

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NATIONAL INSTITUTE OF
TRANSPLANTATION,
AN INDEPENDENT HISTOCOMPATIBILITY
LABORATORY, DID NOT FULLY COMPLY
WITH MEDICARE'S COST-REPORTING
REQUIREMENTS**

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Deputy Inspector General
for Audit Services

September 2018
A-09-16-02010

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

Report in Brief

Date: September 2018
Report No. A-09-16-02010

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

The Centers for Medicare & Medicaid Services requires independent histocompatibility laboratories to report tissue-typing costs and revenues on their Medicare cost reports and to calculate the ratio of kidney tissue-typing revenues to all tissue-typing revenues (referred to as the “reimbursement ratio”). To determine the Medicare reimbursement for kidney tissue-typing services, this ratio is multiplied by the total reported tissue-typing costs. If an independent histocompatibility laboratory incorrectly reports costs and revenues, its ratio may be inflated, resulting in higher Medicare reimbursement. We selected for review the National Institute of Transplantation (NIT) because its reimbursement ratio was 14 percentage points higher than the national average.

Our objective was to determine whether NIT complied with Medicare requirements for reporting tissue-typing costs and revenues on its Medicare cost report for fiscal year (FY) 2012.

How OIG Did This Review

We reviewed NIT’s FY 2012 Medicare cost report, which showed costs of \$10.1 million and revenues of \$4.8 million. To determine whether NIT correctly reported costs and revenues on its cost report, we judgmentally selected for review 186 cost transactions totaling \$884,212 and 751 tissue-typing tests with revenues totaling \$326,455.

National Institute of Transplantation, an Independent Histocompatibility Laboratory, Did Not Fully Comply With Medicare’s Cost-Reporting Requirements

What OIG Found

NIT did not fully comply with Medicare requirements for reporting tissue-typing costs and revenues on its FY 2012 Medicare cost report. Of 186 cost transactions, 177 were correctly reported; however, the remaining 9 transactions, totaling \$81,063, were incorrectly reported. Of 751 tissue-typing tests, 711 were correctly reported; however, the remaining 40 tests and 94 additional tests, with combined revenues totaling \$50,000, were incorrectly reported.

As a result of these reporting errors, NIT incorrectly calculated its total tissue-typing costs and Medicare reimbursement ratio. Consequently, NIT received \$45,940 in overpayments from Medicare. These incorrectly reported costs and revenues were included on NIT’s FY 2012 cost report, which is outside of the 3-year reopening period.

What OIG Recommends and NIT Comments

We recommend that NIT (1) work with the Medicare administrative contractor (MAC) to return \$45,940 in potential overpayments identified in this report that are outside of the 3-year reopening period but within the 6-year lookback period in accordance with the 60-day rule, and identify the returned overpayments as having been made in accordance with this recommendation; and (2) exercise reasonable diligence to identify and return any additional similar overpayments related to cost reports that were not part of our audit in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

NIT concurred with our recommendations and provided information on actions that it planned to take to address them. Regarding our finding that four cost transactions were incurred outside of the cost-reporting period, NIT stated that by removing these costs from the FY 2012 cost report, NIT would suffer the loss of reimbursement because the costs were not reported on the cost report in the year incurred and cannot be recaptured. Although NIT concurred with our first recommendation, NIT stated that it will work with the MAC to return the overpayments identified after our consideration of its comment on our finding. We maintain that our findings and recommendations are valid. Federal regulations state that independent histocompatibility laboratories must provide adequate cost data that are based on the accrual basis of accounting, which means that an expense is reported in the period in which it is incurred, regardless of when it is paid.

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INTRODUCTION

WHY WE DID THIS REVIEW

Independent histocompatibility laboratories provide tissue-typing services in preparation for certain procedures, such as kidney transplants, bone marrow transplants, and blood platelet transfusions. Medicare reimburses these laboratories for costs associated with kidney transplant services for Medicare beneficiaries. These laboratories reported \$82.9 million in reimbursable costs on their Medicare cost reports for fiscal year (FY) 2012.¹

The Centers for Medicare & Medicaid Services (CMS) requires independent histocompatibility laboratories to report tissue-typing costs and revenues for both kidneys and nonkidney organs on their Medicare cost reports and to calculate the ratio of kidney tissue-typing revenues to all tissue-typing revenues (referred to as the “reimbursement ratio” in this report). To determine the Medicare reimbursement for kidney tissue-typing services, this ratio is multiplied by the total reported tissue-typing costs. If an independent histocompatibility laboratory incorrectly reports costs and revenues, its reimbursement ratio may be inflated, resulting in higher Medicare reimbursement.

