Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

MEDICARE PAID INDEPENDENT ORGAN PROCUREMENT ORGANIZATIONS OVER HALF A MILLION DOLLARS FOR PROFESSIONAL AND PUBLIC EDUCATION OVERHEAD COSTS THAT DID NOT MEET MEDICARE REQUIREMENTS

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



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> August 2023 A-09-21-03020

Office of Inspector General

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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. Date: August 2023 Report No. A-09-21-03020

OFFICE OF INSPECTOR GENERAL



Organ procurement organizations (OPOs) perform or coordinate the procurement and preservation of organs, such as kidneys, as well as transportation of organs to hospitals for transplantation into patients on a waiting list to receive a transplant. Prior OIG audits found that two independent OPOs in California did not comply with Medicare requirements for reporting overhead costs as well as administrative and general costs. Specifically, professional and public education overhead costs accounted for 44 percent and 65 percent of the total amount questioned in each report, respectively. We conducted this nationwide audit to determine whether the issues identified in the two prior OIG audits were occurring at independent OPOs nationwide.

Our objective was to determine whether independent OPOs' professional and public education overhead costs met Medicare requirements.

How OIG Did This Audit

Our audit covered \$101.6 million of professional and public education overhead costs (with Medicare payments of \$50.9 million) reported in the 50 independent OPOs' most recently finalized Medicare cost reports with FY end dates from May 31, 2015, through June 30, 2019 (audit period). Our audit covered costs from only 1 FY for each OPO. We randomly sampled for review 30 professional and public education overhead costs from each of the 10 randomly selected OPOs (300 sampled costs totaling \$294,692). Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements

What OIG Found

Not all professional and public education overhead costs reported by independent OPOs met Medicare requirements. Of the 300 sampled professional and public education overhead costs, 264 costs met Medicare requirements. The remaining 36 costs, totaling \$15,852 (with Medicare payments of \$6,423), did not meet Medicare requirements and were therefore unallowable. Furthermore, while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we determined that OPOs reported an additional \$132,898 of unallowable professional and public education overhead costs (with Medicare payments of \$65,785).

On the basis of our sample results and additional findings we identified during our reconciliation, we estimated that \$664,295 (consisting of an estimated \$598,510 based on our sample results and \$65,785 for our reconciliation findings) of the \$50.9 million paid for professional and public education overhead costs was unallowable. The OPOs reported unallowable costs because: (1) they misunderstood Medicare requirements and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements.

What OIG Recommends and CMS Comments

We recommend that CMS: (1) instruct the Medicare administrative contractor (MAC) to recover \$72,208 in unallowable Medicare payments by adjusting the applicable OPOs' Medicare cost reports to correct the \$148,750 of unallowable professional and public education overhead costs reported, consistent with relevant laws and the agency's policies and procedures; and (2) update applicable Medicare requirements to clarify which types of professional and public education overhead costs are unallowable, which could have saved Medicare an estimated \$664,295 for professional and public education overhead costs.

CMS concurred with our recommendations and described corrective actions it planned to take. CMS stated that: (1) it will instruct the MAC to recover unallowable payments from the applicable OPOs in accordance with the agency's policies and procedures and (2) it is reviewing its regulations and guidance and will make updates, as needed, to ensure that OPOs have the tools they need to determine allowable costs for reporting purposes.

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INTRODUCTION

WHY WE DID THIS AUDIT

Organ procurement organizations (OPOs) are not-for-profit organizations that perform or coordinate the procurement and preservation of organs, such as kidneys, as well as transportation of organs to hospitals for transplantation into patients who are on a waiting list to receive a transplant. Prior Office of Inspector General (OIG) audits found that two independent OPOs in California did not comply with Medicare requirements for reporting overhead costs as well as administrative and general costs.¹ Specifically, professional and public education overhead costs accounted for 44 percent and 65 percent of the total amount questioned in each report, respectively. We conducted this nationwide audit to determine whether the issues identified in the two prior OIG audits were occurring at independent OPOs nationwide from May 31, 2015, through June 30, 2019 (audit period).²

