Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS NEEDS TO ISSUE REGULATIONS RELATED TO PHLEBOTOMY TRAVEL ALLOWANCES

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

Amy J. Frontz
Deputy Inspector General
for Audit Services

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Office of Inspector General

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Report in Brief
Date: August 2021
Report No. A-06-20-04000

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

CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances

Why OIG Did This Audit

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. In addition, when a technician travels to a nursing home or to a homebound patient's residence and a specimen collection fee is payable, the Social Security Act provides for payment of a phlebotomy travel allowance.

For this audit, we focused on two previous audits of phlebotomy travel allowance payments for clinical diagnostic laboratory tests made by 2 Medicare administrative contractors (MACs) from January 1, 2015, through December 31, 2016, and on current travel allowance guidance.

Our objectives were to (1) summarize the results of our previous two audits that identified instances in which payments made by two MACs to providers for phlebotomy travel allowances for clinical diagnostic laboratory tests did not always comply with Medicare guidance and (2) review Centers for Medicare & Medicaid Services (CMS) guidance related to phlebotomy travel allowances to determine whether there have been any updates.

How OIG Did This Audit

We summarized the results of our prior audits, which covered 753,410 paid claim lines, totaling $16.4 million, paid by the 2 MACs for phlebotomy travel allowances. We also met with CMS to determine whether it had taken steps to clarify how to properly prorate phlebotomy travel allowances.

What OIG Found

In our two previous audits of MAC payments for phlebotomy travel allowances, we determined that the two MACs paid providers for phlebotomy travel allowances that did not comply with Medicare guidance. Specifically, in our 2 MAC audits, 93 of the 202 sampled paid claim lines we reviewed complied with Medicare guidance, but 109 paid claim lines did not. (Some lines did not comply for more than one reason.) Errors identified in those audits were related to incorrect prorated mileage, incorrect payment rates, and inadequate documentation. On the basis of the sample results, we estimated that the two MACs paid providers a combined $2.7 million in phlebotomy travel allowance payments that were not in accordance with Medicare guidance. In addition, we spoke with CMS in June 2020 and, at that time, it had not begun the notice and comment rulemaking process necessary to clarify provider requirements related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance.

What OIG Recommends and CMS Comments

We recommend that CMS (1) work with the MACs to educate providers about the documentation requirements for phlebotomy travel allowances, (2) instruct the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate, and (3) issue regulations related to phlebotomy travel allowances. (See the report for the more detailed third recommendation.)

In written comments on our draft report, CMS concurred with our first two recommendations. For our third recommendation, CMS stated that the clarifications that we proposed regarding how providers must prorate phlebotomy travel allowances will need to go through notice and comment rulemaking. As part of the calendar year 2022 Physician Fee Schedule Proposed Rule, CMS solicited comments on the policies for specimen collection fees and the travel allowance, as well as the methodology for calculating the travel allowance. CMS stated that it will consider comments received, along with our third recommendation, when determining appropriate next steps for phlebotomy travel allowances.

After reviewing CMS's comments, and their technical comments, we maintain that our findings and recommendations remain valid. We believe that updated regulations are necessary to clarify guidance related to phlebotomy travel allowances.

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INTRODUCTION

WHY WE DID THIS AUDIT

Medicare pays a specimen collection fee when it is medically necessary for a clinical laboratory technician or other trained personnel (collectively called technicians in this report) to draw a specimen for a clinical diagnostic laboratory test.[1] In addition, when a technician travels to a nursing home or to a homebound patient's residence for phlebotomy services or to collect a specimen via catheterization, Medicare pays a travel allowance (collectively called phlebotomy travel allowances in this report) to cover transportation and personnel expenses.[2, 3]

Prior Office of Inspector General (OIG) work identified instances in which phlebotomy travel allowances were overpaid because clinical laboratories (providers) claimed travel mileage exceeding the actual miles traveled.[4] Subsequently, we conducted two audits of Medicare administrative contractors (MACs) that focused on phlebotomy travel allowance payments for clinical diagnostic laboratory tests performed from January 1, 2015, through December 31, 2016.[5] In addition to identifying Medicare payments that did not comply with Federal requirements, these audits identified (1) unclear or conflicting Centers for Medicare & Medicaid Services (CMS) guidance to providers related to phlebotomy travel allowances and (2) the need for MACs to educate providers on their responsibilities related to claiming phlebotomy travel allowances.[6] This audit summarizes the findings and recommendations from the two previous audits of MACs and evaluates CMS's current guidance on phlebotomy travel allowances.[7]

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[1] Section 1833(h)(3)(A) of the Social Security Act (the Act) and 42 U.S.C. § 1395l(h)(3)(A). See also chapter 16, § 60.1.2, of the *Medicare Claims Processing Manual* (the Manual).