After consulting with Cahaba Government Benefit Administrators, the Medicare administrative contractor (MAC) responsible for reviewing the annual Medicare cost reports submitted by independent histocompatibility laboratories nation-wide,² we selected for review the National Institute of Transplantation (NIT), which reported a 91-percent reimbursement ratio. This ratio was 14 percentage points higher than the national average.

OBJECTIVE

Our objective was to determine whether NIT complied with Medicare requirements for reporting tissue-typing costs and revenues on its Medicare cost report for FY 2012 (January 1 through December 31, 2012).³

¹ Medicare requires independent histocompatibility laboratories to submit cost reports annually; the reporting period is based on the laboratory’s FY (42 CFR §§ 413.200(a) and (c)(1)(i) and § 413.24(f)). Therefore, the FYs for the laboratories cover different periods.

² Effective January 29, 2018, this responsibility was transferred to Palmetto GBA.

³ This was the most recently finalized cost report at the start of our review. A provider’s Medicare cost report is considered finalized after the MAC has reviewed and completed the final settlement of the cost report.

BACKGROUND

The Medicare Program and Coverage of Tissue-Typing Services for Kidney Transplants

The Medicare program provides health insurance for people aged 65 and over, those with certain disabilities, and those with end-stage renal disease, which is permanent kidney failure requiring dialysis or a kidney transplant. CMS administers the program.

Medicare covers the costs of kidney transplants, including the costs of testing services provided to prepare for the transplants (pretransplant kidney-related tissue-typing tests).⁴ Such tests include blood tests that determine the compatibility between a donor and potential recipients.

Histocompatibility Laboratories

Histocompatibility laboratories provide tissue-typing services for hospitals and organ procurement organizations (OPOs). A histocompatibility laboratory may be hospital-based or independent: A hospital-based histocompatibility laboratory operates within a hospital's administrative and financial structure. An independent histocompatibility laboratory has a distinct governing body and serves one or more hospitals that are active in the field of human organ transplantation within its service area. In 2012, there were 43 independent histocompatibility laboratories nation-wide.

Histocompatibility Laboratories' Preparation of Medicare Cost Reports

To have its pretransplant kidney-related tissue-typing tests covered under Medicare, an independent histocompatibility laboratory must prepare an annual cost report (Form CMS-216-94). CMS uses the Medicare cost report to determine the total amount payable for the cost of these tests provided to Medicare beneficiaries. The cost report must provide a complete accounting of costs and revenues associated with covered services. Independent histocompatibility laboratories' cost information must be accurate and sufficiently detailed to support payments made for services provided.⁵

CMS requires independent histocompatibility laboratories to identify on their Medicare cost reports kidney and nonkidney tissue-typing costs and revenues. The cost report should include reimbursable, nonreimbursable, and general service costs:

- **Reimbursable costs** include costs for salaries and benefits, equipment maintenance, and other tissue-typing services.

⁴ The Social Security Act (the Act), § 1881(b)(1)(A); 42 CFR §§ 413.200(a) and (c); and CMS's *Provider Reimbursement Manual* (the Manual), Pub. No. 15-2, chapter 33, § 3312, part II.

⁵ 42 CFR §§ 413.24(a) and (c) and § 413.200(e); the Manual, Pub. No. 15-2, chapter 33, § 3312, part II.

