

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE PAYMENTS
FOR LABORATORY TESTS
BILLED WITH AN AY MODIFIER BY
TOTAL RENAL LABORATORIES, INC.**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



David Lamir
Regional Inspector General
for Audit Services

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EXECUTIVE SUMMARY

Total Renal Laboratories, Inc., did not always comply with Medicare requirements for laboratory tests billed with an AY modifier for beneficiaries with end-stage renal disease resulting in at least \$1.3 million in estimated overpayments.

WHY WE DID THIS REVIEW

A bundled end-stage renal disease (ESRD) prospective payment system (PPS) went into effect January 1, 2011. The new ESRD PPS includes a consolidated billing requirement for laboratory services (hereafter referred to as “tests”) that are furnished for the treatment of ESRD. However, a patient’s physician may order a test for reasons other than the treatment of ESRD. These tests can be performed while the patient is in the ESRD facility for the convenience of the patient and to mitigate the need for the patient to receive additional health care visits or have blood drawn at a separate location. The Centers for Medicare & Medicaid Services (CMS) allows for separate payment of tests that are ordered typically for the treatment of ESRD if they are furnished for reasons other than the treatment of ESRD when billed with modifier AY. Using data matching and data analysis techniques, we identified an independent laboratory, Total Renal Laboratories, Inc. (TRL), with significant Part B Medicare claims for tests billed with the AY modifier.

The objective of this review was to determine whether TRL complied with Medicare requirements for laboratory tests billed with an AY modifier for beneficiaries with ESRD.

BACKGROUND

Effective January 1, 2011, Medicare pays dialysis facilities on a bundled per-treatment basis for renal dialysis services. Tests that are furnished to beneficiaries for the treatment of ESRD are included in the new ESRD PPS bundled payment. The patient’s ordering physician decides whether a test is for the treatment of the patient’s ESRD. If the physician orders a test for the treatment of the patient’s ESRD, then CMS considers the test a renal dialysis service and includes it as part of the ESRD PPS bundled payment. In the event that a test is furnished for reasons other than the treatment of ESRD, the dialysis facility (or outside supplier or provider, such as a laboratory or pharmacy) may submit a claim for separate payment using the AY modifier. Tests furnished for reasons other than the treatment of ESRD are subject to skilled nursing facility (SNF) consolidated billing requirements for beneficiaries in a SNF.

Medicare claims must be completed accurately in order for the Medicare administrative contractor to process them correctly and promptly. Furthermore, Federal regulations require that all tests covered under Medicare must be ordered by the physician who is treating the beneficiary and that the physician who orders the tests must maintain documentation of medical necessity in the beneficiary’s medical record. In addition, the ordering physicians must be uniquely identified on all claims for laboratory tests.

TRL, a wholly owned subsidiary of DaVita Healthcare Partners, Inc. (DaVita), performs tests for DaVita owned dialysis facilities. Medicare paid TRL \$2,953,443 for tests billed with the AY modifier and provided to 40,936 beneficiaries in calendar years 2012 through 2013.

WHAT WE FOUND

TRL did not always comply with Medicare requirements for laboratory tests billed with an AY modifier for beneficiaries with ESRD. Specifically, for 60 of the 100 beneficiary-days, TRL submitted separate claims using the AY modifier for laboratory tests furnished for the treatment of ESRD contrary to the consolidated billing requirement. Medicare had already reimbursed the dialysis facilities for these tests as part of the ESRD PPS bundled payment.

In addition, TRL did not always comply with other Medicare requirements. Specifically, TRL:

- improperly used a modifier to bypass SNF consolidated billing requirement edits on its claims (100 beneficiary-days),
- did not maintain adequate documentation of medical necessity (18 beneficiary-days), and
- submitted claims that inaccurately identified the ordering physician (4 beneficiary-days).

These errors occurred primarily because TRL did not have adequate controls to comply with certain Medicare requirements. On the basis of our sample results, we estimated that Medicare overpaid TRL at least \$1,257,774 for tests that were furnished for the treatment of ESRD. In addition, TRL may have received overpayments for beneficiaries in a SNF and may have billed Medicare for medically unnecessary tests. Inaccurate claim information may have hindered CMS's efforts to monitor the physician ordering practices.

Furthermore, some physicians did not provide definitive answers or did not respond to our requests as to whether tests were ordered for the treatment of ESRD or for reasons other than the treatment of ESRD. In addition, sufficient and appropriate evidence was not available to conclude whether valid physician orders for the tests furnished existed because the documentation was not reliable. Therefore, for 25 beneficiary-days, we did not have enough evidence to make a determination whether Medicare appropriately paid TRL an estimated \$604,923 for tests billed with an AY modifier or not ordered by a physician.

WHAT WE RECOMMEND

We recommend that TRL:

- refund to the Medicare contractor \$1,257,774 in estimated overpayments for incorrectly billed Part B claims with the AY modifier because the test was for the treatment of ESRD,

- work with DaVita to identify and refund to Medicare the portion of the \$604,923 for tests incorrectly billed with an AY modifier or not ordered by a physician,
- establish controls to ensure compliance with ESRD PPS consolidated billing requirements,
- strengthen controls to ensure compliance with Medicare requirements that tests billed are reasonable and necessary,
- strengthen controls to ensure that Medicare claims identify the correct ordering physician, and
- discontinue billing the CB modifier with the AY modifier.

TOTAL RENAL LABORATORIES COMMENTS AND OUR RESPONSE

In written comments on our draft report, TRL expressly concurred with our second, fourth, fifth, and sixth recommendations and described the actions it had planned to address them. With respect to our first and third recommendations, TRL agreed to refund the appropriate portion of the \$1,257,774 after taking into consideration any claims from the applicable period that may have already been refunded for reasons separate and apart from this audit, as well as implement our recommendation by improving controls to ensure compliance with the ESRD PPS consolidated billing requirements. However, TRL did not concur with the findings that it incorrectly billed Part B claims with the AY modifier and that it did not comply with the ESRD PPS billing requirements. TRL also described the actions it had planned to address the insufficient supporting documentation of physician reviews of and use of test results as described in the “Other Matters” section of our report.

We maintain that our findings are valid regarding separate payments made to TRL for claims billed with an AY modifier for laboratory tests furnished for the treatment of ESRD that did not comply with consolidated billing requirements.

We have included TRL’s comments in their entirety as Appendix D.

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INTRODUCTION

WHY WE DID THIS REVIEW

A bundled end-stage renal disease (ESRD) prospective payment system (PPS) went into effect January 1, 2011. The new ESRD PPS includes a consolidated billing requirement for laboratory services (hereafter referred to as “tests”)¹ that are furnished for the treatment of ESRD. However, a patient’s physician may order a test for reasons other than the treatment of ESRD. These tests can be performed while the patient is in the ESRD facility for the convenience of the patient and to mitigate the need for the patient to receive additional health care visits or have blood drawn at a separate location. The Centers for Medicare & Medicaid Services (CMS) allows for separate payment of tests that are ordered typically for the treatment of ESRD if they are furnished for reasons other than the treatment of ESRD when billed with modifier AY. Using data matching and data analysis techniques, we identified an independent laboratory, Total Renal Laboratories, Inc. (TRL), with significant Part B Medicare claims for tests billed with the AY modifier.

OBJECTIVE

Our objective was to determine whether TRL complied with Medicare requirements for laboratory tests billed with an AY modifier for beneficiaries with ESRD.

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.

End-Stage Renal Disease Payment System

Before January 1, 2011, Medicare used a prospective payment system with a single composite 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, a new ESRD PPS combined the single composite payment rate and separate reimbursements for dialysis services into a bundled per-treatment base rate (hereafter

¹ Laboratory services include both blood tests and cultures. For this report, we refer to these laboratory services as “tests.”

referred to as the “ESRD PPS bundled payment”) for renal dialysis services.^{2, 3} Tests that are furnished to individuals for the treatment of ESRD are included in the new ESRD PPS bundled payment.

Medicare Consolidated Billing Requirements for Dialysis Services

The new ESRD PPS includes a consolidated billing requirement for renal dialysis services included in the bundled payment rate, including, for example, tests that are furnished for the treatment of ESRD.⁴ With the implementation of the new ESRD PPS bundled payment, all renal dialysis services must be billed by the dialysis facility and are no longer separately payable when furnished by a provider other than the dialysis facility. Dialysis facilities are responsible for reimbursing other entities that provide renal dialysis services to their patients. When an outside supplier or provider (e.g., laboratory or pharmacy) bills for a renal dialysis service, Medicare will reject or deny the claim to prevent duplicate payment.

Medicare Billing Requirements

CMS developed a list of tests that are routinely performed for the treatment of ESRD and subject to consolidated billing.⁵ Tests on this list, if furnished to ESRD patients by an ESRD facility directly or under arrangement (with a laboratory), will be considered renal dialysis services and covered under the new ESRD PPS bundled payment.⁶ A patient’s physician or practitioner may order a test that is included on the list for a reason other than the treatment of ESRD. In the event that a test 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 the AY modifier.⁷

DaVita Healthcare Partners and Laboratories

As of June 30, 2015, DaVita Healthcare Partners, Inc. (DaVita), operated or provided administrative services at 2,210 renal dialysis facilities located in the United States serving

² 75 Fed. Reg. 49029 (Aug. 12, 2010).

³ Congress mandated CMS implement a bundled per-treatment payment rate effective January 1, 2011. Medicare Improvement for Patients and Providers Act of 2008, P.L. 110-275 § 153(b), Social Security Act, § 1881(b)(14).

⁴ Social Security Act, § 1881(b)(14)(B)(iv); 42 CFR § 413.171.

⁵ 75 Fed. Reg. at 49213-49214. CMS has updated this list no less than annually. Information related to the laboratory tests, drugs, and supplies subject to the ESRD consolidated billing requirement are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Last accessed May 19, 2015.

