

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PROFESSIONAL CLINICAL LABORATORY,
INC., GENERALLY DID NOT COMPLY
WITH MEDICARE REQUIREMENTS FOR
BILLING PHLEBOTOMY TRAVEL
ALLOWANCES**

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October 2018
A-06-16-02002

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: October 2018

Report No. A-06-16-02002

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



Why OIG Did This Review

Medicare pays a specimen collection fee when it is medically necessary for a clinical laboratory technician to draw a specimen to perform a clinical diagnostic laboratory test. When a technician travels to a nursing facility or homebound patient, and a specimen collection fee is payable, the Social Security Act provides for payment of a travel allowance. Prior work found that travel allowances were at risk of being overpaid.

The objective of our review was to determine whether Professional Clinical Laboratory, Inc., (ProLab) claimed travel allowances for clinical diagnostic laboratory tests in accordance with Medicare requirements.

How OIG Did This Review

Our review covered 127,168 claim lines totaling \$3.2 million paid to ProLab for Medicare Part B travel allowances from its Euless, Texas facility during 2014–2015. We reviewed documentation from ProLab for a stratified random sample of 100 claim lines.

Professional Clinical Laboratory, Inc. Generally Did Not Comply With Medicare Requirements for Billing Phlebotomy Travel Allowances

What OIG Found

ProLab generally did not comply with Medicare requirements for billing travel allowances. Specifically, of the 100 travel allowance claim lines in our stratified random sample, 35 claim lines complied with Medicare requirements and 65 claim lines did not (some lines had multiple deficiencies). ProLab did not (1) support prorated miles with documentation when multiple patients were served on a single trip; (2) resubmit claims when there was a retroactive change in the clinical laboratory fee schedule; and (3) have documentation to support specimen collections.

What OIG Recommends and ProLab's Comments

We recommended that ProLab (1) refund to the Medicare program the portion of the estimated \$319,277 overpayment for claims incorrectly billed that are within the reopening period; (2) for the remaining portion of the estimated \$319,277 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule and identify any returned overpayments as having been made in accordance with this recommendation; and (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

ProLab did not respond to our draft report upon the advice of their attorney. Based on a discussion with the attorney, we learned that he advised ProLab officials not to answer any follow-up questions or respond to the draft report.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Review.....	1
Objective.....	1
Background.....	1
Medicare Program.....	1
Federal Regulations.....	2
Phlebotomy Travel Allowance Calculation.....	3
ProLab.....	4
How We Conducted This Review.....	4
FINDINGS.....	5
Documentation Did Not Support Prorated Miles.....	5
Difference Due to Change in Fee Schedule.....	6
No Documentation to Support Specimen Collection.....	6
RECOMMENDATIONS.....	7
PROFESSIONAL CLINICAL LABORATORY, INC., COMMENTS.....	7
APPENDICES	
A: Audit Scope and Methodology.....	8
B: Statistical Sampling Methodology.....	10
C: Sample Results and Estimates for Recoverable Overpayments.....	12
D: Sample Results and Estimates for Potential Overpayments.....	13

INTRODUCTION

WHY WE DID THIS REVIEW

Medicare pays a specimen collection fee when it is medically necessary for a clinical laboratory technician to draw a specimen for a clinical diagnostic laboratory test.¹ In addition, when a technician travels to a nursing facility or homebound patient and a specimen collection fee is payable, the Act provides for payment of a travel allowance “to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample.”² Prior Office of Inspector General (OIG) work found that travel allowances have the potential to be overpaid when some clinical laboratories claimed travel mileage in excess of the actual miles traveled.

We reviewed travel allowance claims for Professional Clinical Laboratory, Inc., (ProLab) because it was one of the highest-paid providers for travel allowances in the nation for the period January 1, 2013 through June 30, 2015.

OBJECTIVE

The objective of our review was to determine whether ProLab claimed travel allowances for clinical diagnostic laboratory tests in accordance with Medicare requirements.

BACKGROUND

Medicare Program

Title XVIII of the Act established the Medicare program, which provides health insurance coverage for people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Medicare Part B provides supplementary medical insurance for medical and other health services, including laboratory services. CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Medicare Part B claims submitted by clinical laboratories. Novitas Solutions, Inc., (Novitas) was the MAC responsible for processing and paying all claims associated with this audit.

