' nephrologists stated to us that the tests were ESRD-related.

As a result, DaVita received overpayments of \$47 and Winchester Hospital received \$65 in overpayments for ESRD-related laboratory services. DaVita and Winchester Hospital officials stated that they are working together to identify all ESRD-related laboratory tests inappropriately billed to Medicare.<sup>33</sup>

### *Drugs*

For two beneficiary-months, other entities separately billed ESRD-related drugs to Medicare using the patients' Part D prescription drug benefit. Specifically:

- 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. The ordering nephrologist was not aware that the cream was included in the ESRD PPS. Woburn Dialysis was not aware that the local anesthetic cream was prescribed for the patient.
- For one beneficiary-month, the patient's nephrologist prescribed furosemide for ESRD-related edema that the patient had filled through the DaVita Rx<sup>34</sup> pharmacy. Furosemide is a diuretic in tablet form and has an injectable equivalent. Woburn Dialysis was not aware that this drug was prescribed for the patient.

As a result, Medicare overpaid \$17 under the prescription drug benefit (DaVita received overpayments of \$1 and another entity received \$16 in overpayments) and the beneficiaries unnecessarily incurred copayments totaling \$21.

## **CLAIMS DATA SUBMITTED WITH INACCURATE INFORMATION**

CMS relies on Medicare claims data to develop new and adjust existing payment systems, to monitor payment systems and implementation of policies, and to calculate Medicare payments to providers.

Through our analysis of the 10 beneficiary-months in our review, we found that the claims were submitted with inaccurate information, which could hinder CMS's efforts to monitor the ESRD program.

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<sup>33</sup> For the period January 1, 2011, through December 31, 2012, Winchester Hospital billed Medicare \$14,139 for 2,826 laboratory tests with an "AY" modifier that were not in our sample of the 10 beneficiary-months. However, under the agreement between DVA Healthcare of Massachusetts, Inc., and Winchester Hospital, Winchester Hospital was required to bill DaVita for these services. We did not determine whether these services were subject to consolidated billing requirements.

<sup>34</sup> DaVita Rx, LLC, is a subsidiary of DaVita, Inc.

## **Hematocrit Reading Reported on Claims Were a Calculation Using the Hemoglobin Reading**

CMS requires dialysis facilities to report either a hemoglobin or hematocrit reading on its claims to indicate the patient's most recent reading taken before the start of the billing period.<sup>35</sup>

Dialysis facilities must report the reading on the claim using one of two codes, one of which is specific for hemoglobin and the other for hematocrit. CMS uses the hemoglobin and hematocrit readings reported on claims for ESA monitoring and QIP purposes.

For nine beneficiary-months, Woburn Dialysis was required to report either a hemoglobin or hematocrit reading on its claims. Woburn Dialysis recorded the patient's most recent hemoglobin multiplied by three on its claims as the most recent hematocrit reading. For example, a patient's actual hematocrit reading was 31.9; however, Woburn Dialysis recorded 31.2 (a hemoglobin reading of 10.4 times 3) on the claim as the hematocrit reading. Woburn Dialysis stated that the conversion of hemoglobin to hematocrit is a well-known and established calculation in the medical community. However, adhering to the code definition ensures that all facilities consistently report hemoglobin or hematocrit readings on claims. Not adhering to the code definition can hinder CMS's efforts to monitor safety and quality.

## **Claims Data Incorrectly Identified That Beneficiary Self-Administered Anemia Management Drugs**

CMS requires dialysis facilities to report condition code "70" on the ESRD claim to indicate the billing is for a home dialysis patient that self-administers an anemia management drug.<sup>36</sup>

For one beneficiary-month, Woburn Dialysis incorrectly submitted a claim with condition code "70" for a home dialysis patient who did not self-administer an anemia management drug. On two occasions during the billing period, Woburn Dialysis administered an anemia management drug to the patient at the facility during the patient's visits. The dialysis facility stated that the claim was billed incorrectly because information was incorrectly entered in DaVita's clinical software system.

## **Anemia Management Drug Administered Not Reported on Claim**

CMS requires dialysis facilities to report all ESRD-related drugs and biologicals that are included in the ESRD PPS on the ESRD claim.<sup>37</sup>

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<sup>35</sup> "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 (CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, § 60.4.2).

<sup>36</sup> "Line Item Billing Requirement for Epoetin Alfa (EPO) Submitted on End Stage Renal Disease (ESRD) Claims" *Medicare Claims Processing Manual*, Transmittal 1285 (Change Request 5545; July 13, 2007).