[2] Phlebotomy is the collection of venous blood by venipuncture.

[3] The Act § 1833(h)(3)(B).

[4] Prior work includes OIG investigations and an audit associated with a report titled *Professional Clinical Laboratory, Inc., Generally Did Not Comply With Medicare Requirements For Billing Phlebotomy Travel Allowances* (A-06-16-02002), October 2018. Available online at https://oig.hhs.gov/oas/reports/region6/61602002.asp.

[5] A MAC is a private health care insurer to which CMS has awarded a contract to process medical claims for Medicare fee-for-service beneficiaries and to service providers, including clinical laboratories in a specified geographic jurisdiction.

[6] *Wisconsin Physicians Service Needs Enhanced Guidance and Provider Education Related to Phlebotomy Travel Allowances* (A-06-17-04005), September 2019, and *Novitas Solutions, Inc., Needs Enhanced Guidance and Provider Education Related to Phlebotomy Travel Allowances* (A-06-17-04002), December 2019.

[7] CMS is responsible for providing guidance to providers. Because this audit report contains recommendations to CMS, our focus here is on current CMS guidance.

OBJECTIVES

Our objectives were to (1) summarize the results of our previous two audits that identified instances in which payments made by two MACs to providers for phlebotomy travel allowances for clinical diagnostic laboratory tests did not always comply with Medicare guidance and (2) review CMS guidance related to phlebotomy travel allowances to determine whether there have been any updates.[8]

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. CMS administers the Medicare program. Part B of the Medicare program provides supplementary insurance for medical and other health services, including laboratory services. CMS contracts with MACs to process and pay claims submitted by providers. CMS provides education and guidance to MACs and Medicare providers through various methods, including Quarterly Provider Updates, Change Requests, Medicare Learning Network (MLN) Matters Articles, and on its website.

Federal Guidance

A provider may claim a phlebotomy travel allowance to collect a sample from a nursing home or homebound patient's residence only when a specimen collection fee is also payable.[9] A specimen collection fee is payable for specimens extracted by a technician, such as a blood sample drawn through venipuncture or a urine sample drawn by catheterization.[10] No fee is allowed for samples for which the cost of collection is minimal, such as throat cultures, blood draws by capillary puncture, urine collection absent catheterization, or simply transporting a sample not drawn or collected by the technician (referred to as a "pickup" throughout this report).

[8] The previous audits of the two MACs included recommendations specific to the MACs and not to CMS. Therefore, we did not review CMS actions on those MAC-specific recommendations in this audit.

[9] The Act § 1833(h)(3).

[10] CMS told us that a specimen may refer to blood, urine, or micro. A micro, such as a culture swab or stool specimen, is collected and tested by the clinical laboratory's microbiology department.

The phlebotomy travel allowance is based on the actual distance traveled to each nursing home or residence on a route until the specimen draws or pickups[11] are dropped off at a clinical laboratory, a reference laboratory, or other drop location (referred to as a "trip" throughout this report).[12]

Phlebotomy Travel Allowance Calculation

There are two Healthcare Common Procedure Coding System (HCPCS) codes used for phlebotomy travel allowances: P9603 and P9604.[13] P9603 is used when the average round trip to a patient's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. P9604 is used when the average round trip is less than or equal to 20 miles, paid on a flat rate per trip basis. In our previous audits, we reviewed only those claims with HCPCS code P9603 because prior OIG work identified errors in the calculation of the mileage travel allowance with this code.[14]

Under either code, when one trip is made for specimen draws or pickups from multiple patients (e.g., at a nursing home), the travel payment component is prorated based on the number of Medicare and non-Medicare patients on that trip (the Manual, chapter 16, § 60.2). All draws and pickups are included in the proration, and the prorated phlebotomy travel allowance is billed on behalf of each Medicare patient.