- **Nonreimbursable costs** include costs for research, non-tissue-typing services, and nonkidney organ acquisition services.
- **General service costs** include two types of costs: (1) overhead costs, which include costs for capital, building operation, housekeeping, and movable equipment; and (2) administrative and general costs, which include costs for accounting and legal fees, office salaries and supplies, rent and lease expenses, and travel and meetings.⁶

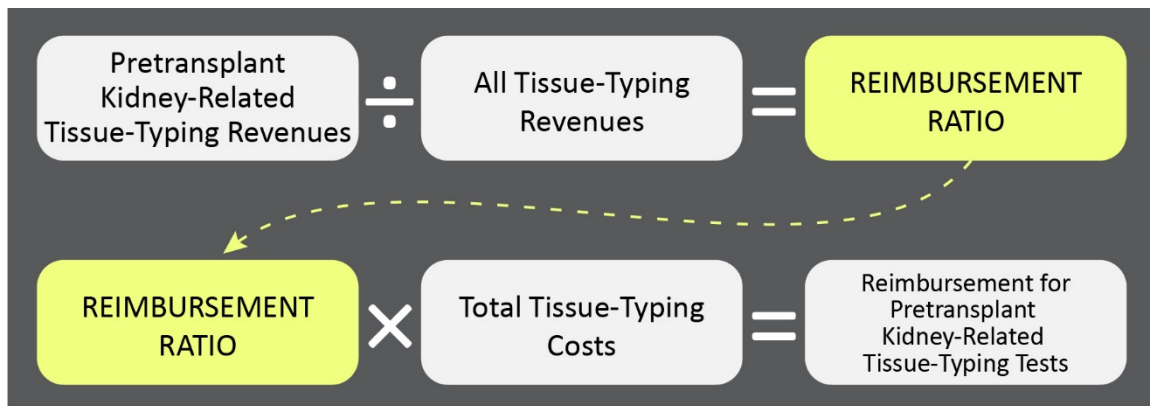
Revenues are the amounts that independent histocompatibility laboratories charge to hospitals and OPOs for performing tissue-typing tests.

Medicare Reimbursement of Independent Histocompatibility Laboratories

The Medicare program reimburses independent histocompatibility laboratories on the basis of reasonable costs.⁷ To determine the reimbursement for pretransplant kidney-related tissue-typing tests, an independent histocompatibility laboratory must:

- calculate its reimbursement ratio by dividing the total revenues for pretransplant kidney-related tissue-typing tests by the total revenues for all tissue-typing tests and
- multiply the reimbursement ratio by its total tissue-typing costs. (See the figure below.)

Figure: Determining the Reimbursement for Pretransplant Kidney-Related Tissue-Typing Tests⁸



⁶ The Manual, Pub. No. 15-2, chapter 33, §§ 3304 and 3390.

⁷ The Act § 1881(b)(2)(A). Reasonable costs are the costs actually incurred, excluding any part of incurred costs found to be unnecessary in the efficient delivery of services (the Act § 1861(v)).

⁸ The Manual, Pub. No. 15-2, chapter 33, § 3312, part II.

An independent histocompatibility laboratory does not bill Medicare directly for tissue-typing services. Instead, the laboratory is reimbursed through:

- indirect interim payments from CMS to the transplant hospitals, which then pay the OPOs and the laboratory,⁹ and
- an annual direct retroactive adjustment from CMS on the basis of the independent histocompatibility laboratory's cost report, to reconcile any overpayment or underpayment resulting from the total payments that the independent histocompatibility laboratory received from the transplant hospitals.¹⁰

Medicare Requirements for Providers To Identify and Return Overpayments

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Providers that receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments by the later of either 60 days of identifying those overpayments or the date any corresponding cost report is due, if applicable (60-day rule).¹¹

National Institute of Transplantation

NIT was incorporated in 1984 as a nonprofit corporation and was located in Los Angeles, California. During our audit period, NIT operated two laboratories, including an independent histocompatibility laboratory that provided tissue-typing services for organ transplantation to 12 different hospitals, OPOs, and other histocompatibility laboratories throughout southern California.¹²

HOW WE CONDUCTED THIS REVIEW

We reviewed NIT's FY 2012 Medicare cost report, which showed total costs of \$10,065,154 (including tissue-typing costs of \$4,912,854) and revenues of \$4,841,465. We obtained from NIT detailed reports listing the specific cost transactions and the tissue-typing tests associated with the revenues included on its cost report. To determine whether NIT correctly reported costs and revenues on its cost report, we judgmentally selected for review 186 cost

⁹ OPOs also pay the laboratory for tissue-typing services that the OPOs request directly from the laboratory.

¹⁰ 42 CFR § 413.200.