<sup>37</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §60.2.

For one beneficiary-month, Woburn Dialysis did not report the administration of an anemia management drug to a patient on the ESRD claim. The facility medical records showed that the patient was administered an anemia management drug three times during the month. However, only two instances were recorded on the claim. According to Woburn Dialysis, the administration of the drug not reported on the claim was added to the medical record after the claim was submitted to Medicare; however, DaVita did not resubmit a corrected claim.

## **IMPROPER SUBMISSION OF MULTIPLE CLAIMS FOR REPETITIVE SERVICES**

CMS requires dialysis facilities to submit bills monthly for repetitive ESRD services.<sup>38</sup>

For three beneficiary-months, Woburn Dialysis submitted multiple claims for repetitive services. Woburn Dialysis official stated that DaVita's billing system has been programmed to submit a new ESRD claim to Medicare each time a different type of dialysis service is provided to a beneficiary rather than waiting until the end of the month to submit one claim for each type of service provided during the beneficiary-month. Submitting multiple claims for repetitive dialysis services may hinder CMS's efforts to monitor the ESRD program. Specifically:

- For two beneficiary-months, Woburn Dialysis did not report a hematocrit or hemoglobin reading on some of the claims submitted during the month because the patients were not administered an ESA during the period covered by the claim. However, the patients were administered an ESA during the month.
- For one beneficiary-month, Woburn Dialysis submitted four separate claims for hemodialysis treatments, three of which had a different hematocrit reading because the dialysis facility recorded the most recent hematocrit reading taken before the start of the each claim's billing period. CMS uses the hemoglobin and hematocrit readings reported on claims for ESA monitoring and QIP purposes.
- For one beneficiary-month, Woburn Dialysis submitted three claims for separate ultrafiltration services. Ultrafiltration is used in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. Occasionally, medical complications may occur which require that ultrafiltration be performed separately from the dialysis treatment. CMS pays for separate ultrafiltration if performed on a day other than when a dialysis treatment is furnished and it is medically justified.<sup>39</sup> The requirement that one claim be submitted for repetitive ultrafiltration services ensures that the MAC is aware of the frequency in which ultrafiltration services are being performed and assesses the need for all ultrafiltration services billed to Medicare on a monthly basis.

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<sup>38</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §50.3.

<sup>39</sup> *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 11, § 50.A3; *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §50.7.

## HOME DIALYSIS RECORDS INCOMPLETE AND NOT MAINTAINED

Dialysis facilities must review patients self-monitoring data at least every 2 months and maintain it in patient medical records.<sup>40</sup> A review of the home patient's self-monitoring data helps ensure appropriate clinical care and provides an opportunity for dialysis facilities to educate the patient about the importance of following the plan of care. Furthermore, a review of the home patient's self-monitoring data monthly helps ensure that only completed treatments are billed to Medicare.

For three beneficiary-months, Woburn Dialysis furnished home dialysis services to patients but did not always maintain records or ensure that the patient's self-monitoring data was correct. Specifically:

- For two beneficiary-months, Woburn Dialysis did not maintain patient self-monitoring data in its medical records for all or some of the days the patient was furnished home dialysis services.
- For one beneficiary-month, the patient did not record self-monitoring data for three separate dates. In addition, on four dates of services, the patient recorded an ESA dosage on the daily record even though the patient did not self-administer ESAs. In addition, the patient's record inaccurately reflected the actual dates and dosages an ESA was administered in the facility.

Woburn Dialysis stated that home patients do not always fully and accurately document their self-monitoring data. As a result, Woburn Dialysis could not be assured that the patients were following the plan of care and that only completed treatments were billed to Medicare.

## RECOMMENDATIONS

We recommend that Woburn Dialysis:

- work with Winchester Hospital to identify and refund to Medicare for all separately billed ESRD-related laboratory services subject to consolidated billing requirements,
- 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,
- strengthen controls to ensure compliance with monthly billing requirements for repetitive services,
- educate home dialysis patients on how to record and report health status information, and

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<sup>40</sup> 42 CFR §§ 494.100 (b)(2) and 494.100 (b)(3).

- maintain home dialysis self-monitoring data in the medical records.