¹ Section 1833(h)(3)(A) of the Social Security Act (the Act), 42 U.S.C. § 1395l(h)(3)(A). See also Chapter 16, section 60.1.2 of the Medicare Claims Processing Manual (the Manual), Rev. 3425, 12-18-15.

² The Act § 1833(h)(3)(B).

Under section 1128J(d) of the Act and 42 CFR part 401 subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (§ 42 CFR 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663 (February 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

Federal Regulations

A travel allowance to collect a sample from a nursing facility or homebound patient may only be claimed by a clinical laboratory when a specimen collection fee is also payable.³ A specimen collection fee is payable for specimens extracted by a laboratory technician, such as a blood sample drawn through venipuncture, or a urine sample drawn by catheterization. No fee is allowed for samples where the cost of collection is minimal, such as throat cultures, blood draws by capillary puncture, or urine collection absent catheterization. The travel allowance is based on the actual distance traveled to each nursing facility or residence on a route until the blood, urine, and micro draws or pick-ups (collectively called specimens)⁴ are dropped off at a clinical laboratory, a reference laboratory,⁵ or other drop location (referred to as a trip throughout this report). According to the Manual, Chapter 16, section 60.2:

- The allowance cannot be claimed if the technician does not draw the sample but merely performs a messenger service to pick up a blood or urine specimen drawn by a physician or nursing facility personnel.
- At no time is the clinical laboratory allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

³ The Act § 1833(h)(3).

⁴ A micro is collected and will be tested by the clinical laboratory's microbiology department, such as culture swabs, stool specimens, etc. A draw is either a blood sample taken by venipuncture or a urine sample by catheterization. A pick-up is simply transporting a sample not drawn or collected by the laboratory technician. A specimen collection fee is not payable for pick-up services. Per discussions with CMS, specimens include blood, urine, and micro draws or pick-ups.

⁵ A reference laboratory is defined as the clinical laboratory that receives a specimen from another clinical laboratory and performs one or more tests on such specimen.

- Carriers⁶ must prorate travel allowance amounts claimed by suppliers by the number of patients (including Medicare and non-Medicare patients) from whom specimen draws or pick-ups were made on the same trip.⁷

Phlebotomy Travel Allowance Calculation

There are two Healthcare Common Procedure Coding System codes (HCPCS)⁸ used for travel allowances, P9603 and P9604. P9603 is used when the average round-trip to a patient's nursing facility is longer than 20 miles, paid on a mileage per trip basis. P9604 is used when the average round trip is less than 20 miles, paid on a flat rate per trip basis.

Under either code, when one trip is made for specimen draws or pick-ups from multiple patients (i.e., at a nursing facility), the travel payment component is prorated based on the number of patients on that trip, for both Medicare and non-Medicare patients.⁹ All draws and pick-ups are prorated on the day of the pickup, and only the Medicare patients are billed for the travel allowance.

The prorated mileage is calculated as follows:

- The numerator is the sum of all miles driven by a phlebotomist to all nursing facilities or homebound patients for a single trip to collect all specimens.
- The denominator is the total number of Medicare and non-Medicare patients with specimen draws and pick-ups on a trip.

The result is the prorated travel allowance mileage per patient. To calculate the total Medicare travel allowance, the prorated mileage is then multiplied by a per-mile reimbursement rate set by CMS each year.

⁶ Carriers pre-dated MACs as entities that processed and paid Medicare Part B claims.

⁷ A CMS Recurring Update Notification states that "the travel payment component is prorated based on the number of specimens collected on the trip, for both Medicare and non-Medicare patients. . . ." CMS acknowledged during our review that the guidance is conflicting on whether to prorate based on the number of "patients" or "specimens." CMS stated that "the policy is intended to determine Medicare's portion of the travel allowance by dividing by the total number of patients (Medicare and non-Medicare)." CMS also stated it would work to clarify the guidance.

⁸ HCPCS is a medical code set used throughout the healthcare industry as a standardized system for describing and identifying health care procedures, equipment, and supplies in health care transactions.