⁶ 75 Fed. Reg. at 49169

⁷ *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §§ 50.1.5 and 60.1.

approximately 176,000 patients.⁸ TRL located in Deland, Florida, and DVA Laboratory Services, Inc., located in Fort Lauderdale, Florida, are wholly owned subsidiaries of DaVita. TRL provides tests to ESRD beneficiaries for DaVita-owned dialysis facilities, and DVA Laboratory Services provides tests to ESRD beneficiaries for DaVita-owned dialysis facilities and other dialysis facilities. Together both laboratories are known as DaVita Labs; they have centralized billing and use the same billing procedures.

TRL⁹ is an independent laboratory that performs tests for dialysis facilities. Medicare paid TRL \$2,953,443 for 229,087 tests billed with the AY modifier and provided to 40,936 beneficiaries in calendar years (CYs) 2012 through 2013.¹⁰ First Coast Service Options, Inc., is the Medicare administrative contractor (MAC) for DaVita Labs.¹¹

For each laboratory test ordered by a physician at a DaVita facility, TRL receives and maintains a laboratory requisition. However, TRL does not receive a copy of the actual physician order.

Total Renal Laboratories Use of Diagnosis Codes to Determine the Use of the AY Modifier

For DaVita-owned ESRD facilities DaVita's coding team and coding software assign diagnosis codes to the tests billed to Medicare on the basis of the clinical justifications provided by the physician ordering the laboratory test. TRL worked with DaVita's revenue operations and its office of the chief medical officer to identify a list of diagnosis codes that, when assigned to the test, would indicate the test was performed for the treatment of ESRD. For cultures, DaVita's office of the chief medical officer also identified a list of access sites where a specimen was collected which would indicate whether the culture was performed for the treatment of ESRD.

TRL received laboratory test requisitions from ESRD facilities containing limited clinical information (i.e., diagnosis codes). TRL had a process in place such that when certain diagnosis codes accompanied requests for certain tests, TRL would bill for those tests using the AY modifier. TRL did not solicit or receive information from ordering physicians or ESRD facilities that would explicitly indicate whether the physicians ordered the tests for reasons other than the treatment of ESRD.

Medicare Payment Requirements

Medicare claims must be completed accurately in order for the MAC to process them correctly and promptly.¹²

⁸ Available at <http://www.davita.com/about>. Last accessed September 2, 2015.

⁹ TRL is the subject of this report. We plan to issue a separate report to DVA Laboratory Services.

¹⁰ TRL did not submit claims to Medicare with the AY modifier for tests furnished after July 16, 2013.

¹¹ Palmetto GBA, the Railroad MAC, processes the Part B claims for the Railroad Retirement beneficiaries that DaVita Labs serviced. We excluded these claims from our population.

¹² *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 1, § 80.3.2.2.

Under the Act, §1881(b)(14)(A)(i), the Secretary implemented a bundled per-treatment base rate for renal dialysis services furnished on or after January 1, 2011. Pursuant to section 1881(b)(14)(B), the new ESRD bundled payment rate included a requirement for consolidated billing by defining “renal dialysis services” to encompass items and services included in the composite rate for renal dialysis services as of December 31, 2010, as well as diagnostic laboratory tests and other items and services not included in the prior composite rate that are furnished to individuals for the treatment of ESRD.

Skilled nursing facilities (SNFs) are subject to consolidated billing requirements and some Medicare Part A and Part B services are included in a SNF’s bundled payment. CMS has SNF consolidated billing edits in place to ensure that providers and suppliers cannot receive payment for these services since SNFs are being paid for them. Renal dialysis services are excluded from SNF consolidated payments (the Act, § 1888(e)(2)(A)(ii)). Providers and suppliers use the CB modifier in order to bypass the edits and get paid for tests that are for the treatment of ESRD.¹³

Medicare payments may not be made for items and 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 Act, § 1862(a)(1)(A)). Federal regulations (42 CFR § 410.32(a)) state: “All ... diagnostic laboratory tests ... must be ordered by the physician who is treating the beneficiary Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary”

In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (section 1833(e)). Federal regulations (42 CFR § 410.32(d)(2)(ii)) require that the entity submitting a claim for diagnostic laboratory tests maintain the documentation it receives from the ordering physician. Federal regulations (42 CFR § 410.32(d)(3)(i)) also require that, upon request by CMS the entity that submitted the claim (e.g., the laboratory) must provide, “[d]ocumentation of the order for the service billed,” as well as diagnostic or other medical information that the entity received from the ordering physician. Federal regulations (42 CFR §§ 410.32(d)(2)(iii) and (d)(3)(iii)) further state that the entity submitting the claim (e.g., the laboratory) may request additional diagnostic and other medical information from the ordering physician to document that the services it bills are reasonable and necessary (e.g., a missing order). Federal regulations (42 CFR § 410.32(d)(2)(i)) require physicians who order diagnostic laboratory tests maintain documentation of medical necessity in beneficiaries’ medical records. If a laboratory bills for a diagnostic laboratory test and the physician who ordered the test cannot produce documentation of the medical necessity of the test, CMS denies the claim (42 CFR § 410.32(d)(3)(ii)(C)).¹⁴

¹³ *Medicare Claims Processing Manual*, chapter 16, § 40.6.2.3.

¹⁴ In commenting on a change in policy to no longer require physicians or nonphysician practitioners (NPPs) to sign requisitions for laboratory tests, CMS said, “We believe it is the responsibility of the clinical diagnostic laboratory, as it is for the provider of any service, to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by a physician or NPP” (76 Fed. Reg. 73025, 73304 (Nov. 28, 2011)).

Other Medicare Requirements

All claims for diagnostic laboratory tests must contain the legal name and National Provider Identifier (NPI) of the physician or eligible professional who ordered the test (42 CFR § 424.507(a)(1)(ii)).

HOW WE CONDUCTED THIS REVIEW

We used CMS's National Claims History file to identify 229,087 Part B paid line items for tests billed by TRL with an AY modifier that were provided to 40,936 beneficiaries receiving dialysis treatments for ESRD. These tests were associated with 200,372 claims with dates of service in CY 2012 or CY 2013.¹⁵ We grouped those treatments by beneficiary and date of services (200,181 beneficiary-days). We contacted the ordering physicians for a stratified random sample of 100 beneficiary-days and asked whether the tests were furnished for the treatment of ESRD or for reasons other than the treatment of ESRD. Using medical and billing records, we also determined whether the claims complied with certain other Medicare requirements.

We limited our review of internal controls to those applicable to billing procedures and medical record documentation for tests furnished by TRL and billed with an AY modifier. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary.

We performed a limited review of DaVita's internal controls with respect to DaVita's policies and procedures applicable to medical record documentation and physician orders. We did not evaluate DaVita's electronic medical records system or test the applicable internal controls related to entering medical information, including physician orders, into the system. However, we used spreadsheets and screen printouts DaVita provided from its electronic medical records as well as other medical record documentation, such as rounding reports, as corroborating evidence to identify the ordering physicians. In addition, we determined whether there were valid physician orders for the laboratory tests in our sample.

This report does not represent an overall assessment of all claims submitted by TRL 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.

We conducted our audit work from July 2014 through May 2015.

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.

¹⁵ TRL did not submit claims to Medicare with the AY modifier for tests furnished after July 16, 2013.

Appendix A contains the details of our scope and methodology, Appendix B contains statistical sampling methodology, and Appendix C contains our sampling results and estimates.

FINDINGS

TRL did not always comply with Medicare requirements for tests billed with an AY modifier for beneficiaries with ESRD. Specifically, for 60 of the 100 beneficiary-days, TRL submitted separate claims using the AY modifier for tests furnished for the treatment of ESRD contrary to the consolidated billing requirement. Medicare had already reimbursed the dialysis facilities for these tests as part of the ESRD PPS bundled payment.

In addition, TRL did not always comply with other Medicare requirements.¹⁶ Specifically, TRL:

- improperly used a modifier to bypass SNF consolidated billing requirement edits on its claims (100 beneficiary-days),
- did not maintain adequate documentation of medical necessity (18 beneficiary-days), and
- submitted claims that inaccurately identified the ordering physician (4 beneficiary-days).

These errors occurred primarily because TRL did not have adequate controls to comply with certain Medicare requirements. On the basis of our sample results, we estimated that Medicare overpaid TRL at least \$1,257,774 for tests that were furnished for the treatment of ESRD. In addition, TRL may have received overpayments for beneficiaries in a SNF and may have billed Medicare for medically unnecessary tests. Inaccurate claim information may have hindered CMS's efforts to monitor the physician ordering practices.

Furthermore, some physicians did not provide definitive answers or did not respond to our requests as to whether tests were ordered for the treatment of ESRD or for reasons other than the treatment of ESRD. In addition, sufficient and appropriate evidence was not available to conclude whether valid physician orders for the laboratory tests furnished existed because the documentation was not reliable. Therefore, for 25 beneficiary-days, we did not have enough evidence to make a determination whether Medicare appropriately paid TRL an estimated \$604,923 for tests billed with an AY modifier or not ordered by a physician.

SEPARATE PAYMENTS DID NOT COMPLY WITH CONSOLIDATED BILLING REQUIREMENTS

Section 1881(b)(14)(B)(iv) of the Act states that, effective for claims with dates of service on or after January 1, 2011, all tests furnished for the treatment of ESRD are included in the ESRD bundled per-treatment base rate and are not separately paid. Tests that are not related to the treatment of ESRD are separately billable under the new ESRD PPS and may be billed by either

¹⁶ Some sample items contained more than one type of error.

the ESRD facility or the independent laboratory. If the ESRD facility or independent laboratory bills a test that was not related to the treatment of ESRD, the bill must include the modifier AY.¹⁷

The MAC makes payments to dialysis facilities for all renal dialysis services, including laboratory tests, when they are furnished to Medicare ESRD patients for the treatment of ESRD. Dialysis facilities are responsible for reimbursing other entities that provide renal dialysis services for the treatment of ESRD to their patients. Other entities providing renal dialysis services, including laboratories, must bill the ESRD facility for payment.