We had several discussions with CMS officials during our previous audits, and they acknowledged that the phlebotomy travel allowance calculation guidance was unclear, conflicting, and lacking in some instances.

Also, CMS agreed that guidance is conflicting on whether to prorate based on the number of patients or on the number of specimens. According to the Manual, chapter 16, section 60.2, carriers[15] must prorate phlebotomy travel allowance amounts claimed by providers based on the number of patients (including Medicare and non-Medicare patients) from whom specimen draws or pickups were made on the same trip. However, a CMS Recurring Update Notification

[11] A draw is either a blood sample taken by venipuncture or a urine sample by catheterization. A pickup is simply the transporting of a sample not drawn or collected by the technician. A specimen collection fee is not payable for pickup services.

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

[13] HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services to ensure that these claims are processed in an orderly and consistent manner.

[14] These were errors such as "documentation did not support prorated miles," "difference due to change in fee schedule," and "no documentation to support specimen collection."

[15] Carriers predated MACs as entities that processed and paid Medicare Part B claims.

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 . . . ."[16] CMS officials told us that the policy is intended to determine Medicare's portion of the phlebotomy travel allowance by dividing the total miles traveled by the total number of patients (Medicare and non-Medicare).[17]

Therefore, on the basis of our conversations with CMS, we determined that for the purpose of this audit the prorated mileage for claims including P9603 should be calculated as follows:

- The numerator is the sum of all miles driven by a technician to all nursing homes 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 pickups on a trip.[18]

The result is the prorated phlebotomy travel allowance mileage per patient. To calculate the total Medicare phlebotomy travel allowance, this amount is then multiplied by a mileage reimbursement rate set by CMS each year. The reimbursement rates are announced through Change Request transmittals from CMS, which, during our audit period, were sometimes released after the start of a new calendar year but were always effective as of January 1 of that year.[19] Providers are responsible for ensuring that their claims are processed using the correct reimbursement rate; they should bring to their MAC's attention any claims paid using an incorrect rate.

According to the Manual, at no time is the provider allowed to bill for more miles than are reasonable or for miles not actually traveled by the technician. During our discussions with CMS officials, they stated that mileage to a location without any specimens collected should not be included when calculating the prorated mileage; however, there is no clear guidance from CMS on how to calculate the total miles when a trip includes multiple locations and one or more of the locations does not have any specimens collected.

[16] See Change Request 8641.

[17] On the basis of our conversations with CMS staff, we performed travel allowance calculations for a trip based on the total number of patients, both Medicare and non-Medicare, with specimen draws or pickups.

[18] We based our calculations on the clarification CMS provided during the prior audits of the two MACs.

[19] CMS released calendar year 2014 rates on March 14, 2014 (Change Request 8641); calendar year 2015 rates on January 23, 2015 (Change Request 9066); and calendar year 2016 rates on December 31, 2015 (Change Request 9485).

Proposed Regulation

In 1993, CMS proposed a rule that would have clarified some of the guidance. This rule, which was never finalized, would have codified in regulation that providers prorate all phlebotomy travel allowances by the number of patients served rather than the total number of draws.[20] Specifically, CMS proposed that "[p]ayment is prorated by the number of patients served, both Medicare and non-Medicare, and both patients from whom specimens are drawn and patients for whom specimens are only transported."

HOW WE CONDUCTED THIS AUDIT

During our previous audits of 2 MACs, our sample frames included 753,410 paid claim lines for HCPCS P9603 totaling $16.4 million that were paid between January 1, 2015, and December 31, 2016, by the 2 MACs for Medicare Part B phlebotomy travel allowances. Each claim line represented a Medicare phlebotomy travel allowance. We selected from each of the 2 MACs a stratified random sample of 120 paid claim lines that were each part of a trip. We summarized the results of those audits for this report. To address our second objective, we reviewed relevant Federal guidance governing phlebotomy travel allowances and spoke with CMS in June 2020 to determine whether it had taken steps to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances following the previous audits.