¹¹ The Act § 1128J(d); 42 CFR part 401, subpart D; 42 CFR §§ 401.305(a)(2), (b)(1), and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

¹² On December 10, 2013, Viracor-IBT Laboratories acquired NIT's histocompatibility laboratory. On April 30, 2014, NIT merged with the Mendez National Institute of Transplantation Foundation (the Foundation).

transactions (such as costs for salaries and supplies) totaling \$884,212 and 751 tissue-typing tests with revenues totaling \$326,455.

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

Appendix A contains the details of our audit scope and methodology.

FINDINGS

NIT did not fully comply with Medicare requirements for reporting tissue-typing costs and revenues on its FY 2012 Medicare cost report:

- Of 186 cost transactions, 177 were correctly reported; however, the remaining 9 transactions, totaling \$81,063, were incorrectly reported.
- Of 751 tissue-typing tests, 711 were correctly reported; however, the remaining 40 tests and 94 additional tests, with combined revenues totaling \$50,000, were incorrectly reported.¹³

As a result of these reporting errors, NIT incorrectly calculated its total tissue-typing costs and Medicare reimbursement ratio. Consequently, NIT received \$45,940 in overpayments from Medicare. These incorrectly reported costs and revenues were included on NIT's FY 2012 cost report, which is outside of the 3-year reopening period.¹⁴ These overpayments occurred because NIT did not have adequate policies and procedures for complying with Medicare cost-reporting requirements. Specifically, NIT did not have written policies and procedures for generating and reviewing the information used to prepare its Medicare cost reports.

NATIONAL INSTITUTE OF TRANSPLANTATION DID NOT FULLY COMPLY WITH MEDICARE REQUIREMENTS FOR REPORTING COSTS AND REVENUES ON ITS MEDICARE COST REPORT

NIT incorrectly reported costs of \$81,063 and revenues of \$50,000.

¹³ The 94 additional tests were not included in our judgmental sample. We identified these tests during our reconciliation of the FY 2012 Medicare cost report with detailed revenue reports.

¹⁴ In general, a MAC can reopen a Notice of Amount of Program Reimbursement on its own motion or at the request of CMS no later than 3 years after the date of the notice (42 CFR §§ 405.1885(b)(1) and (c)(1); the Manual, Pub. No. 15-1, chapter 29, §§ 2931.1.A and .C). A cost report may be reopened at any time for fraud or similar fault (42 CFR § 405.1885(b)(3); the Manual, Pub. No. 15-1, chapter 29, § 2931.1.F).

Incorrectly Reported Costs

A Medicare cost report must provide a complete accounting of reimbursable and nonreimbursable costs (42 CFR § 413.200(e); the Manual, Pub. No. 15-2, chapter 33, § 3390). Providers receiving payment on the basis of reimbursable cost must provide data that are accurate and in sufficient detail to accomplish the purposes for which they are intended (42 CFR § 413.24).

An independent histocompatibility laboratory that files a cost report in accordance with Federal regulations is reimbursed for items and services furnished to beneficiaries on a reasonable cost basis for the period covered by the cost report (42 CFR § 413.200(a)).¹⁵ Costs incurred for gifts or donations to charitable, civic, educational, medical, or political entities are not allowable (the Manual, Pub. No. 15-1, chapter 21, § 2105.7).

NIT incorrectly reported costs of \$81,063. Of the 186 cost transactions that we reviewed, 9 transactions were incorrectly reported:

- Five transactions, totaling \$53,495, were incorrectly reported as reimbursable. NIT stated that it incorrectly reported these costs because of human error. For example, NIT reported as reimbursable a sponsorship donation of \$25,000. NIT stated that it adjusts these donations out of its internal report every year but forgot to remove this donation for FY 2012.
- Four transactions, totaling \$27,568, were incurred outside of the cost-reporting period. NIT explained that it reported these costs in the FY 2012 cost report because it paid them in 2012. For example, NIT reported \$6,418 in supply costs for 2011. NIT stated that it did not report these costs on its FY 2011 cost report because it did not receive an invoice until 2012.

NIT's overstated costs of \$81,063 included general service costs that did not directly affect the total reported tissue-typing costs.¹⁶ In aggregate, these overstated costs increased total reported tissue-typing costs by \$36,677, resulting in higher Medicare reimbursement.