For 60 of the 100 selected beneficiary-days, TRL incorrectly billed Medicare Part B with an AY modifier for 86 tests totaling \$1,548 because physicians stated they ordered these tests for the treatment of ESRD. For example:

- TRL billed a sodium test with an AY modifier. However, the patient's physician stated she ordered the sodium test for the treatment of the patient's ESRD. The physician further stated the sodium test is one of the laboratory tests included in a monthly panel of tests routinely ordered for the treatment of the patient's ESRD.
- TRL billed a vitamin D test and lipid panel with an AY modifier. However, the patient's physician stated that both tests were ordered for the treatment of the patient's ESRD.

Separate payments did not comply with consolidated billing requirements because TRL does not require ordering physicians to notify the laboratory when they order tests for reasons other than the treatment of ESRD. Rather, if the test was assigned a diagnosis code that was not included on DaVita's list of diagnosis codes that it considered were performed for the treatment of ESRD, then TRL separately billed the laboratory test with an AY modifier. In addition, TRL did not inform physicians that it would be using DaVita's list of diagnosis codes to determine whether tests were furnished for the treatment of ESRD. Even though DaVita requires that medical records contain the medical justification for all orders, DaVita does not require facilities to maintain information in the patient's medical record indicating whether tests were ordered for the treatment of ESRD.

On the basis on our sample results, we estimated that Medicare overpaid TRL at least \$1,257,774 for tests that were furnished for the treatment of ESRD.

CLAIMS SUBMITTED WITH IMPROPER MODIFIER

Medicare claims must be completed accurately in order for the MAC to process them correctly and promptly.¹⁸

¹⁷*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §§ 50.1.5 and 60.1.

¹⁸*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 1, § 80.3.2.2.

Renal dialysis services are excluded from a SNF's bundled payment (the Act, § 1888(e)(2)(A)(ii)). Therefore, tests furnished to Medicare beneficiaries in a SNF that are for the treatment of ESRD would not be included in the SNF bundled payment; however, tests furnished to Medicare beneficiaries in a Part A SNF that are not for treatment of ESRD would be subject to the SNF consolidated billing requirements.

Section 40.6.2.3, chapter 16, of the *Medicare Claims Processing Manual* states a provider or supplier may use the CB modifier only when it has determined that: (a) the beneficiary has ESRD entitlement, (b) the test is related to the dialysis treatment for ESRD, (c) the test is ordered by a doctor providing care to patients in the dialysis facility, and (d) the test is not included in the dialysis facility's composite rate payment.¹⁹

When a test is billed with the CB modifier, the test will bypass SNF consolidated billing edits. As such, Medicare will make duplicate payments for tests furnished for reasons other than the treatment of ESRD that are provided to beneficiaries in a SNF when tests are billed with both the AY modifier and the CB modifier.

The AY modifier is used for tests that are not for the treatment of ESRD to allow for separate payment from the ESRD PPS bundled payment. The CB modifier, however, is used for tests that are furnished for the treatment of ESRD to allow for a payment separate from the SNF bundled payment.

For 100 of the 100 selected beneficiary-days, TRL incorrectly submitted claims for laboratory tests provided to ESRD beneficiaries with both the AY modifier and the CB modifier. For example:

- If a test is furnished for reasons other than the treatment of ESRD, then the AY modifier would be correct and the CB modifier would be incorrect. TRL would receive separate payment unless the beneficiary is in a SNF, then the SNF consolidated billing edits would determine whether the test is included in the SNF bundled payment. If the test is included in the SNF's bundled payment then TRL would not receive separate payment and should seek reimbursement from the SNF. The CB modifier would inappropriately allow the test to bypass SNF consolidated billing edits.
- If a test is furnished for the treatment of ESRD, then TRL should not separately bill Medicare because the dialysis facility's ESRD PPS bundled payment would include reimbursement for tests that are furnished for the treatment of ESRD. TRL should seek reimbursement from the dialysis facility. Therefore, separately billing Medicare for the test would be incorrect.

¹⁹ Prior to the implementation to the new ESRD PPS, in certain circumstances, laboratory tests furnished for the treatment of ESRD were separately billable.

DaVita officials said that these errors occurred because DaVita billing staff follows guidance from the MAC that predated the implementation of the new ESRD PPS to ensure separate payment.

As a result, TRL may have received overpayments for beneficiaries who stayed in a SNF.²⁰

ADEQUATE DOCUMENTATION OF MEDICAL NECESSITY NOT MAINTAINED

Medicare payments may not be made for items and 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 Act, § 1862(a)(1)(A)). Federal regulations (42 CFR § 410.32(a)) state: “All ... diagnostic laboratory tests ... must be ordered by the physician who is treating the beneficiary Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary”

In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (section 1833(e)). Federal regulations (42 CFR § 410.32(d)(2)(ii)) require that the entity submitting a claim for diagnostic laboratory tests maintain the documentation it receives from the ordering physician. Federal regulations (42 CFR § 410.32(d)(3)(i)) also require that, upon request by CMS the entity that submitted the claim (e.g., the laboratory) must provide, “[d]ocumentation of the order for the service billed,” as well as diagnostic or other medical information that the entity received from the ordering physician. Federal regulations (42 CFR §§ 410.32(d)(2)(iii) and (d)(3)(iii)) further state that the entity submitting the claim (e.g., the laboratory) may request additional diagnostic and other medical information from the ordering physician to document that the services it bills are reasonable and necessary (e.g., a missing order). Federal regulations (42 CFR § 410.32(d)(2)(i)) require physicians who order diagnostic laboratory tests maintain documentation of medical necessity in beneficiaries’ medical records. If a laboratory bills for a diagnostic laboratory test and the physician who ordered the test cannot produce documentation of the medical necessity of the test, CMS denies the claim (42 CFR § 410.32(d)(3)(ii)(C)).²¹

DaVita’s policies and procedures state that physician orders for laboratory tests are to be signed by the physician within 30 days of a verbal order and annual orders are to be signed every 12 months.

For 18 beneficiary days,²² TRL submitted claims to Medicare for laboratory tests with inadequate documentation of physician orders. Specifically:

²⁰ We did not determine whether TRL received overpayments under the SNF consolidating billing requirements because we did not determine whether any of the beneficiaries were in a SNF; this was not the focus of our review.

²¹ See footnote 14.

²² The number of beneficiary-days does not add to 18 because 2 beneficiary-days had tests in both categories below.

- For 12 beneficiary-days (16 tests), DaVita’s electronic medical records indicated that the source of the physician order for the test was a written order or a protocol but the patients’ medical records did not contain a written physician order or a protocol. However, DaVita’s electronic medical records indicated that the physician ordered the test.
- For 8 beneficiary-days (12 tests), physician orders were signed more than 1 year prior to the date of service or more than 30 days after the date of service.

These errors occurred because TRL only obtained a laboratory requisition from the dialysis facilities. TRL did not ensure that valid physician orders existed or that only medically necessary tests were billed to Medicare.

CLAIMS SUBMITTED WITH INACCURATE ORDERING PHYSICIAN INFORMATION

All claims for diagnostic laboratory tests must contain the legal name and NPI of the physician or eligible professional who ordered the test (42 CFR § 424.507(a)(1)(ii)). Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the ordering/referring provider on the claim if that service or item was the result of an order or referral.

For 4 of the 100 selected beneficiary-days, TRL submitted 4 claims to Medicare with an incorrect ordering physician identified on the claim. On the basis of our review of medical records and discussion with physicians, a physician other than the physician identified on the claim ordered the tests.

TRL officials said the laboratory submitted claims with inaccurate ordering physician information because there are instances when DaVita’s clinical software has missing, incomplete, or incorrect information regarding the physician order for the test. In such cases, the laboratory’s billing software sometimes populated the claim with a physician other than the ordering physician. In addition, TRL also stated that when it received a laboratory requisition for tests ordered by multiple physicians, the billing system defaults to a physician of record. Furthermore, TRL did not have controls in place to submit separate claims for a beneficiary when multiple physician ordered tests on a date of service.

These errors could hinder CMS’s efforts to monitor the Medicare program. CMS relies on Medicare claims data to monitor the activity of ordering physicians. Identifying the correct ordering physician on the Medicare claim gives CMS the ability to tie specific claims to the ordering physician and helps ensure beneficiaries receive quality care because CMS can verify the credentials of a provider who is ordering the test. Furthermore, identification of the ordering physician is necessary for claim review in order to examine the ordering physician’s medical records to determine medical necessity.

CLAIMS MAY NOT HAVE BEEN BILLED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Separate Payments May Not Have Complied With Consolidated Billing Requirements

Section 1881(b)(14)(B)(iv) of the Act states that, effective for claims with dates of service on or after January 1, 2011, all tests furnished for the treatment of ESRD are included in the ESRD bundled per-treatment base rate and are not separately paid. Tests that are not related to the treatment of ESRD are separately billable under the new ESRD PPS and may be billed by either the ESRD facility or the independent laboratory. If the ESRD facility or independent laboratory bills a test that was not related to the treatment of ESRD, the bill must include the modifier AY.²³

For 13 of the 100 selected beneficiary-days, physicians did not provide us with definitive decisions as to whether they ordered 14 tests totaling \$351 for the treatment of the patients' ESRD. The physicians were not able to make the determination because they did not have access to the medical records, stated they did not order the tests, did not remember ordering the tests, were unsure whether the tests constituted a service furnished for the treatment of ESRD, or declined to answer our questions. Furthermore, for 1 of the 100 selected beneficiary-days, we were unable to contact the ordering physician for one test totaling \$41. Therefore, for 14 of the 100 selected beneficiary-days, we could not determine whether 15 laboratory tests totaling \$392 were billed correctly with the AY modifier.