In the 2 audits of the MACs, we obtained documentation from 24 providers associated with 202 of the 240 paid claim lines in our samples. The remaining 38 paid claim lines were associated with 8 providers that could not be contacted because they no longer operated; therefore, we were unable to review these claim lines. We treated the 38 paid claim lines as non-errors.

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.

[20] 58 Fed. Reg. 43832 (Aug. 18, 1993). Specifically, the rule proposed at 42 CFR § 414.366(b) stated that:

> (b) Payment for travel allowances. Payment of a travel allowance is made if it is necessary for trained personnel to travel to the location of a homebound or nursing facility patient in order to collect a specimen.
>
> > (1) Payment is prorated by the number of patients served, both Medicare and non-Medicare and both patients from whom specimens are drawn and patients for whom specimens are only transported.

FINDINGS

In our two previous audits of MAC payments for phlebotomy travel allowances, we determined that the two MACs paid providers for phlebotomy travel allowances that did not comply with Medicare guidance. Specifically, 93 of the 202 sampled paid claim lines we reviewed complied with Medicare guidance, but 109 paid claim lines did not. (Some lines did not comply for more than one reason.) Errors identified in those audits were related to incorrect prorated mileage, incorrect payment rates, and inadequate documentation. On the basis of the sample results, we estimated that the 2 MACs paid providers a combined $2.7 million[21] in phlebotomy travel allowance payments that were not in accordance with Medicare guidance.

We spoke with CMS in June 2020 and, at that time, it had not begun the notice and comment rulemaking process necessary to clarify provider requirements related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance.

SUMMARY OF RESULTS OF PREVIOUS AUDITS OF MEDICARE ADMINISTRATIVE CONTRACTORS

Our two previous audits of MAC payments for phlebotomy travel allowances found the following:

- claims for phlebotomy travel allowances were paid using incorrect prorated mileage,
- claims for phlebotomy travel allowances were paid using incorrect payment rates, and
- provider documentation was insufficient to warrant payment of the phlebotomy travel allowances.

Of the 202 sampled paid claim lines, 76 were improperly paid because providers claimed incorrect prorated mileage. In some instances, this occurred because providers associated with claims in our samples calculated the prorated mileage using the number of specimens or blood draws on a trip, not the total number of patients with specimens collected.[22] In other instances, providers claimed incorrect prorated mileage because the technician included mileage to locations without any specimens collected or because the technician included mileage related to personal business. While reviewing the prorated mileage criteria, we identified areas where CMS's phlebotomy travel allowance calculation guidance was unclear, conflicting, and lacking.

In addition, 22 of the 202 sampled paid claim lines were paid using incorrect payment rates. Payment for the phlebotomy travel allowance is made based on the clinical laboratory fee

[21] The actual amount was $2,726,431.

[22] What constituted a specimen was never defined in the guidance, so we asked CMS what should be considered a specimen. See footnote 10.

schedule. The CMS Change Requests revising the payment rate for phlebotomy travel allowances were released annually (sometimes several weeks after the start of the year), with an effective date of January 1 of each year.[23] Claims for phlebotomy travel allowances paid using the payment rate for the previous year are not automatically adjusted. Providers are responsible for ensuring that their claims are processed using the correct reimbursement rate; they should bring to their MAC's attention any claims paid using an incorrect rate.

Finally, for 19 of the 202 sampled paid claim lines, the providers did not provide us with sufficient documentation. Without sufficient documentation, we were unable to determine whether the correct prorated mileage was submitted to the MACs and paid.

On the basis of our sample results, we estimated that the 2 MACs paid providers a combined $2.7 million in phlebotomy travel allowance payments that were not in accordance with Medicare guidance.

Following are the recommendations we made to the two MACs and a brief description of the MACs' responses to those recommendations:

- The MACs should work with CMS to clarify guidance to providers, which could have resulted in savings totaling an estimated $2,726,431 during the audit periods.

    - One MAC concurred and pointed us to a CMS MLN Matters article that clarified the requirements for providers billing specimen collection services provided to Medicare beneficiaries.

    - One MAC did not indicate concurrence or nonconcurrence but stated that before and during development of its education, it would work with CMS, as needed, to clarify any guidance.

- The MACs should educate providers on how to correctly calculate the prorated mileage for phlebotomy travel allowance payments.