⁹ The Manual, Chapter 16, § 60.2.

ProLab

ProLab was an independently-owned clinical laboratory based out of Euless, Texas. It operated in 11 states and provided 24-hour laboratory services, including drawing, transporting, and processing blood draws to provide diagnostic information to nurses and physicians.

ProLab officials reported that most of their phlebotomists traveled a standard route each day, from their homes to various nursing facilities, and that some were STAT phlebotomists, meaning they were on call. When a doctor needed an immediate blood draw, these STAT phlebotomists would go to the nursing facility, perform the blood draw, and take it directly to the clinical laboratory for testing.

In June 2016, during the course of our audit, ProLab was sold to another lab testing company.¹⁰

HOW WE CONDUCTED THIS REVIEW

Our review covered 127,168 claim lines totaling \$3,159,036 paid to ProLab for Medicare Part B travel allowances from its Euless, Texas facility between January 1, 2014, and December 31, 2015. Each claim line represented a Medicare travel allowance. We reviewed a stratified random sample of 100 claim lines that were each part of a trip.

ProLab officials provided us with requested documentation and answered our questions during the course of the audit. Following discussion of our preliminary findings and upon advice of their counsel, ProLab declined our request to clarify additional questions about documentation for particular claim lines. ProLab also declined a request for an official exit conference.

After we discussed our preliminary findings with ProLab, we received further clarification from CMS on the travel allowance calculation. Based on this clarification, it was determined that the prorated travel allowance mileage should be based on the number of patients, not specimens. The documentation we received from ProLab reported the number of blood, urine, and micro draws or pick-ups, but did not specify the number of patients. Since ProLab declined to provide additional documentation or answer additional questions, we were unable to determine the number of patients. To be conservative, we calculated the prorated travel allowance mileage using the smallest possible number of patients for each nursing facility. For example, if there were five blood draws, seven urine pick-ups and two micro pick-ups, we divided the total mileage by seven, when there could have been up to 14 patients.

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

¹⁰ Despite being sold during the course of our audit, ProLab was responsible for claims submitted during our audit period.

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, Appendix B contains our statistical sampling methodology, Appendix C contains our sample results and estimates for recoverable overpayments, and Appendix D contains our sample results and estimates for potential overpayments.

FINDINGS

ProLab generally did not comply with Medicare requirements for billing travel allowances. Specifically, of the 100 claim lines in our stratified random sample, 35 claim lines complied with Medicare requirements and 65 claim lines did not (some lines had multiple deficiencies). On the basis of our sample results, we estimated that at least \$319,277 for travel allowances for clinical laboratory services claimed by ProLab was not paid in accordance with Medicare requirements.¹¹

DOCUMENTATION DID NOT SUPPORT PRORATED MILES

The Manual states that at no time will the clinical laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.¹²

Of the 100 claim lines, 56 were part of a trip that did not prorate mileage correctly based on the documentation provided. For 45 of the 56 claim lines, ProLab claimed more prorated miles than their mileage logs supported for a single trip. Specifically, ProLab claimed up to 66 more prorated miles than had actually occurred on the trips for these 45 claim lines. ProLab officials told us that this was due to a data entry clerk misreading or incorrectly adding the number of miles, the number of draws documented on the mileage logs, or both. ProLab officials also told us that they did not prorate the travel allowance mileage using pick-ups because they were not aware of any criteria requiring them to do so.

Nine of the 56 claim lines included mileage from a second trip when the mileage count from the claimed trip should have stopped when the specimens were dropped off at a lab. Specifically, ProLab claimed up to 41 more prorated miles than had actually occurred on the trips for these nine claim lines by including mileage from a subsequent trip. ProLab officials told us that sometimes the data entry clerk mistakenly miscalculated multiple trips after blood draws were dropped off. For example, the data entry clerk incorrectly prorated mileage for a single trip to

¹¹ This estimate is based on our conservative approach. However, if each specimen collection represented a different patient, then we estimated that at least \$664,670 for travel allowances for clinical laboratory services claimed by ProLab was not paid in accordance with Medicare requirements. See Appendix D.