Unreliable Documentation of Physician Orders for Laboratory Tests

Medicare payments may not be made for items and 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 Act, § 1862(a)(1)(A)). Federal regulations (42 CFR § 410.32(a)) state: “All ... diagnostic laboratory tests ... must be ordered by the physician who is treating the beneficiary Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary”

In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (section 1833(e)). Federal regulations (42 CFR § 410.32(d)(2)(ii)) require that the entity submitting a claim for diagnostic laboratory tests maintain the documentation it receives from the ordering physician. Federal regulations (42 CFR § 410.32(d)(3)(i)) also require that, upon request by CMS the entity that submitted the claim (e.g., the laboratory) must provide, “[d]ocumentation of the order for the service billed,” as well as diagnostic or other medical information that the entity received from the ordering physician. Federal regulations (42 CFR §§ 410.32(d)(2)(iii) and (d)(3)(iii)) further state that the entity submitting the claim (e.g., the laboratory) may request additional diagnostic and other medical information from the ordering physician to document that the services it bills are reasonable and necessary (e.g., a missing order). Federal regulations (42 CFR §

²³*Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 8, §§ 50.1.5 and 60.1.

410.32(d)(2)(i)) require physicians who order diagnostic laboratory tests maintain documentation of medical necessity in beneficiaries' medical records. If a laboratory bills for a diagnostic laboratory test and the physician who ordered the test cannot produce documentation of the medical necessity of the test, CMS denies the claim (42 CFR § 410.32(d)(3)(ii)(C)).²⁴

For 26 of the 100 selected beneficiary-days containing 33 tests totaling \$878, DaVita did not provide us with sufficient and appropriate evidence to conclude whether there was a valid physician order for the laboratory tests furnished.

In response to our original request for medical record documentation, for each sample item, including physician orders, DaVita provided us with order inquiry reports (OIRs). During our audit, DaVita discovered that the information in the OIRs was sometimes incomplete or incorrect, which DaVita officials attributed to "display issues" and stated that we should not use the OIRs in our audit. DaVita stated OIRs are used for internal auditing purposes and occasionally provided to Government agencies in response to medical record requests since they listed patient orders in one summary document. DaVita officials stated that we should instead rely on a spreadsheet they provided to us that included pertinent order information derived from DaVita's electronic medical records. DaVita also provided us with screen printouts from its electronic medical records showing the dialysis facility's ordering history for the test.

However, the screen prints did not always corroborate with information in the spreadsheets for tests ordered by the physician. In addition, physician correspondences with us did not always corroborate DaVita's documentation. For example:

- TRL furnished lipid panel on September 5, 2012. DaVita provided us with Excel spreadsheets that showed the physician ordered a lipid panel on July 29, 2010. However, the screen print that DaVita provided to us from its clinical software system showed the physician ordered the test on December 3, 2013.
- TRL furnished an assay of vitamin D test on June 12, 2012. The physician identified as the ordering physician on the Excel spreadsheet and screen print from DaVita's clinical software system stated to us that he did not order the vitamin D test on June 12, 2012.

DaVita's documentation of physician orders was not reliable. In addition, we did not evaluate DaVita's electronic medical records system or the applicable internal controls related to entering physician orders into the system.

As a result, for the 25 beneficiary-days (30 tests)²⁵ totaling estimated payments of \$604,923, we could not determine whether TRL complied with Medicare requirements because we were unable

²⁴ See footnote 14.

²⁵ The number of beneficiary-days does not add to 25 and the number of tests does not add to 30 because for 2 beneficiary-days (2 tests) we did not determine whether the tests were billed correctly with the AY modifier, and we could not conclude whether there was a valid physician order for the tests furnished. Furthermore, we excluded 16 tests (15 beneficiary-days) totaling \$453 because they were counted in the finding for tests incorrectly billed with an AY modifier. These 25 beneficiary-days (30 tests) total \$791.

to obtain an attestation from the ordering physician regarding whether the tests were furnished for the treatment of ESRD or we were not provided sufficient and appropriate evidence to conclude whether there was a valid physician order for the tests furnished.

RECOMMENDATIONS

We recommend that TRL:

- refund to the Medicare contractor \$1,257,774 in estimated overpayments for incorrectly billed Part B claims with the AY modifier because the test was for the treatment of ESRD,
- work with DaVita to identify and refund to Medicare the portion of the \$604,923 for tests incorrectly billed with an AY modifier or not ordered by a physician,
- establish controls to ensure compliance with ESRD PPS consolidated billing requirements,
- strengthen controls to ensure compliance with Medicare requirements that laboratory tests billed are reasonable and necessary,
- strengthen controls to ensure that Medicare claims identify the correct ordering physician, and
- discontinue billing the CB modifier with the AY modifier.

OTHER MATTERS

Federal regulations (42 CFR § 410.32(a)) require that diagnostic tests be ordered **and used by** the treating physician (emphasis added). *The Medicare Benefit Policy Manual*, chapter 15, section 80.1, states, “Clinical laboratory services must be ordered and **used promptly by** the physician who is treating the beneficiary ...” (emphasis added). Moreover, Federal regulations (42 CFR § 410.32(d)(2)(i)) require that the ordering physician maintain documentation of the medical necessity of a diagnostic laboratory test in the beneficiary’s medical record. In addition, Federal regulations (42 CFR § 410.32(d)(2)(iii)) provide that the entity submitting the diagnostic laboratory claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary.

We understand that the ordering physician uses the results of the tests after TRL conducts the tests and we are not suggesting that TRL be responsible for the actions of the ordering physicians after a test has been completed. However, during our review, we noticed that for 66 beneficiary-days (96 tests), DaVita’s medical records contained insufficient supporting documentation that the physician reviewed and/or used the results of the test. Some medical records contained a

general statement that the physician reviewed all tests performed (36 tests), and other medical records did not contain any evidence that the physician reviewed the test results (60 tests). We are including this information in our report in order to bring this matter to CMS's attention.

TOTAL RENAL LABORATORIES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, TRL expressly concurred with our second, fourth, fifth, and sixth recommendations and described the actions it had planned to address them. With respect to our first and third recommendations, TRL agreed to refund the appropriate portion of the \$1,257,774 after taking into consideration any claims from the applicable period that may have already been refunded for reasons separate and apart from this audit, as well as implement our recommendation by improving controls to ensure compliance with the ESRD PPS consolidated billing requirements. However, TRL did not concur with the findings that it incorrectly billed Part B claims with the AY modifier and that it did not comply with the ESRD PPS billing requirements. TRL, also, described the actions it had planned to address the insufficient supporting documentation of physician reviews of and use of test results as described in the "Other Matters" section of our report.

We maintain that our findings are valid regarding separate payments made to TRL for claims billed with an AY modifier for laboratory tests furnished for the treatment of ESRD that did not comply consolidated billing requirements. Below is a summary of the reasons TRL did not concur with our findings and our response.

We have included TRL's comments in their entirety as Appendix D.

PHYSICIAN DETERMINATION

Total Renal Laboratories Comments

TRL stated that the OIG applied the "physician determination standard" retroactively. TRL states that prior to the September 9, 2013, implementation of CMS Transmittal 171, Change Request 8261, CMS did not require that the treating physician specifically make the clinical decision of whether a test was ordered for the treatment of ESRD. TRL stated that prior to September 9, 2013, CMS provided a clear list of laboratory tests that were subject to the ESRD PPS unless billed with a modifier. TRL said that it implemented a process which used the list and diagnosis codes on laboratory requisitions to determine whether a laboratory service should be part of the ESRD PPS or billed using the AY modifier.

TRL also commented that physicians making individualized determinations as to whether a test was ordered for the treatment of ESRD will lead to inconsistent billing practices.

Office of Inspector General Response

The Social Security Act and Federal regulations require that tests furnished for the treatment of ESRD be included in the ESRD consolidated payment for renal dialysis services. CMS billing

requirements provide that the AY modifier be used when a test was furnished for reasons other than the treatment of ESRD. Our audit methodology applied those requirements and not CMS Transmittal 171. We maintain that the physicians who ordered the tests for their patients made the clinical determinations as to whether tests were furnished for the treatment of ESRD in each particular circumstance. Our audit methodology used that clinical decision, recalled by the physicians, in determining whether each test met Medicare requirements. All tests identified in our population were included on the CMS list of tests that are routinely performed for the treatment of ESRD and subject to consolidated billing that was in effect during our audit period.

OFFICE OF INSPECTOR GENERAL USE OF PHYSICIAN QUESTIONNAIRES

Total Renal Laboratories Comments

TRL stated that the OIG's use of questionnaires to determine whether tests should be billed separately from the ESRD PPS was inconsistent and unreliable because (1) the questionnaires were confusing and no guidance was provided to physicians on how to respond to the questions and the legal impact of their determinations as to whether the test was furnished for the treatment of ESRD, and (2) many physicians' responses contradict the contemporaneous medical records. TRL also raises concerns because the OIG originally sent physicians a questionnaire with an incorrect question of "was the test ordered for the treatment of ESRD or an ESRD-related condition?" TRL maintains that the use of the phrase "or an ESRD-related condition" is not consistent with and significantly broader than the regulatory standard. TRL said that this incorrect language could have confused physicians. TRL notes that the OIG stated it reissued its questionnaire with the correct language, but raised additional concerns that the revised questionnaires caused further confusion and caused physicians to change their responses incorrectly. TRL said that the confusion undermines the credibility of the audit finding.