Incorrectly Reported Revenues

Independent histocompatibility laboratories are required to submit cost reports that generally cover a consecutive 12-month period of their operations and must report their revenue for all

¹⁵ The reasonable cost for any service is the cost that was actually incurred, excluding any portion that could be considered unnecessary. Reasonable costs must be properly allocated and apportioned to ensure that Medicare pays only for costs related to the care provided to Medicare beneficiaries and only its share of those costs (the Act § 1861(v)(1)(A)).

¹⁶ General service costs were costs, such as rent and insurance, that were shared by all NIT departments. NIT allocated these costs to all departments on the basis of square footage and total costs for each department.

tests (kidney and nonkidney) performed in the tissue-typing laboratory within the period in which the revenue is earned, regardless of when it is collected (42 CFR §§ 413.24(a) and (b) and the Manual, Pub. No. 15-2, chapter 33, § 3300; § 3302.1, part I, line 3; and § 3312, part II, line 1).

Providers receiving payment on the basis of reimbursable cost must provide data that are accurate and in sufficient detail to accomplish the purposes for which they are intended (42 CFR § 413.24(c)). Providers must report on separate lines of the cost report the total number of all tests performed, the total number of tissue-typing tests performed, and the total number of pretransplant kidney-related tissue-typing tests performed (the Manual, Pub. No. 15-2, chapter 33, § 3303.2, part II).

NIT incorrectly reported revenues of \$50,000. Of the 751 tissue-typing tests that we reviewed, 40 tests, with associated revenues totaling \$19,785, were incorrectly reported:

- Thirty-three duplicate tests, with revenues totaling \$11,160, were included on the cost report. For example, on August 15, 2012, NIT billed a transplant hospital for six tests for one patient and then rebilled the transplant hospital for the same six tests for the same patient on August 31, 2012. NIT stated that its list of tests and revenues included 33 duplicate tests because it had inadvertently billed the transplant hospitals twice for these tests.
- Seven nonkidney-related tests, with revenues totaling \$8,625, were reported as reimbursable. For example, NIT conducted two tests on a deceased donor for the transplantation of one pancreas and reported the revenues for these tests as reimbursable. NIT stated that it mistakenly included these tests as reimbursable even though they were nonkidney-related tests. As a result, NIT overstated the total reported pretransplant kidney-related tissue-typing revenues. This overstatement did not affect the total reported tissue-typing revenues.

In addition, during our reconciliation of the FY 2012 Medicare cost report with detailed revenue reports, we identified an additional 94 tests, with associated revenues totaling \$30,215, that were incorrectly reported:

- Eighty-four tests, with revenues totaling \$22,865, had dates of service outside of the cost-reporting period. For example, NIT conducted 14 tests on January 3, 2013, but reported these tests as reimbursable on its FY 2012 Medicare cost report. NIT stated that it reported all tests that NIT billed to the hospitals for 2012. NIT explained that in 2012, it billed the transplant hospitals for tests with service dates in 2011. NIT also stated that the bills submitted to the transplant hospitals for December 2012 were processed in January 2013 and included some tests with service dates in 2013.

- Ten duplicate tests, with revenues totaling \$7,350, were included on the cost report. NIT identified these tests as duplicate tests on its internal report; however, it incorrectly reported these tests and revenues on the cost report.

NIT's incorrect reporting of revenues increased the total reported pretransplant kidney-related tissue-typing revenues by \$50,000 and the total reported tissue-typing revenues by \$41,375, resulting in a reimbursement ratio of 90.66 percent rather than 90.40 percent (a 0.26-percentage-point difference).

NATIONAL INSTITUTE OF TRANSPLANTATION RECEIVED MEDICARE OVERPAYMENTS

As a result of the incorrectly reported costs and revenues on its FY 2012 Medicare cost report, NIT overstated its total tissue-typing costs by \$36,677 and its Medicare reimbursement ratio by 0.26 percentage points, resulting in \$45,940 in overpayments from Medicare. Table 1 shows the change in the reimbursement ratio, and Table 2 shows how the overstated total tissue-typing costs and reimbursement ratio resulted in an overpayment.