¹² The Manual, Chapter 16, § 60.2.

and from the clinical laboratory which included miles not actually traveled by the laboratory technician (i.e., miles after blood draw was dropped off at the clinical laboratory).

The travel allowance is based on the actual distance traveled to each nursing facility or residence on a route until the specimens are dropped off at a clinical laboratory, a reference laboratory, or other drop location. Two of the 56 claim lines were part of a trip where ProLab did not include all of the mileage traveled in the calculation for prorated mileage or just claimed the wrong prorated mileage. ProLab officials were not available to discuss why they did not include the correct mileage in the calculation.

DIFFERENCE DUE TO CHANGE IN FEE SCHEDULE

Payment for the travel allowance is made based on the clinical laboratory fee schedule. The Change Requests¹³ revising the payment rate for travel allowances were released in February or March of each year with an effective date of January 1 of each year. Claims for travel allowances will not be automatically adjusted. Providers must bring any previously paid claims to their contractors' attention.

For 12 of our sampled claim lines, a change in the payment rate caused an overpayment or underpayment. ProLab officials told us that they did not resubmit claims that were paid the previous year's rate and should have been resubmitted for an adjustment once the new payment rate was released.

NO DOCUMENTATION TO SUPPORT SPECIMEN COLLECTION

Payments to Medicare providers should not be made unless the provider has furnished information necessary to the MAC to determine the amount owed to the provider.¹⁴ The policy states that the travel allowance should be prorated by dividing the mileage by the total number of patients from whom specimen draws or pick-ups were made in the same trip.

For seven of our sampled claim lines, ProLab officials provided us with documentation that did not indicate the number of patients or specimens collected on each trip.¹⁵ Instead of mileage logs, ProLab provided us with a printed Google map showing the route and the miles traveled by a phlebotomist. In addition, documentation of the trips for:

- Five of the seven claim lines included a form that showed certain patient information, but nothing indicating the number of specimen draws or pick-ups.

¹³ Change Requests 8203, 8641, and 9066.

¹⁴ The Act § 1833(e).

¹⁵ A typical ProLab claim includes beneficiary information, HCPCS billed, and the mileage claimed for payment. ProLab must maintain other documentation to support the claim, but only submits it if Novitas requests it.

- Two of the seven claim lines included a typed note stating how many blood draws were made on the trip, but nothing indicating the number of patients or total specimens collected.

Without adequate documentation, we cannot be assured that the correct prorated mileage was submitted to the MAC and paid. ProLab officials were not available to discuss why they did not have documentation to support specimen collections on the trips for these seven claim lines.

RECOMMENDATIONS

We recommend that ProLab:

- refund to the Medicare program the portion of the estimated \$319,277 overpayment for claims incorrectly billed that are within the reopening period;¹⁶
- for the remaining portion of the estimated \$319,277 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation.

PROFESSIONAL CLINICAL LABORATORY, INC. COMMENTS

ProLab did not respond to our draft report upon the advice of their attorney. Based on a discussion with the attorney, we learned that he advised ProLab officials not to answer any follow-up questions or respond to the draft report.

¹⁶ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 127,168 claim lines of Medicare Part B travel allowances totaling \$3,159,036, paid to ProLab during our audit period, January 1, 2014, through December 31, 2015. The claims data was obtained from the CMS National Claims History file on the OIG Data Warehouse. We selected a stratified random sample of 100 travel allowance claim lines to review.

We did not perform an overall assessment of ProLab's internal control structure. Rather, we reviewed only the internal controls that related directly to our objective. Our review allowed 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 performed our audit work from May 2016 through January 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials to gain a better understanding of Medicare requirements for travel allowances and obtained their interpretation of the Medicare regulations related to travel allowances;
- interviewed Novitas officials to gain a better understanding of Medicare requirements for travel allowances and obtained their interpretation of the Medicare regulations related to travel allowances;
- interviewed ProLab officials to gain an understanding of their policies and procedures related to travel allowances and how they are calculated and paid;
- interviewed two ProLab phlebotomists to gain an understanding of the process they followed on their routes as they made their blood draws and pick-ups;
- obtained data from CMS's National Claims History file of ProLab's travel allowance claims (HCPCS codes P9603 and P9604) and extracted from CMS's National Claims History file a sampling frame of 127,168 Medicare Part B travel allowance claim lines, totaling \$3,159,036, paid to ProLab from January 1, 2014, through December 31, 2015;