Office of Inspector General Response

We maintain that our findings are valid based on our communications with physicians. We acknowledge that our original questionnaire to physicians contained the phrase "an ESRD-related condition." We then contacted physicians with the revised question: "Did you order this laboratory test for the treatment of the patient's ESRD or did you order this laboratory test for reasons other than the treatment of ESRD?" However, we did not subsequently contact the physicians who responded that they ordered the laboratory test for a reason that was not ESRD-related. We informed physicians that we were rephrasing our question so that it accurately reflected the language in the ESRD PPS bundled payment guidance. We purposely did not provide physicians with guidance on how to answer our question because we did not want to influence their response. We fully expected that physicians would know why they ordered a specific test for a specific patient, and we relied on the professional medical judgement of the ordering physician to make the determination. We acknowledge in our audit report that some physicians were unsure as to whether a test constituted a service furnished for the treatment of the ESRD. Our audit report has a separate finding entitled "Separate Payments May Not have Complied With Consolidated Billing Requirements" that addresses the cases in which a physician did not provide us with a definitive decision.

TOTAL RENAL LABORATORIES USE OF DIAGNOSIS CODES

Total Renal Laboratories Comments

TRL stated that CMS has issued no specific requirement or guidance for how the treating physician should communicate to a lab that a test was ordered for the treatment of ESRD. TRL said the use of diagnosis codes as evidence of physician intent is reasonable and is the industry standard. TRL said that the ESRD PPS consolidated billing rules do not specifically require TRL to solicit or receive information from ordering physicians or ESRD facilities that would explicitly indicate whether the physicians ordered the tests for reasons other than “for the treatment of ESRD” or to inform physicians that it would be using DaVita’s list of diagnosis codes to determine whether tests were “furnished for the treatment of ESRD.” In addition, TRL said ESRD PPS consolidated billing rules do not specifically require that DaVita require facilities to maintain information in the patient’s medical record indicating whether tests were ordered “for the treatment of ESRD.”

Office of Inspector General Response

While there is no specific guidance on how a laboratory must ensure they are using the AY modifier appropriately, we maintain that TRL and DaVita did not establish adequate controls to ensure compliance with ESRD PPS consolidated billing requirements. As indicated in our audit report, it is DaVita’s coding team and coding software that generally assigns diagnosis codes to the ordered laboratory tests on the basis of the clinical justifications provided by the physician ordering the laboratory test. We did not audit the appropriateness of the diagnosis code submitted with the Medicare claim or the appropriateness of TRL’s list of which diagnosis codes that were associated with the treatment of ESRD. Rather, we relied on the professional medical judgement of the ordering physician to make the determination as to whether the test was ordered for the treatment of the patient’s ESRD or for reasons other than the treatment of ESRD.

LIPID PANELS

Total Renal Laboratories Comments

TRL stated: “Prior to 2012, and beginning again on January 1, 2016, lipid panels were, and will not be considered by CMS to be commonly furnished ‘for the treatment of ESRD.’” TRL said that, therefore, the use of the AY modifier would not be applicable. While lipid panels were considered part of the ESRD PPS consolidated billing for the period related to the audit, the notion that lipid panels are ordinarily ordered for reasons unrelated to ESRD applies equally to the retrospective time period. TRL stated that lipid panels should not be included in the audit or in the overpayment calculation. TRL stated, in an effort to resolve this issue expeditiously, it will include any lipid panels not already refunded in the amounts paid to the MAC and will not seek those claims to be removed from the sample.

Office of Inspector General Response

We maintain that lipid panels are appropriately included in our sampling frame, and our findings are valid. Lipid panels were included on CMS's list of tests that are routinely performed for the treatment of ESRD and subject to consolidated billing in effect during our audit period. Furthermore, in the ESRD PPS CY 2016 Final Rule, CMS states that even though it removed lipid panels from the ESRD PPS consolidated billing list, if an ESRD patient's ordering practitioner orders a lipid panel for the treatment of ESRD then it should not be billed separately.²⁶

²⁶ 80 Fed. Reg. 68967, 69030 (Nov. 6, 2015)

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$2,953,443 in Medicare payments to TRL for 200,181 beneficiary-days with 229,087 tests billed on a Part B claim with the AY modifier with dates of service in CYs 2012 and 2013.²⁷

We evaluated compliance with ESRD PPS consolidating billing requirements based on our communications with the ordering physicians. We did not use medical review to determine whether the tests billed were medically necessary. Using medical and billing records, we also evaluated compliance with other Medicare requirements.

We limited our review of TRL's internal controls to those applicable to billing procedures for tests provided to ESRD beneficiaries and DaVita's policies and procedures applicable to medical record documentation and physician orders.

We did not evaluate DaVita's electronic medical records system or test the applicable internal controls related to entering medical information, such as orders, into the system. However, we used spreadsheets and screen printouts DaVita provided from its electronic medical records as well as other medical record documentation, including rounding reports, as corroborating evidence to identify the ordering physician. In addition, we determined whether there was a valid physician order for the laboratory tests in our sample.

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 TRL for Medicare reimbursement.

Our fieldwork consisted of contacting the ordering physicians for laboratory services in the beneficiary days we sampled. We conducted our fieldwork from July 2014 through May 2015.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

²⁷ TRL did not submit claims to Medicare with the AY modifier for tests furnished after July 16, 2013.

- used CMS’s National Claims History file to identify CYs 2012 and 2013 services billed with the AY modifier²⁸ for beneficiaries receiving dialysis treatments and reimbursed to TRL for Part B claims processed by First Coast Service Options, Inc., the MAC for Jurisdiction 9;
- grouped those tests by beneficiary-days;²⁹
- identified 2 strata from which we selected our sample (stratum 1 contained 172,625 beneficiary-days with \$1,667,176 in Medicare payments to TRL for which the Medicare payments ranged from \$1 to \$23, and stratum 2 contained 27,556 beneficiary-days with 1,286,267 in Medicare payments to TRL for which the Medicare payments exceeded \$23);
- selected a stratified random sample of 100 beneficiary-days: 50 from stratum 1 and 50 from stratum 2 (Appendix B);
- interviewed TRL personnel and reviewed the laboratory’s policies and procedures applicable to billing Part B claims with an AY Modifier;
- interviewed DaVita personnel and reviewed DaVita’s dialysis facilities’ policies and procedures applicable to medical record documentation and physician orders;
- reviewed TRL billing records, claims, laboratory results, and remittance advices to support each test billed for the sample selected;
- reviewed all beneficiary information (including dialysis treatment records, physician orders, protocols, electronic medical record screen printouts, progress notes, rounding reports, test results, plans of care, and other information from the medical records) that DaVita provided³⁰ from its dialysis facilities to support the tests billed for the sample selected;
- identified the ordering physician from the claims information and/or the medical records and contacted that physician to determine whether the tests were ordered for the treatment of ESRD (or for reasons other than the treatment of ESRD);

²⁸ All tests identified in our population were included on the CMS list of tests that are routinely performed for the treatment of ESRD and subject to consolidated billing in effect during our audit period. CMS’s list of tests subject to the ESRD consolidated billing requirement are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Last accessed May 19, 2015.

²⁹ A beneficiary-day consists of all tests billed with an AY modifier and reimbursed by Medicare for an ESRD beneficiary on a date of service.

³⁰ To assist in the audit process, DaVita provided us with those parts of the beneficiaries’ medical records obtained from the ordering physician that were relevant to the specific claims reviewed. See 42 CFR § 410.32(d)(2)(ii)(B).

- determined whether the tests in the 100 sample items were supported and billed correctly;
- determined whether the medical records contained a physician order for the tests in our sample;
- discussed the incorrectly billed tests with TRL and DaVita personnel to determine the underlying causes of noncompliance with Medicare requirements;
- used the results of the sample review to calculate the estimated Medicare overpayment to TRL³¹ (Appendix C); and
- discussed the results of our review with DaVita 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.

³¹ On October 22, 2014, DaVita entered into a Corporate Integrity Agreement (CIA) with the Office of Counsel to the Inspector General of the Department of Health and Human Services regarding claims that DaVita violated the False Claims Act. The CIA included a list of 26 facilities as part of the settlement reached with the Department of Justice. In our sampling frame we found 4,867 beneficiary-days totaling \$51,867 in laboratory claims submitted by TRL in which the beneficiary was also receiving dialysis services during the same month at a facility that is contained in the CIA. We subtracted \$51,867 from the lower limit of \$1,309,641 (see Appendix C) to calculate the estimated overpayment to be \$1,257,774.

APPENDIX B: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of Medicare Part B laboratory services billed with an AY modifier by TRL during CYs 2012 and 2013.

SAMPLING FRAME

The sampling frame was an Access database of 200,181 beneficiary-days for tests billed with an AY modifier during CYs 2012 and 2013 with a total Medicare line payment amount of \$2,953,443. The sampling frame only consisted of claims processed by First Coast Service Options, Inc., the MAC for Jurisdiction 9. We only included beneficiary-days in which the laboratory date of service was between an ESRD claim from and through date of service. We obtained the data from CMS's National Claims History file.

SAMPLE UNIT

The sample unit was a beneficiary-day.

SAMPLE DESIGN

Our sample design consisted of a stratified random sample. We used an optimal strata determination formula to determine the following two stratum boundaries:

Stratum	Stratum Boundaries	Number of Beneficiary-Days	Total Medicare Paid Amount for Tests
1	\$1.03 to \$22.95	172,625	\$1,667,176.17
2	\$23.02 or more	27,556	1,286,266.84
Total		200,181	\$2,953,443.01

SAMPLE SIZE

We randomly selected 50 beneficiary-days from stratum 1 and 50 beneficiary-days from stratum 2. Our total sample size was 100 beneficiary-days.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software (RAT-STATS).