OBJECTIVE

Our objective was to determine whether independent OPOs' professional and public education overhead costs met Medicare requirements.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance for people aged 65 or older, people under the age of 65 with certain disabilities, and people of all ages with end-stage renal disease, which is permanent kidney failure requiring dialysis or a kidney transplant (Title XVIII of the Social Security Act (the Act)). Section 1881 of the Act authorizes Medicare Part A reimbursement for procurement and transplantation of kidneys. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

CMS contracts with Medicare administrative contractors (MACs) to, among other things, handle provider reimbursement services, conduct audits, and safeguard against fraud and abuse. As of the time of our audit, Palmetto GBA (Palmetto) was the only MAC contracted to review independent OPOs' Medicare cost reports and determine amounts due to or from independent OPOs.

¹ Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs (<u>A-09-08-00033</u>), issued Jan. 21, 2010; and Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs (<u>A-09-09-00087</u>), issued Oct. 1, 2010. See Appendix B for a list of related OIG reports on OPOs.

² The OPOs had varying fiscal year (FY) end dates. Our audit covered costs from only 1 FY for each OPO.

Organ Procurement Organizations

OPOs are not-for-profit organizations that perform or coordinate the procurement and preservation of organs, as well as the transportation of organs to hospitals for transplantation into patients who are on a waiting list to receive a transplant. Other specific OPO responsibilities include identifying potential organ donors, requesting consent from and providing support to families of donors, and working with other agencies to identify potential transplant recipients. OPOs also provide education on organ donation and transplantation to hospital personnel, physicians, and the public.

CMS certifies OPOs to recover or procure organs. Section 1138 of the Act and 42 U.S.C. section 273 provide the statutory qualifications and requirements that an OPO must meet to be reimbursed under Medicare. Qualified OPOs have an agreement with the Secretary of Health and Human Services to be reimbursed under Title XVIII of the Act for the procurement of kidneys.

An OPO may be independent or hospital-based:

- An independent OPO is a freestanding organization that files a Medicare cost report separately from a hospital and is not subject to the control of any hospital. Independent OPOs work closely with donor hospitals (i.e., hospitals where organs were retrieved) and transplant centers to facilitate organ donation and transplantation.
- A hospital-based OPO is considered a department of the transplant hospital and reports organ acquisition costs it incurs on the transplant hospital's Medicare cost report.

As of January 1, 2023, there were 56 OPOs (49 independent and 7 hospital-based). Each OPO is assigned to its own donation service area.

Medicare Cost Reports and Reimbursement of Independent Organ Procurement Organizations

Medicare does not reimburse independent OPOs for the costs of procuring organs other than kidneys. Organ procurement overhead costs, such as professional and public education costs, are allocated to kidneys on the basis of the total number of organs procured.³ CMS requires independent OPOs to submit Medicare cost reports (Form CMS-216-94) to the MAC annually to determine the amounts payable under Medicare associated with procurement of kidneys (42 CFR §§ 413.420 and 413.20(b)).⁴ As of the time of our audit, Palmetto was the only MAC that reviewed the Medicare cost reports submitted by independent OPOs. Generally, cost

³ Organ procurement overhead costs are referred to as "organ acquisition overhead costs" in the Medicare cost report.

⁴ During our audit period, the relevant requirements were found at 42 CFR § 413.200, which were moved to 42 CFR § 413.420, effective Feb. 25, 2022.

reports from independent OPOs are due on or before the last day of the fifth month following the close of the period covered by the cost report. OPOs have varying fiscal year (FY) end dates (Medicare cost-reporting periods). An OPO's Medicare cost report is considered finalized (settled) when Palmetto completes its review of the cost report and furnishes a written notice to the OPO reflecting the contractor's final determination of the total amount of reimbursement. The year of the most recently finalized cost report may be different for each OPO depending on when Palmetto completes its review.⁵

Independent OPOs do not bill Medicare directly for organ procurement services. Independent OPOs are paid for procuring kidneys and other organs, generally by transplant hospitals, which pay the OPOs' standard acquisition charges for those organs. Using the independent OPOs' cost reports, CMS makes retroactive settlements for kidneys for Medicare enrollees directly with the OPOs to reconcile any overpayments or underpayments resulting from the total payments that these OPOs received from the transplant hospitals for kidneys; however, there are no such settlements for nonkidney (nonrenal) organs (42 CFR § 413.420).