- sent ProLab the list of 100 travel allowance claim lines that were associated with a trip to obtain the documentation supporting these claims lines (e.g. mileage logs, requisition orders);
- evaluated the documentation obtained from ProLab for each sample claim line from a trip to determine whether the travel allowances were paid in accordance with Medicare requirements;
- performed two distinct calculations to determine the recoverable and potential overpayments in the total population of 127,168 travel allowance claim lines. We did this because the documentation that we received from ProLab reported the number of blood, urine, and micro draws or pick-ups, but did not specify the number of patients;
- for the recoverable overpayment estimate (Appendix C), we used the smallest number of possible patients for each nursing facility, which resulted in more prorated travel allowance miles per patient, therefore resulting in a more conservative overpayment estimate;
- for the potential overpayment estimate (Appendix D), we assumed each blood, urine, and micro draw or pick-up was for a different patient, which resulted in fewer prorated travel allowance miles per patient, resulting in a larger overpayment estimate; and
- discussed the preliminary results of our audit with the ProLab officials.

See Appendix B for the details of our statistical sampling methodology, Appendix C for our sample results and estimates for recoverable overpayments, and Appendix D for our sample results and estimate for potential overpayments.

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: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of travel allowances for which Medicare Part B paid ProLab from January 1, 2014, through December 31, 2015.

SAMPLING FRAME

The sampling frame consisted of 127,168 Medicare Part B travel allowance claim lines totaling \$3,159,036, paid during our audit period, January 1, 2014, through December 31, 2015.

SAMPLE UNIT

The sample unit was a Medicare travel allowance claim line.

SAMPLE DESIGN

We used a stratified sample consisting of three strata. The strata were divided based upon the Medicare payment amount for the travel allowance claim line.

Stratum	Number of Claim Lines	Stratum Boundaries	Value
1	83,358	\$10 to less than \$22	\$1,220,054
2	36,077	\$22 to less than \$58	1,182,445
3	7,733	\$58 to \$613.07	756,537
Total	127,168		\$3,159,036

SAMPLE SIZE

We selected a sample of 100 travel allowance claim lines; 33 lines from stratum 1, 33 lines from stratum 2, and 34 lines from stratum 3.

SOURCE OF RANDOM NUMBERS

Random numbers were generated by the Region VI Statistical Specialist using the HHS-OIG Office of Audit Services RAT-STATS 2010 Version 4 statistical software package.

METHOD OF SELECTING SAMPLE UNITS

We sequentially numbered the sample frame from 1 to 83,358 for stratum 1, 83,359 to 119,435 for stratum 2, and 119,436 to 127,168 for stratum 3. After generating 33 random numbers for stratum 1, 33 random numbers for stratum 2, and 34 random numbers for stratum 3, we selected the corresponding claim lines in each stratum.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of unallowable Medicare payments for travel allowances.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES FOR RECOVERABLE OVERPAYMENTS

Sample Details and Results

Stratum	Sampling Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Travel Allowances	Value of Unallowable Travel Allowances
1	83,358	\$1,220,054	33	\$478	18	\$36
2	36,077	1,182,445	33	1,031	26	162
3	7,733	756,537	34	2,849	21	838
Total	127,168	\$3,159,036	100	\$4,358	65	\$1,036

**Estimated Value of Travel Allowance Overpayments
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$457,782
Lower limit	\$319,277
Upper limit	\$596,286

APPENDIX D: SAMPLE RESULTS AND ESTIMATES FOR POTENTIAL OVERPAYMENTS

Sample Details and Results

Stratum	Sampling Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Travel Allowances	Value of Unallowable Travel Allowances
1	83,358	\$1,220,054	33	\$478	29	\$90
2	36,077	1,182,445	33	1,031	31	279
3	7,733	756,537	34	2,849	27	1,171
Total	127,168	\$3,159,036	100	\$4,358	87	\$1,540

**Estimated Value of Travel Allowance Overpayments
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$797,683
Lower limit	\$664,670
Upper limit	\$930,697