METHOD OF SELECTING SAMPLE UNITS

We consecutively numbered the sample units in our sampling frame from 1 to 172,625 for stratum 1, and 1 to 27,556 for stratum 2. After generating 50 random numbers for stratum 1 and 50 random numbers for stratum 2, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used RAT-STATS to estimate the amount of the overpayment for tests incorrectly billed with the AY modifier as well as the amount we could not determine as overpayments.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Results for Overpayments

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Overpayments	Value of Overpayments
1	172,625	\$1,667,176	50	\$528	31	\$261
2	27,556	1,286,267	50	2,307	29	1,287
Total	200,181	\$2,953,443	100	\$2,835	60	\$1,548

Estimated Value of Overpayments

(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$1,610,520
Lower limit	1,309,641
Upper limit	1,911,400

Sample Results for Potential Overpayment

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Potential Overpayments	Value of Potential Overpayments
1	172,625	\$1,667,176	50	\$528	6	\$58
2	27,556	1,286,267	50	2,307	19	733
Total	200,181	\$2,953,443	100	\$2,835	25	\$791

Estimated Value of Potential Overpayments

(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$604,923
Lower limit	409,018
Upper limit	800,829

APPENDIX D: TOTAL RENAL LABORATORIES COMMENTS



December 9, 2015

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

OIG Report Number A-01-14-00505

Dear Mr. Lamir,

Total Renal Laboratories, Inc. (d/b/a DaVita Labs (“DaVita Labs”)) appreciates the opportunity to comment on The U.S. Department of Health and Human Services Office of Inspector General (“OIG”) draft report titled *Review of Medicare Payments for Laboratory Tests Billed With an AY Modifier by Total Renal Laboratories, Inc.* (OIG Report Number A-01-14-00505) (“Draft Report”). DaVita Labs and its parent company, DaVita HealthCare Partners Inc., (“DaVita”) are committed to compliance and take seriously any feedback from the OIG on how it can improve its processes and controls. In its Draft Report, the OIG recommends that DaVita Labs do the following:

1. Refund to the Medicare contactor \$1,257,774 in estimated overpayment for incorrectly billed Part B claims with the AY modifier because the test was for the treatment of ESRD;
2. Work with DaVita to identify and refund to Medicare the portion of the identified \$604,923 for tests incorrectly billed with an AY modifier or not ordered by a physician;
3. Establish controls to ensure compliance with the ESRD PPS consolidated billing requirements;
4. Strengthen controls to ensure compliance with Medicare requirements that tests billed are reasonable and necessary;
5. Strengthen controls to ensure the Medicare claims identify the correct ordering physician; and
6. Discontinue billing the CB modifier with the AY modifier.

Since the inception of the ESRD PPS, DaVita Labs and DaVita, with the assistance of their clinical leadership, have worked diligently to build effective and efficient processes to comply with the Medicare ESRD PPS billing requirements. We believe that we did so in a way that was both consistent and accurate, but we have also worked to improve processes and adapt to

changing interpretations of the requirements related to the consolidated billing requirements for laboratory services. With that backdrop, DaVita Labs responds to each of the OIG's recommendations below and it will continue to evaluate its processes to ensure accurate billing of laboratory services to the Medicare program.

1. Refund to the Medicare contractor \$1,257,774 in estimated overpayment for incorrectly billed Part B claims with the AY modifier because the test was for the treatment of ESRD.

In an effort to resolve this matter expeditiously, so that DaVita Labs can move forward with implementing the OIG's recommendations contained in its Draft Report, DaVita Labs will work with its Medicare contractor (MAC) to refund the appropriate portion of the \$1,257,774 after taking into consideration any claims from the applicable period that may have already been refunded for reasons separate and apart from the OIG's review. DaVita Labs, however, respectfully does not concur with the finding that it incorrectly billed Part B claims with the AY modifier.

DaVita Labs will include lipid panels not yet refunded in the above amount, although it continues to believe they should not be part of the sample and refund amount, given CMS' current view that lipid panels are not ordered "for the treatment of ESRD."¹ While lipid panels were considered part of the ESRD PPS consolidated billing for the time periods related to the audit, the notion that lipid panels are ordinarily ordered for reasons unrelated to ESRD applies equally to the retrospective time period. As such, we believe that no refunds should be due on those amounts.

The appropriate billing for laboratory services has been an area of significant confusion for ESRD suppliers and laboratories alike since the ESRD PPS took effect on January 1, 2011. In the face of this confusion, DaVita Labs has always intended its billing for laboratory tests to comply with CMS guidance and believes that it has done so. As a result, DaVita Labs does not concur with the finding for the following reasons:

a. The "Physician Determination Standard" is being applied retroactively.

The OIG makes this recommendation with the underlying assumption that the ordering physician must notify the laboratory when they order a test for reasons other than for the treatment of ESRD. Prior to June 7, 2013, however, CMS did not require that the treating physician specifically make the clinical decision of whether he or she ordered a test "for the treatment of ESRD." Instead, CMS provided a clear list of laboratory tests (by HCPCS code), that, absent a modifier, "will be subject to the ESRD PPS."² This list became known as Table F. Lab tests not included on Table F were not subject to the ESRD PPS. Table F defined the scope of tests subject to the ESRD PPS and CMS noted that a clinical review of the proposed lab tests on Table F was necessary to distinguish between those lab tests that are specifically necessary for the treatment of ESRD from those that could be ordered for other reasons. CMS stated that it

¹ 80 Fed. Reg. 68968, 69030 (Nov. 6, 2015).

² 75 Fed. Reg. 49030, 49055 (Aug. 12, 2010).

performed this clinical analysis with CMS physicians and other medical professionals.³ In subsequent ESRD final rules, CMS continued to update Table F without additional comment related to the structure or use of Table F.⁴ DaVita Labs implemented a process under the CMS-defined Table F and developed a list of diagnosis codes that would be used to determine whether a test was for the treatment of ESRD. Those diagnosis codes were based on information provided by the ordering physician and taken by DaVita Labs directly from the laboratory requisition to determine whether the test was appropriately billed with the AY modifier.

On June 7, 2013, CMS issued Transmittal 171, CR 8261 (the “Transmittal”) with an implementation date of September 9, 2013. Without the benefit of notice and comment that should accompany regulatory changes, the Transmittal revised significantly CMS policy regarding laboratory services included in the ESRD PPS. Instead of continuing the clear policy of providing a bright line test for what laboratory tests CMS considered part of the ESRD PPS, the Transmittal rendered Table F moot. The Transmittal stated that “[t]he distinction of what is considered to be an ESRD-related laboratory test is a clinical decision determined by the ESRD patient’s ordering practitioner.” This guidance is what DaVita Labs refers to herein as the “Physician Determination Standard.” Physicians have always been required to order laboratory tests with an appropriate diagnosis, but the Transmittal was the first time CMS articulated a policy that made a physician’s subjective view of what is considered “ESRD-related” to be the determinative factor in deciding what is to be included in the ESRD PPS. Notably, however, CMS did not provide any specific guidance to laboratories regarding how they should implement the “Physician Determination Standard,” nor did CMS provide any guidance to physicians regarding how, or why, they should determine if a laboratory test was ordered “for the treatment of ESRD.”

DaVita Labs’ good faith belief that the Transmittal was a substantive departure from previous CMS guidance and its ongoing commitment to compliance prompted DaVita Labs to take several steps in direct response to the Transmittal. First, DaVita Labs suspended billing for Medicare claims effective July 23, 2013 until it could establish new internal billing guidelines. Second, DaVita Labs worked with DaVita’s Office of the Chief Medical Officer (“OCMO”) to create a clinical decision tree based on ICD-9 codes to determine whether a lab test is ordered for the treatment of ESRD, and therefore, paid within the ESRD PPS. An independent third-party nephrologist, who was a faculty member at a large academic medical center, reviewed and commented on that clinical decision tree. Third, DaVita Labs, in an effort to solicit suggestions for further improvement, presented its updated billing guidelines to its MAC - First Coast Service Options, Inc. on December 8, 2014. In the absence of more specific guidance from CMS, DaVita Labs’ approach was demonstrably thoughtful, compliance-minded, and a reasonable interpretation of the available rules.

Prior to the Transmittal, implemented September 9, 2013, Table F was the stated mechanism for determining whether a laboratory service was considered part of the ESRD PPS payment. To retroactively apply a standard to claims prior to that date when that standard (i) was not made available to providers and laboratories until June 7, 2013 and (ii) was not to be implemented

³ *Id.* at 49169.

⁴ E.g., CMS added additional tests; *See* 76 Fed. Reg. 70228, 70252 (Nov 10, 2011).

until September 9, 2013 has the effect of penalizing DaVita Labs for non-compliance with a standard of which it had no notice and which, at the time, was not in effect. As such, the OIG should rely on Table F to determine whether a laboratory service should be part of the ESRD PPS prior to September 9, 2013.

In summary, the “Physician Determination Standard” as applied by OIG to claims during CY 2012 and CY 2013 was not made public until June 7, 2013 and was not required to be implemented until September 9, 2013.

b. The use of questionnaires to determine whether payments are appropriate is inconsistent and unreliable.

The use of questionnaires to determine whether billing laboratory services separately from the ESRD PPS is inconsistent and unreliable because (i) the questionnaires were confusing and no guidance was provided to physicians on how to respond to the questions or the legal impact of their determination; and (ii) many physicians’ responses contradict the contemporaneous medical records.

i. **The questionnaires were confusing and no explanation of how to answer the questions was provided.**

Given the general lack of clarity around what constitutes a service furnished “for the treatment of ESRD,” DaVita Labs believes that, without the benefit of explanations of how to complete the questionnaire and the legal impact of their responses (or lack thereof), the questionnaire process was unreliable for purposes of determining whether DaVita Labs appropriately billed for laboratory services with the AY modifier. CMS has given inconsistent guidance around the ESRD PPS payment rule and how to determine whether certain tests are considered part of the ESRD PPS. Because the standard is difficult even for CMS to articulate – after many pages of discussion in multiple regulations – DaVita Labs continues to express concern that physicians may be misled, or, at the very least, confused, by the lack of explanation of what is meant by “ordered for the treatment of ESRD.”