Table 1: Changes to NIT's Reimbursement Ratio

	Information Reported by NIT in Its Cost Report	Adjustment Based on OIG Findings	Corrected Cost Report Information
Total Pretransplant Kidney-Related Tissue-Typing Revenues	\$4,389,315	(\$50,000)	\$4,339,315
Divided by Total Tissue-Typing Revenues	\$4,841,465	(\$41,375)	\$4,800,090
Reimbursement Ratio	0.9066	(0.26)	0.9040

Table 2: Calculation of Overpayment for Pretransplant Kidney-Related Tissue-Typing Tests

	Information Reported by NIT in Its Cost Report	Adjustment Based on OIG Findings	Corrected Cost Report Information
Total Tissue-Typing Costs	\$4,912,854	(\$36,677)	\$4,876,177
Multiplied by Reimbursement Ratio	0.9066	(0.26)	0.9040
Medicare Reimbursement	\$4,454,038	\$45,940	\$4,408,098

NATIONAL INSTITUTE OF TRANSPLANTATION DID NOT HAVE ADEQUATE POLICIES AND PROCEDURES TO COMPLY WITH MEDICARE REQUIREMENTS

NIT did not have adequate policies and procedures for complying with Medicare cost-reporting requirements. Specifically, NIT did not have written policies and procedures for generating and reviewing the information used to prepare Medicare cost reports.¹⁷ According to NIT, human error and its misunderstanding of cost report guidance caused it to incorrectly report costs and revenues on the internal reports that it submitted to the consultant who prepared the cost report.

RECOMMENDATIONS

We recommend that NIT:

- work with the MAC to return \$45,940 in potential overpayments identified in this report that are outside of the 3-year reopening period but within the 6-year lookback period in accordance with the 60-day rule, and identify the returned overpayments as having been made in accordance with this recommendation; and
- exercise reasonable diligence to identify and return any additional similar overpayments related to cost reports that were not part of our audit in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

NATIONAL INSTITUTE OF TRANSPLANTATION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIT concurred with our recommendations and provided information on actions that it planned to take to address our recommendations. NIT also provided comments on our finding on incorrectly reported costs. NIT's comments are included in their entirety as Appendix B.

Regarding our finding that four cost transactions, totaling \$27,568, were incurred outside of the cost-reporting period, NIT stated that these costs were general service costs that it incurred as part of its tissue-typing services. NIT stated that by removing these costs from the FY 2012 cost report, NIT would suffer "the loss of reimbursement for these costs because they were not reported on the cost report in the year incurred and now cannot be recaptured."

¹⁷ Although Viracor-IBT Laboratories acquired NIT in 2013, the Foundation is responsible for any overpayments identified in the FY 2012 cost report. NIT and the Foundation no longer provide tissue-typing services for organ transplantation; therefore, they no longer prepare Medicare cost reports to receive Medicare reimbursement for pretransplant kidney-related tissue-typing tests. Accordingly, we are not recommending that NIT strengthen its policies and procedures for preparing Medicare cost reports.

Although NIT concurred with our first recommendation, NIT stated that it “will work with the MAC to return the overpayments identified, after consideration by the OIG of the comment above regarding costs that were in fact incurred and not reported in another cost reporting period.”

After reviewing NIT’s comments, we maintain that our findings and recommendations are valid. Federal regulations state that independent histocompatibility laboratories must provide adequate cost data that are based on the accrual basis of accounting, which means that revenue is reported in the period in which it is earned, regardless of when it is collected, and an expense is reported in the period in which it is incurred, regardless of when it is paid.¹⁸

OTHER MATTERS: NATIONAL INSTITUTE OF TRANSPLANTATION INCORRECTLY REPORTED TEST STATISTICS

Independent histocompatibility laboratories must maintain sufficient financial records and statistical data for proper determination of costs.¹⁹ In addition, these laboratories must include in their cost reports (1) the total number of all tests performed, (2) the total number of kidney pretransplantation tests performed, and (3) the number of each test performed. Kidney pretransplantation tests include tests that are performed for potential kidney recipients, living related and unrelated donors, and kidneys of deceased donors.²⁰

NIT did not comply with Medicare requirements for reporting the number of deceased-donor tests on its FY 2012 Medicare cost report. Specifically, NIT reported 294 deceased-donor tests on its cost report. However, after reviewing the detailed list of tests that NIT performed, we determined that it conducted 1,641 deceased-donor tests. NIT incorrectly reported the number of deceased donors that it tested rather than the number of tests performed.