## **WOBURN DIALYSIS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Woburn Dialysis concurred with our first, fifth, and sixth recommendations, partially concurred with our second recommendation, and did not express concurrence or nonconcurrence with our third and fourth recommendations. Woburn Dialysis described the corrective actions it had taken or plans to take for all recommendations except for certain findings related to our second recommendation.

Woburn Dialysis concurred with our second recommendation regarding consolidated billing requirements with respect to the laboratory tests separately billed by Winchester Hospital; however, Woburn Dialysis stated that the services separately billed by DaVita's laboratory were billed appropriately because the diagnosis codes provided by the nephrologist were not ESRD-related. Woburn Dialysis also stated that it is unable to determine whether other providers submitted claims for ESRD-related services and supplies that are subject to consolidated billing requirements. We maintain that these services were ESRD-related and that Woburn Dialysis should establish controls to ensure full compliance with consolidated billing requirements.

Woburn Dialysis' comments are included in their entirety as Appendix B.

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our audit covered \$27,346 in Medicare payments to Woburn Dialysis for 10 beneficiary-months (each beneficiary-month consisted of 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 but did 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 Woburn Dialysis. 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 Woburn Dialysis for Medicare reimbursement.

We conducted our fieldwork at Woburn Dialysis from April 2012 through November 2013.

### **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 Woburn Dialysis under the ESRD PPS and grouped those treatments by beneficiary-months;
- identified 522 beneficiary-months with \$1,243,553 in Medicare payments to Woburn Dialysis under the ESRD PPS for 71 beneficiaries from which we selected our sample;
- identified all other CY 2011 Medicare claims submitted by any other provider(s) for the 71 beneficiaries
- selected a judgmental sample of 10 beneficiary-months to obtain a variety of treatment

modalities, beneficiary characteristics, and billing scenarios 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 Woburn Dialysis personnel and reviewed the Dialysis Facilities policies and procedures applicable to billing ESRD claims;
- toured Woburn Dialysis’s facility to gain an understanding of its operations;
- reviewed the itemized bills and medical record documentation provided by Woburn Dialysis to support the selected claims;
- determined whether the ESRD PPS claims submitted by the facility were supported and billed correctly;
- contacted nephrologists at Woburn Nephrology Associates, P.C., to determine whether separately billed services were ESRD-related;
- contacted Winchester Hospital to discuss the ESRD-related laboratory services separately billed by the hospital;
- determined whether any services subject to consolidated billing were inappropriately separately billed;
- discussed the incorrectly billed claims with Woburn Dialysis personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used CMS’s National Claims History file to identify CYs 2011 and 2012 laboratory services billed by Winchester Hospital for patients at DaVita’s Woburn Dialysis and Wellington Circle Dialysis facilities and provided the results to Winchester Hospital; and
- discussed the results of our review with Woburn Dialysis 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 B: WOBURN DIALYSIS COMMENTS



March 14, 2013

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

RE: Report Number A-01-12-00516

Dear Mr. Lamir:

Woburn Dialysis appreciates the opportunity to comment on The U.S. Department of Health and Human Services Office of Inspector General (OIG) draft report entitled *Compliance Review of Woburn Dialysis*. Woburn Dialysis and DaVita HealthCare Partners Inc. are committed to compliance with all statutes and regulations governing reimbursement for dialysis services. The OIG's recommendations from its report and Woburn's responses are as follows:

- 1. Work with Winchester Hospital to identify and refund to Medicare for all separately billed ESRD-related laboratory services subject to consolidated billing requirements.**

Woburn concurs with this recommendation. Woburn will provide information to Winchester Hospital indicating which laboratory services Woburn believes were subject to consolidated billing and will request that Winchester refund such claims to Medicare.

- 2. Establish controls to ensure compliance with consolidated billing requirements.**

Woburn concurs with this recommendation with respect to the labs that were separately billed by Winchester Hospital. As Woburn previously explained to the OIG, Woburn has already remediated the process breakdown that resulted in Winchester Hospital submitting claims for laboratory services that were subject to consolidated billing requirements.