The “ordered for the treatment of ESRD” standard is both clinical and legal, but physicians are being asked to opine on both (here, retrospectively), without any explanation as to what CMS or the OIG consider “for the treatment of ESRD” and what the legal/billing result is of their decision. The fact is that the physician makes the clinical determination of whether a laboratory test is medically necessary indicates the related diagnosis information to support that service. Whether that test is related to the “treatment of ESRD” is a legal construct that does not affect the physician’s clinical decision making as to the necessity of the test – it is a standard created by CMS for purposes of defining the appropriate billing result, not the appropriate clinical result. Without guidance and definition around that standard, it is impossible to achieve any consistency in the responses. The OIG confirmed this in its Draft Report where it stated that some physicians declined to participate because they “were unsure whether the tests

constituted a service furnished for the treatment of ESRD.”⁵ Other physicians highlighted the confusion by providing contradictory responses, indicating that the same test with the same diagnosis was both ordered “for the treatment of ESRD” and not “for the treatment of ESRD.”

For example, there were 10 total albumin tests in the OIG’s sample. For 3 of the 10 tests, the physician did not provide a clear response to the OIG’s question “was the laboratory test ordered for the treatment of ESRD?” Of the 7 remaining albumin tests for which the OIG received either a “yes” or “no” response, 6 were ordered with a diagnosis code of 263.9 (malnutrition). Physicians indicated that 1 of those 6 tests were “not for the treatment of ESRD” and 5 were “for the treatment of ESRD.” As evidenced by the results of the OIG questionnaire process physicians (i) provided inconsistent responses to whether a test was “ordered for the treatment of ESRD” even for the same test and with the same supporting diagnosis code and (ii) favored the designation of “for the treatment of ESRD” contrary to the documentation in the contemporaneous medical record.

The general confusion around when a test should be considered “ordered for the treatment of ESRD” was aggravated by the fact that the OIG issued two versions of the questionnaire. The original questionnaire articulated an incorrect question of “was the test ordered for the treatment of ESRD or an ESRD-related condition?” The addition of “or an ESRD-related condition” is not consistent with and significantly more broad than the regulatory standard. This incorrect language could have confused physicians and caused them to respond incorrectly to the questionnaire.

DaVita Labs raised its concerns about the questionnaire to the OIG in a letter dated August 12, 2014. The OIG advised DaVita Labs during the exit conference on July 16, 2015 that it re-issued questionnaires with the correct request/standard, but DaVita Labs is still concerned that this additional communication may have confused the physicians further. To the extent the physicians did (or did not) change their answer, they may have done so out of confusion rather than understanding because even the correct question/standard is not entirely clear even to those well-versed on the ESRD PPS. This confusion undermines the credibility of the responses received and thus the recommendation that DaVita Labs should refund any amounts.

ii. Some physician responses contradicted the contemporaneous medical record.

Highlighting the unreliability of the responses the OIG received in the questionnaires, DaVita Labs identified 14 instances where a physician responded that a test was ordered “for the treatment of ESRD” in direct contradiction of the medical record. Despite this contradiction, the OIG used the questionnaire responses as the sole standard for determining whether CMS appropriately paid the laboratory test outside of the ESRD PPS.

⁵ See Draft Report at 11.

DaVita Labs has provided the OIG with documentation from the contemporaneous medical record in order to demonstrate that the 14 tests at issue were not ordered “for the treatment of ESRD,” but those services are still included within the recommended refund amount.

To illustrate, we provide two representative examples and a summary of the typical accompanying documentation in the medical record:

- Albumin Tests – Albumin tests are commonly ordered and performed to evaluate patient nutritional status and not for the treatment of ESRD. In these cases, the medical record typically includes a diagnosis of malnutrition and is accompanied by a signed physician order, with the ICD-9 code 263.9 (malnutrition). The diagnosis is supported by documentation of appropriate monitoring and interventions some of which are medication orders, notes from the patient’s care team describing the patient’s nutritional status, weight loss, nausea and vomiting, poor intake, appetite, need for peg tube, the consideration of hospice, etc.
- Vitamin D – Physicians commonly order vitamin D tests to evaluate a patient’s vitamin D status where the patient has a vitamin D deficiency. In these cases, the medical record does not reflect that the physician ordered the test for the treatment of ESRD. The two primary reasons to track vitamin D levels are associated with (1) the increased risk of cardiovascular disease due to low vitamin D, and (2) the potential for decreased vitamin D levels based on the degree and severity of hypothyroidism – neither of which are “for the treatment of ESRD”. Physicians may advise monitoring vitamin D levels, and, potentially supplementation, even when not associated with the treatment of ESRD. In these cases the medical record typically reflects a diagnosis of chronic vitamin D deficiency that is accompanied by a signed order with the ICD-9 code of 268.9 (vitamin D deficiency).

For these reasons, DaVita Labs asserts that the questionnaire responses are not reliable evidence of whether a physician ordered a test “for the treatment of ESRD” and therefore whether an overpayment was made.

- c. Even assuming the Transmittal applied, DaVita Labs’ use of diagnosis codes pursuant to the billing logic it applied during the OIG’s audit period satisfies the “Physician Determination Standard.”

While the Transmittal materially changed how a lab could determine whether a lab test was subject to the ESRD PPS (i.e., use of Table F was no longer determinative and the Physician Determination Standard was introduced), the Transmittal did not go on to describe how the treating physician’s determination should be communicated to DaVita Labs. To date, CMS has issued no specific requirement or guidance for how the treating physician should communicate to a lab that a test was ordered “for the treatment of ESRD.” DaVita Labs believes that use of diagnosis codes as evidence of physician intent is reasonable and is the industry standard.

Because a laboratory does not have a direct connection with the patient, the patient's full medical history or the physician's total insight, DaVita Labs must rely on the clinical communication that it does receive from the ordering physicians. This communication typically involves a requisition that includes diagnosis codes to support medical necessity of the test and equally can be used to determine whether the test was ordered "for the treatment of ESRD." The diagnosis code identifies the clinical basis for the test. DaVita Labs has used its clinical team to match diagnosis codes to lab tests to identify those lab test/diagnosis code combinations that are "for the treatment of ESRD." Clinicians made the determination of these combinations (in a similar manner CMS used to establish the Table F tests). These combinations, anchored by the ordering physician's clinical judgment relating to the identified diagnosis code, are used to determine whether a test was ordered "for the treatment of ESRD."

OIG states that: (i) DaVita Labs did not (a) solicit or receive information from ordering physicians or ESRD facilities that would explicitly indicate whether the physicians ordered the tests for reasons other than "for the treatment of ESRD"; (b) inform physicians that it would be using DaVita's list of diagnosis codes to determine whether tests were "furnished for the treatment of ESRD," and (ii) DaVita did not require facilities to maintain information in the patient's medical record indicating whether tests were ordered "for the treatment of ESRD." Despite these assertions, neither (i) nor (ii) is specifically required by the ESRD consolidated billing rules.

As discussed above, it is industry standard for clinical laboratories to use diagnosis codes as evidence of the ordering physician's intent. It is also consistent with the CMS practice of issuing a list of acceptable or unacceptable diagnosis codes along with an NCD allowing for reimbursement of certain tests pursuant to that NCD when ordered by a physician with the appropriate diagnosis code.

As a result, in the absence of more prescriptive guidelines from CMS, the industry-standard process of utilizing diagnosis codes as evidence of physician intent fits squarely within the current and limited guidance from CMS regarding the determination of whether a lab test is ordered for the treatment of ESRD. Further, DaVita Labs' use of diagnosis codes pursuant to the billing logic it applied during the OIG's audit period satisfies the "Physician Determination Standard."

d. Lipid panels should not be included in any refunded amounts.

Prior to 2012, and beginning again on January 1, 2016, lipid panels were, and will not be considered by CMS to be commonly furnished "for the treatment of ESRD" and thus not included in Table F.⁶ The AY modifier is only required for tests that appear on Table F but are not "furnished for the treatment of ESRD."⁷ As a result, prior to 2012 and after beginning on

⁶CMS did not include lipid panels in the original Table F in 2011. See 75 Fed. Reg. 49030 (Aug. 12, 2010). CMS then added Lipid panels to Table F effective January 1, 2012. See CMS Transmittal 150 (Nov. 11, 2011); ESRD Consolidated Billing List for CY 2012. In the final rule for 2016, CMS has once again removed lipid panels from Table F. 80 Fed. Reg. 68968, 69030 (Nov. 6, 2015).

⁷ See Draft Report at 2.

January 1, 2016, the AY modifier was not, and will not be, required on claims for lipid panels. So while the AY would have been required during the OIG's audit period, and was applied to claims for lipid panels by DaVita Labs when appropriate during that period, it will no longer be required after January 1, 2016. As CMS now recognizes that lipids panels are not commonly furnished for the treatment of ESRD and has removed lipid panels from Table F and, as a result, lipid panels will once again no longer require the AY modifier, DaVita Labs believes they should not be included in the audit or any ultimate refund amounts. There is no difference in the clinical determination as between the audit period and the time periods where lipids panels were not considered part of the ESRD PPS, even though the legal standard changed.

Further, the OIG questionnaires highlighted the confusion around the inclusion or exclusion of lipid panels in the ESRD PPS. Given the inconsistency in CMS's position on lipid panels, physicians were likely to be equally as inconsistent in their responses as to whether they ordered a lipid panel "for the treatment of ESRD". That was seen in the responses where physicians at times said the lipid panels were related to the treatment of ESRD and at other times, said they were not.

Despite these arguments, and solely in an effort to resolve this issue expeditiously, DaVita will include any lipid panels not already refunded in the amounts paid to the MAC and will not seek those claims to be removed from the sample.

In summary, DaVita Labs does not concur with the finding but nonetheless will comply with the recommendation to work with its MAC to refund the appropriate portion of the \$1,257,774, less amounts previously refunded for reasons unrelated to the OIG recommendation. It does so to resolve the matter expeditiously and to focus on implementing the balance of the OIG's recommendations contained in the Draft Report.

2. Work with DaVita to identify and refund to Medicare the portion of the \$604,923 for tests incorrectly billed with an AY modifier or not ordered by a physician.