    - One MAC concurred and has a laboratory specialty page available to providers providing a consolidated resource center for laboratory-related resources.

    - One MAC did not indicate concurrence or nonconcurrence but stated that it would develop education that includes information on how to calculate the prorated mileage for phlebotomy travel allowance payments.

- The MACs should educate providers on their responsibility to bring any previously paid claims to their MAC's attention if they were paid using the wrong rate.

[23] Change Requests 8641, 9066, and 9485.

- One MAC concurred and had already started educating providers on how to send in claim corrections if providers billed these claims in error.

- One MAC did not indicate concurrence or nonconcurrence but stated that it would develop education that advised providers on their responsibility to bring any previously paid claims to their MAC's attention if they were paid the wrong rate.

- The MACs should educate providers on their responsibility to maintain adequate documentation to support phlebotomy travel allowance payments.

    - One MAC concurred and had already started educating providers on what to include in their documentation.

    - One MAC did not indicate concurrence or nonconcurrence but stated that it would develop education that advised providers of their responsibility to maintain adequate documentation to support phlebotomy travel allowance payments.

CMS HAS NOT TAKEN STEPS TO CLARIFY HOW PROVIDERS MUST PRORATE PHLEBOTOMY TRAVEL ALLOWANCES

We had several discussions with CMS officials during this audit and our previous MAC audits, and they acknowledged that the phlebotomy travel allowance calculation guidance was unclear, conflicting, and lacking. As of June 2020, CMS had not begun the notice and comment rulemaking process necessary to clarify provider requirements related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance. We identified the following problems with CMS's guidance:

- the guidance was unclear regarding which pickups or draws to include in the prorated calculation,

- certain guidance conflicted with other guidance regarding whether to base the proration on the number of patients or on the number of specimens related to a trip, and

- guidance did not explain what mileage could be included in the prorated calculation.

Unclear Guidance Regarding Which Pickups or Draws To Include in the Prorated Calculation

CMS transmittals regarding prorated mileage were unclear as to whether specimen collections refer only to specimens that are drawn by a technician or whether they include specimens that are drawn by another individual and are merely being picked up by a technician. A phlebotomy travel allowance is allowed only when a specimen collection fee is payable (the Manual, chapter

16, § 60.2), and a specimen collection fee is payable only for specimens extracted by a technician, such as a blood sample drawn through venipuncture or a urine sample drawn by catheterization (the Manual, chapter 16, § 60.1.2). However, there is no mention of which specimens to consider when calculating prorated mileage. CMS officials told us that for purposes of calculating the prorated mileage, specimen collections were to include all draws and pickups, regardless of collection method. This interpretation is consistent with the 1993 proposed regulation that states that "payment is prorated . . . for patients from whom specimens are drawn and patients for whom specimens are only transported."

Conflicting Guidance Regarding Whether To Base the Proration on the Number of Patients or the Number of Specimens

CMS's guidance is conflicting on whether mileage should be prorated based on the number of patients or the number of specimens. According to the Manual, carriers must prorate phlebotomy travel allowance amounts claimed by providers by the number of patients (including Medicare and non-Medicare patients) from whom specimen draws or pickups were made on the same trip (chapter 16 § 60.2).[24] However, 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 officials told us during the two MAC audits that the policy is intended to determine Medicare's portion of the phlebotomy travel allowance by dividing the total miles traveled by the total number of patients (Medicare and non-Medicare). This is consistent with the regulation proposed in 1993, which states that "[p]ayment is prorated by the number of patients served, both Medicare and non-Medicare . . . ."

Lack of Guidance Regarding What Mileage To Include in the Prorated Calculation

CMS guidance states that laboratories are not allowed to bill for more miles than are reasonable or for miles not actually traveled by a technician. CMS officials told us that mileage to a location without any specimens collected should not be included when calculating the prorated mileage. However, there is no guidance from CMS on how to calculate the total miles when a trip includes multiple locations and no specimens were collected at one or more of the locations. Specific areas where we saw differences in how providers billed included:

- how they accounted for mileage related to stops that did not involve specimen pickups or draws and

- how they accounted for personal miles (i.e., when to start or stop counting mileage) in their proration calculations.