Woburn does not concur with the OIG's recommendation with respect to the labs that were separately billed by DaVita Labs or the medications separately billed by pharmacies:

- Woburn reasonably relies on the ordering nephrologist to provide accurate diagnosis information at the time he or she orders an item or service. Woburn believes that the claims separately billed by DaVita Labs were done so appropriately, because the diagnosis codes provided by the nephrologist at the time the labs were ordered were not ESRD-related. It is not appropriate for Woburn to second-guess a nephrologist's medical justification for an item or service.
- Beneficiaries with ESRD typically have multiple co-morbidities and seek care from many providers outside of the dialysis facility. Woburn has no insight into the billing of other providers, and therefore is unable to determine whether other providers are submitting claims for ESRD-related services and supplies that are subject to consolidated billing requirements. Woburn believes the OIG's recommendation instead should be for CMS to establish or improve its controls, as it has more complete information on all the items and services provided to ESRD-patients and is in a better position to determine whether those items and services are subject to consolidated billing requirements.
- With respect to the claim for furosemide, this drug was not specifically included on CMS' list of drugs subject to consolidated billing for the date of service in question. However, Woburn will work with DaVita Rx to refund this claim.

**3. Strengthen controls to ensure that required information is accurately recorded on the ESRD claims in accordance with Medicare billing requirements.**

Woburn appreciates the OIG's comments. Woburn is carefully analyzing the OIG's findings and recommendations and will look for opportunities to improve its processes and controls so that all required information is accurately reported on its claims. Woburn will reeducate its clinical staff on measuring patient height on a yearly basis and the importance of recording weight accurately.

**4. Strengthen controls to ensure compliance with monthly billing requirements for repetitive services.**

Woburn appreciates the OIG's comments and is carefully analyzing the OIG's findings and recommendations. As previously explained to the OIG during our in-person meeting, Woburn splits claims during a month as a result of CMS' instruction that certain revenue codes cannot be reported together on the same claim. However, DaVita is exploring the implementation of a new billing system, which should reduce the number of claims for repetitive services submitted within a month. Woburn will look for additional opportunities to improve its processes and controls to address the OIG's concerns.

**5. Educate home dialysis patients on how to record and report health status information.**

Woburn concurs with the OIG's recommendation because Woburn already provides extensive education to home modality patients about how to record and report their health status information.

Woburn hopes the OIG can appreciate that "to err is human." It is not realistic to expect perfect documentation from dialysis patients, who are extremely sick with a complex disease state and may not fully appreciate all of the billing and compliance implications that may flow from their own documentation. CMS directs dialysis providers to bill for home dialysis services based upon the patient's plan of care, which is an implicit acknowledgement that the dialysis provider may not receive completely accurate information from the patient.

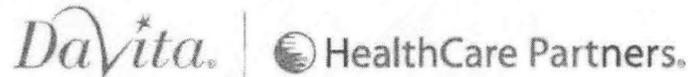
Further, Woburn has already taken steps to address this issue. In addition to the monthly collection of flow sheets, Woburn asks patients to sign an attestation indicating that they completed all treatments as ordered, or indicating any missed treatments. This allows the nurse to educate the patients about the importance of following the plan of care and documenting accurately. We do not believe these additional safeguards are required by the CMS billing guidance, but were put in place to provide additional documentation that treatments were performed per the plan of care. Further, in response to the OIG's recommendation, Woburn commits to re-educating all of its home modality patients specifically on the importance of accurate documentation.

**6. Maintain home dialysis self-monitoring data in the medical records.**

Woburn concurs with the OIG's recommendation because Woburn already requires patients to bring their flowsheets to the facility on a monthly basis and the flowsheets are maintained in the patients' records. Absence of self-monitoring data is usually an indication that the patient failed to bring in their records for a given month, rather than a failure to maintain the records.

As stated above, Woburn hopes the OIG can appreciate that it is not realistic to expect perfect documentation from dialysis patients. CMS directs dialysis providers to bill for home dialysis services based upon the patient's plan of care, which is an implicit acknowledgement that the dialysis provider may not receive complete or fully accurate information from the patient.

Further, Woburn has already taken steps to address this issue. In addition to the monthly collection of flow sheets, Woburn asks patients to sign an attestation indicating that they completed all treatments as ordered, or indicating any missed treatments. This allows the nurse



to educate the patients about the importance of following the plan of care and documenting accurately. We do not believe these additional safeguards are required by the CMS billing guidance, but were put in place to provide additional documentation that treatments were performed per the plan of care. Further, in response to the OIG's recommendation, Woburn commits to re-educating all of its home modality patients specifically on the importance of accurate documentation and remembering to bring their flowsheets to the clinic.

Thank you again for the opportunity to review and provide comments on the Draft Report. Please do not hesitate to contact me if you have any questions.

Regards,

A handwritten signature in black ink, appearing to read "Doug Klof".

Doug Klof

Senior Director, Compliance