DaVita Labs concurs with this recommendation. DaVita Labs has begun reviewing the 25 beneficiary days (30 tests) at issue, totaling estimated payments of \$604,923, to determine the following for each laboratory tests that:

- a. there was a valid order; and
- b. the correct ordering physician was listed on the claim; and
- c. the laboratory test was ordered for a reason other than "for the treatment of ESRD."

DaVita Labs will issue a refund for claims at issue that do not satisfy all three elements listed above and which it has not refunded previously for reasons separate and apart from the OIG review. Based on the results of the review DaVita Labs will also work with its MAC to refund the appropriate portion of the \$604,923.

DaVita Labs did have, and continues to have, controls for establishing the criteria above prior to the OIG review. It does take the OIG's feedback seriously, however, and it will work to improve those controls. We discuss some of those improvements in sections 3 through 5 below.

3. Establish controls to ensure compliance with the ESRD PPS consolidated billing requirements.

DaVita Labs will implement this recommendation in that it will take steps to improve its controls to ensure compliance with the ESRD PPS consolidated billing requirements, even though DaVita Labs respectfully does not concur with the finding that it did not comply with the ESRD PPS billing requirements. DaVita Labs, in collaboration with DaVita, has initiated a process to evaluate options to leverage DaVita's clinical software system (Snappy), as well as DaVita Labs' and DaVita's training capabilities, to improve its controls related to billing laboratory services. Specifically, it intends to improve documentation reflecting the ordering physician's determination of whether a laboratory test was "ordered for the treatment of ESRD."

For its ESRD patients, DaVita Labs will require a justification to be selected in Snappy for each laboratory test at the time the test is ordered that will include one of the following designations: (a) "for the treatment of ESRD"; (b) "not for the treatment of ESRD"; and (c) "other." "Other" will allow for a free text description to be entered into Snappy, prompting DaVita to follow-up in order to assign the appropriate justification. The designations (either "for the treatment of ESRD" or "not for the treatment of ESRD") will appear on the order to be signed by the ordering physician. If the ordering physician disagrees with the designation on the order, he or she can dispute the order via DaVita's order dispute process and DaVita will update the order accordingly for signature by the ordering physician. DaVita Labs will work with DaVita to create and provide training on this process for physicians and DaVita teammates. Based on the feedback received during the exit conference with the OIG on July 16, 2015, DaVita Labs suspended its use of the AY modifier effective July 17, 2015 and it will not lift that suspension until these new controls are in place.

DaVita Labs believes this effort will better comply with the OIG's and CMS' view that physician determinations are required and will minimize the need for auditors to utilize a questionnaire process like the OIG's in the future.

We continue to believe that DaVita Labs vetted its processes thoroughly, which led to a more consistent approach with respect to what lab services it could appropriately bill with the AY modifier. We believe that physicians making an individualized determination of whether he/she orders a test "for the treatment of ESRD" will lead to inconsistent billing practices as noted above and thus make ongoing compliance monitoring by labs and providers, and enforcement for contractors and regulators increasingly difficult. As we know from the questionnaire process, we will get conflicting and inconsistent responses, some of which may directly conflict with the medical record. It is because of the confusion among ESRD providers regarding the definition of "for the treatment of ESRD" that DaVita Labs reiterates the need for CMS to provide guidance on how to determine whether a physician orders a test "for the treatment of ESRD". This guidance is required both from a clinical and legal standpoint – the physician determination standard cannot alone answer the legal question of what tests a lab may appropriately bill separately.

In the absence of clear guidance regarding the meaning of “for the treatment of ESRD,” we would like to highlight that we agree with CMS statements from 2010 where it said that:

- We agree with commenters that *limiting the laboratory tests for payment under the ESRD PPS payment bundle to specific tests that are customarily performed in connection with the treatment of ESRD* comports with section 1881(b)(14)(B)(iv) of the Act and would be a straight forward method of capturing only ESRD-related laboratory testing. In addition, we needed to develop a list of ESRD-related laboratory tests for consolidated billing edits to ensure that payment is not made to independent laboratories for ESRD-related laboratory tests.⁸
- The ESRD related *laboratory tests that will be subject to the ESRD PPS are identified in Appendix Table F* of this final rule.⁹
- The laboratory tests listed [in Table F], if furnished to ESRD patients by the ESRD facility directly or under arrangement, will be considered renal dialysis services (unless otherwise specified as being performed for non-ESRD-related conditions) and will be covered under the ESRD PPS bundled payment.¹⁰

As discussed by CMS in 2010, and as implemented in the 2011 ESRD PPS final rule, Table F was the definitive list of laboratory tests included in the ESRD PPS and it was a reasonable and clear standard for determining which laboratory tests are “for the treatment of ESRD.” But in addition, to bring further clarity, CMS should also provide a list of ICD-9 or ICD-10 codes that will classify a laboratory test that appears on Table F to be “for the treatment of ESRD” and part of the ESRD PPS.

4. Strengthen controls to ensure compliance with Medicare requirements that laboratory tests billed are reasonable and necessary.

DaVita Labs concurs with this recommendation. DaVita Labs, in collaboration with DaVita, has initiated a process to evaluate options to strengthen their controls so that:

- Claims are only submitted for orders signed in accordance with DaVita policies and procedures
- Claims for laboratory tests are submitted with the correct ordering physician listed on the claim
- DaVita Labs can improve its ability to request and receive proof of signed orders from ordering physicians
- DaVita better documents that all laboratory results are (i) reviewed and (ii) used by physicians

a. Information received by DaVita Labs from DaVita facilities – DaVita Labs is in the process of increasing the scope of the interface between DaVita’s clinical system (Snappy) and the DaVita Labs’ laboratory information system (Reflab) so that it receives additional data

⁸ 75 Fed. Reg. at 49054 (emphasis added).

⁹ Id. at 49055 (emphasis added).

¹⁰ Id. at 49169.

points when it receives requisitions for laboratory services from DaVita. DaVita Labs now receives the order type and the date that the physician signed the order and it is using this information to develop additional controls.

b. Signed orders – Using the additional information it now receives from DaVita, DaVita Labs has made systems improvements so that, as of the date of this response, all claims will be held until it is confirmed that the order has been signed in accordance with DaVita policies and procedures. In addition, DaVita will add these laboratory services to its existing processes to track and resolve any unsigned orders in accordance with its policies and procedures.

c. Ordering physicians - DaVita Labs is exploring improvements to its processes so that where an ordering physician is unrecognized by DaVita Labs systems, the claim will be held until the ordering physician has been correctly identified and validated.

DaVita Labs and DaVita will continue to develop improvements to its controls to ensure that the medical record reflects the correct ordering physician. In addition, DaVita Labs will work with its MAC to develop improvements so that each claim identifies the correct ordering physician. This process is complicated by the fact that multiple physicians from the same practice may order laboratory services within the same date of service or claim period.

d. Review of laboratory results – DaVita Labs appreciates the OIG acknowledgement in the Draft Report that DaVita Labs is not responsible for the actions of the ordering physician after a lab completes a test. We believe that specific documentation of review, and use, of laboratory results is not required by the regulations, and is not required to establish that the clinical laboratory services were either “reasonable and necessary” or “used promptly” by the ordering physician. In an abundance of caution, however, DaVita Labs, in collaboration with DaVita, agrees to take steps to develop additional system improvements to allow physicians to create a record of receipt and review of laboratory results. For example, DaVita and DaVita Labs have initiated the process to improve its reporting and documentation functions in DaVita’s EMR product, Falcon Silver, so that for physicians that use Falcon Silver a report will now list all laboratory results ordered by that physician and record the date on which that physician reviewed the results. This will provide documentation of the physician’s review, even in situations where no change to the care plan is required based on the lab result. DaVita and DaVita Labs are committed to develop additional improvements to ensure the greatest number of physicians create a similar record of receipt and review of results. Further, DaVita Labs will collaborate with DaVita in order to develop training and education materials for physicians and DaVita teammates in order to educate them on the importance of their documentation that laboratory results are reasonable and necessary, reviewed by the physician and used promptly.

5. Strengthen controls to ensure that Medicare claims identify the correct ordering physician.

DaVita Labs concurs with this recommendation. See DaVita Labs’ response to OIG recommendation #4 above.

6. Discontinue billing the CB modifier with the AY modifier.

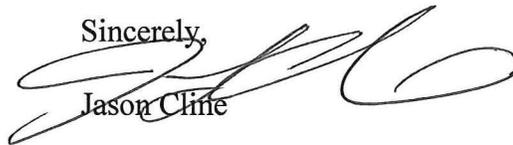
DaVita Labs concurs with this recommendation and it will suspend use of the CB modifier on or before December 17, 2015.

DaVita Labs appreciates that the OIG included in its Draft Report that DaVita Labs use of the CB modifier complies with its understanding of its MAC's guidance on the CB modifier. The OIG is correct that the MAC guidance did predate the ESRD PPS. As part of DaVita Labs' commitment to transparency, compliance and continuous improvement, however, it also presented its process for use of the CB modifier to its MAC in a meeting on December 8, 2014. During that December 2014 meeting, as reflected in the meeting recap shared with the MAC, DaVita Labs requested guidance on future use of the CB modifier. The MAC did not provide any additional guidance in response to the request.

* * * * *

Thank you for the opportunity to share DaVita Labs feedback on the OIG's Report as we continue to implementing improvements based on the recommendations offered by the OIG.

Sincerely,



Jason Clife

Attachment: Review of Medicare Payments for Laboratory Tests Billed With an AY Modifier by Total Renal Laboratories, Inc. (OIG Report Number A-01-14-00505)

cc: Brian Burns, DaVita, Group General Counsel
Chandra Westergaard, DaVita, Assistant General Counsel
Trenille Brewer-Moore, DaVita, Compliance, Senior Director
Keith Carrington, DaVita, Compliance Director
Caylon Cannon, DaVita Labs, Senior Director