Although NIT incorrectly reported the number of deceased-donor tests, the revenues associated with these tests were correctly reported. Therefore, this error did not affect NIT’s reimbursement.

¹⁸ 42 CFR §§ 413.24(a) and (b) and § 413.200(e)(1).

¹⁹ 42 CFR § 413.20(a).

²⁰ The Manual, Pub. No. 15-2, chapter 33, § 3303.2, part II.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed NIT's FY 2012 Medicare cost report,²¹ which showed total costs of \$10,065,154 (including tissue-typing costs of \$4,912,854) and revenues of \$4,841,465. We obtained from NIT detailed reports listing the specific cost transactions and the tissue-typing tests associated with the revenues included on its cost report. To determine whether NIT correctly reported costs and revenues on its cost report, we judgmentally selected for review 186 cost transactions (such as costs for salaries and supplies) totaling \$884,212 and 751 tissue-typing tests with revenues totaling \$326,455.

We did not review NIT's overall internal control structure. We limited our review of NIT's internal controls to obtaining an understanding of its policies and procedures for reporting tissue-typing costs and revenues on its Medicare cost report.

We conducted our audit from November 2015 to October 2017, which included fieldwork performed at NIT's office in Los Angeles, California.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed officials of Cahaba Government Benefit Administrators to obtain an understanding of Medicare reimbursement requirements for kidney tissue-typing services;
- interviewed NIT officials and personnel to obtain an understanding of NIT's policies and procedures for reporting costs and revenues on its Medicare cost report;
- obtained NIT's FY 2012 Medicare cost report;
- obtained NIT's detailed reports listing the specific cost transactions and the tests associated with the revenues included on its cost report;
- reconciled the total costs and revenues reported on NIT's FY 2012 Medicare cost report with its detailed trial balance and supporting documentation;

²¹ This was the most recently finalized cost report at the start of our review.

- judgmentally selected 186 cost transactions and 751 tests and obtained supporting documentation to determine whether NIT complied with Medicare requirements for reporting each selected item;
- reconciled the cost report with detailed revenue reports and identified an additional 94 tissue-typing tests that were incorrectly reported;
- calculated the Medicare overpayments related to incorrectly reported tissue-typing services provided by NIT; and
- shared the results of our review with NIT officials.

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

APPENDIX B: NATIONAL INSTITUTE OF TRANSPLANTATION COMMENTS



August 7, 2018

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

Re: Report #A-09-16-02010

Dear Ms. Ahlstrand,

We have reviewed the draft report entitled *National Institute of Transplantation, an Independent Histocompatibility Laboratory, Did not Fully Comply With Medicare's Cost-Reporting Requirements* and have the following comments regarding this report.

NIT would like to make a general comment in reference to the information provided under "Why OIG Did This Review". NIT was selected for review because we reported a 90.6 percent reimbursement ratio which was 14 percentage points higher than the national average. We want to point out that, after this lengthy and intensive audit, the OIG findings were that NIT's reimbursement ratio remains substantially higher than the national average, at 90.4.

Comments regarding specific findings:

- **Incorrectly Reported Costs:** The four transactions totaling \$27,568 that were incurred outside of the cost-reporting period are nonetheless general service costs that NIT incurred as part of its tissue typing services. With these costs pulled out of the 2012 cost report because they were paid in 2012, not incurred in 2012, NIT suffers the loss of reimbursement for these costs because they were not reported on the cost report in the year incurred and now cannot be recaptured.

Comments regarding Recommendations:

- We concur that we will work with the MAC to return the overpayments identified, after consideration by the OIG of the comment above regarding costs that were in fact incurred and not reported in another cost reporting period. We will identify any returned overpayment as having been made in accordance with this recommendation. NIT will take care to properly accrue costs in the year incurred rather than report them in the year paid, if different.

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- We concur that reasonable diligence will be exercised to identify and return any additional similar overpayments related to cost reports that were not part of this audit in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

Sincerely,

A handwritten signature in cursive script that reads "Mary McDonell".

Mary McDonell, CPA
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