CONCLUSION

[24] Although the Manual states that carriers must prorate phlebotomy travel allowance amounts, this step is performed by the providers.

CMS has issued guidance for the MACs and providers to follow; however, this guidance is unclear or conflicting, and there is no guidance on how to account for mileage that is unrelated to specimen collection.[25] Had CMS finalized the 1993 proposed rule, it would have addressed and resolved some of these issues. Because the proposed rule was never finalized, and no other guidance has been issued to address the unclear, conflicting, and lacking guidance, MACs may continue to pay millions of dollars in potentially unallowable phlebotomy travel allowances.

We spoke with CMS in June 2020 and, at that time, it had not begun the notice and comment rulemaking process necessary to clarify provider requirements related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- work with the MACs to educate providers about the documentation requirements for phlebotomy travel allowances;

- instruct the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate;

- issue regulations related to phlebotomy travel allowances clarifying:

    - whether specimen collections refer only to specimens that were drawn by a technician or whether it includes all specimens that were drawn by another individual and were merely picked up by a technician;

    - whether a specimen includes blood, urine, and micros;

    - whether to prorate based on the number of patients or on the number of specimens;

    - how to calculate mileage when a location is included without any specimens collected; and

    - how to calculate mileage when personal miles are included (i.e., when to start or stop counting mileage) in their proration calculations.

[25] This CMS guidance includes the Manual, Transmittals, and Change Requests.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first two recommendations. For our third recommendation, CMS stated that the clarifications that we proposed regarding how providers must prorate phlebotomy travel allowances will need to go through notice and comment rulemaking. Also, as part of the calendar year 2022 Physician Fee Schedule Proposed Rule, CMS solicited comments related to the policies for specimen collection fees and the travel allowance, as well as the methodology for calculating the travel allowance. CMS stated that it will consider comments received, along with our third recommendation, when determining appropriate next steps for phlebotomy travel allowances.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix B.

After reviewing CMS's comments, and their technical comments, we maintain that our findings and recommendations remain valid. We believe that updated regulations are necessary to clarify guidance related to phlebotomy travel allowances.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our previous audits of 2 MACs, our sample frames included 753,410 paid claim lines for HCPCS P9603 totaling $16.4 million that were paid between January 1, 2015, and December 31, 2016, by the 2 MACs for Medicare Part B phlebotomy travel allowances. We audited only those claim lines that included HCPCS code P9603 because prior OIG work found errors in the calculation of the prorated mileage phlebotomy travel allowance for claims with this code. We obtained the claim data from the CMS National Claims History file. We selected from each MAC a stratified random sample of 120 phlebotomy travel allowance paid claim lines to review. To address our first objective, we summarized the results of those audits.

To address our second objective, we reviewed relevant Federal guidance governing phlebotomy travel allowances. We also spoke with CMS in June 2020 to determine whether it had taken steps to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances following the previous audits.

We determined that the control activities component of internal control was significant to these objectives, along with the underlying principles that management should design control activities to achieve objectives and respond to risks, and that management should implement control activities through policies. Specifically, we interviewed officials at CMS regarding how CMS developed and applied guidance for phlebotomy travel allowance.

We performed our audit work from November 2019 through May 2021.

METHODOLOGY

To accomplish our objectives, we summarized the results of our previous two MAC audits and met with CMS to discuss Federal guidance related to phlebotomy travel allowances.

To accomplish our objectives for the two previous MAC audits, we:

- reviewed applicable Federal laws, regulations, and guidance;

- interviewed CMS officials to gain a better understanding of Medicare requirements for phlebotomy travel allowances and to obtain their interpretation of the Medicare guidance related to phlebotomy travel allowances;

- interviewed officials from both MACs to gain an understanding of their policies and procedures related to how they process and pay for phlebotomy travel allowances;

- obtained data from CMS's National Claims History file of both MACs' phlebotomy travel allowance claims (HCPCS code P9603) and extracted from CMS's National Claims History

file 2 sampling frames totaling 753,410 Medicare Part B phlebotomy travel allowance claim lines, totaling $16.4 million, paid by the 2 MACs from January 1, 2015, through December 31, 2016;

- selected from each MAC a statistical sample of 120 phlebotomy travel allowance paid claim lines for review;

- sent a letter to each provider that we could contact associated with 202 paid claim lines from our samples to request documentation (e.g., mileage logs, requisition orders) to support each claim line in our samples (the remaining 38 paid claim lines came from 8 providers that are no longer in operation and we were unable to contact, so we were unable to review these claim lines);

- evaluated the documentation obtained from providers that we could contact for each sample claim line to determine how many miles were traveled and how many patients were served during each trip;

- calculated what the phlebotomy travel allowance should have been for 202 sample paid claim lines according to Medicare requirements and compared it with the actual amount paid and noted any differences;

- estimated the overpayment of all paid claim lines in our 2 sampling frames during our audit period;

- discussed the results of our audit with each provider that supplied documentation; and

- discussed the results of our audits with officials from both MACs.

To accomplish our objective to review CMS guidance related to phlebotomy travel allowances, we:

- reviewed applicable Federal laws, regulations, and guidance;

- spoke with CMS in June 2020 to determine whether it had taken steps to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances following the previous audits; and

- discussed the results of our audit with CMS officials.

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

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 16, 2021

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances (A-06-20-04000)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to providing Medicare beneficiaries with high quality health care while protecting taxpayer dollars.

Section 1833(h)(3)(B) of the Social Security Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility other than a hospital. In accordance with this provision, CMS established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. Under current guidance, the travel allowance is intended to cover the estimated travel costs of collecting a specimen and reflect the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable, such as a blood sample drawn through venipuncture or a urine sample drawn by catheterization, and is not available if the technician is merely performing a messenger service to obtain a specimen drawn by a physician or nursing home personnel. The methodology for determining the travel allowance depends on the round trip mileage to patients' homes. More specifically, a per mile travel allowance methodology applies when the round trip to a patients' home is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip is less than 20 miles.

CMS continues to consider updates to payment policies to improve payment for laboratory specimen collection for clinical diagnostic laboratory tests. For example, to reduce administrative burden on health care providers, in the interim final rule with comment period (IFC) titled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (March 2020 IFC) CMS clarified that laboratories could use electronic travel logs rather than paper logs, if preferred, when documenting their travel.[1] In July 2021, CMS announced via the Calendar Year (CY) 2022 Physician Fee Schedule Proposed Rule that this operational guidance on use of electronic travel logs would be made a permanent option. CMS also solicited comments regarding the general policies for specimen collection fees and the travel allowance to aide in our consideration of updating these policies in the future through notice and comment rulemaking.[2]

[1] https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf
[2] https://public-inspection.federalregister.gov/2021-14973.pdf

CMS appreciates OIG's review in this area and looks forward to working collaboratively on this and other issues in the future.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services work with the MACs to educate providers about the documentation requirements for phlebotomy travel allowances.

CMS Response

CMS concurs with this recommendation and will work with the MACs to educate providers on documentation requirements. As stated above, CMS recently announced that laboratories could use electronic travel logs rather than paper logs, if preferred, when documenting their travel. CMS will work with the MACs to determine what documentation would assist them and provide guidance in future instructions via forthcoming Change Requests and other materials such as Medicare Learning Network Matters Articles.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services instruct the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate.

CMS Response

CMS concurs with this recommendation. CMS will instruct the Medicare Administrative Contractors to identify and adjust any paid claims that incorrectly used the previous year's rate.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services issue regulations related to phlebotomy travel allowances clarifying:

- whether specimen collections refer only to specimens that were drawn by a technician or whether it includes all specimens that were drawn by another individual and were merely picked up by a technician;
- whether a specimen includes blood, urine, and micros;
- whether to prorate based on the number of patients or on the number of specimens;
- how to calculate mileage when a location is included without any specimens collected; and
- how to calculate mileage when personal miles are included (i.e., when to start or stop counting mileage) in their proration calculations.

CMS Response

Clarifications such as these require notice and comment rulemaking. As part of the CY 2022 Physician Fee Schedule Proposed Rule, CMS solicited comments related to the policies for specimen collection fees and the travel allowance, as well as the methodology for calculating the travel allowance, including calculation of mileage specific to per mile or flat rate and proration when there are multiple patients or specimens. CMS will consider comments received, along with this recommendation, when determining appropriate next steps for phlebotomy travel allowances.