The cost report, which is divided into multiple worksheets, summarizes an OPO's financial records and organ statistics data (such as the number of kidneys and other organs procured) to determine the Medicare reimbursable amount for kidney acquisition. An independent OPO's Medicare cost report includes direct costs, administrative and general costs, and overhead costs associated with procuring organs.

Organ procurement overhead costs include costs for professional education and public education (which we refer to as "education overhead costs" in this report):

- *Professional education costs* are expenses associated with the education of donor hospital personnel and physicians and include the expenses of meetings, seminars, slide shows, and presentations.
- *Public education costs* are expenses associated with organizing awareness programs designed to inform the general public of the need for organs and organ transplant services.

Using information from their accounting records, OPOs record their expenses on Worksheet A of the Medicare cost report, where the expenses (i.e., costs) are grouped into cost categories, called cost centers, based on the type of costs (e.g., professional or public education overhead costs). Each cost center is reported as a line on Worksheet A. (See Appendix C for an example of Worksheet A in the OPOs' Medicare cost report.)

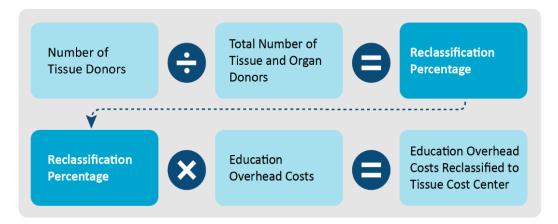
⁵ For example, in 2021, Palmetto had completed its reviews and finalized Medicare cost reports with FY end dates in 2019 for some OPOs, but for other OPOs, Palmetto had finalized Medicare cost reports with FY end dates before 2019.

To properly allocate costs between Medicare reimbursable costs (i.e., costs associated with kidneys) and nonreimbursable costs, OPOs record adjustments and reclassifications on Worksheet A:

- *Adjustments* are reductions or increases to costs within cost centers. For example, an OPO may remove unallowable costs from a certain cost center by making an adjustment (i.e., by reducing the amount in a cost center).
- Reclassifications are the reallocation of costs from one cost center to another. For example, an OPO may reclassify education overhead costs related to tissue recovery by reallocating a percentage of those costs to the nonreimbursable cost center on Worksheet A.⁶ The OPO calculates the reclassification percentage, which is generally the ratio of the number of tissue donors to the total number of tissue and organ donors.⁷

The figure shows how the reclassification percentage is calculated and how the percentage is used to determine the amount of education overhead costs that should be reallocated to the nonreimbursable tissue cost center.

Figure: Determining the Amount of Professional and Public Education Overhead Costs Related to the Tissue Cost Center Using the Reclassification Percentage



⁶ In addition to procuring organs, OPOs coordinate the recovery of tissue for transplant, such as skin, cornea, bone, heart valves, and the pancreas islet.

⁷ Because recovery of tissues is less time-consuming than recovery of organs, tissue donors are counted using a 10-to-1 ratio, in which every 10 tissue donors are counted as 1 organ donor. For example, if an OPO has 500 tissue donors and 100 organ donors, the reclassification percentage is calculated as follows: 50 tissue donors divided by 150 total tissue and organ donors.

Medicare Requirements and Guidance for Costs That Organ Procurement Organizations Report in the Medicare Cost Report

Independent OPOs must follow Medicare laws and regulations to ensure that costs reported in the Medicare cost report are supported, reasonable, and related to patient care.

The reasonable cost of any services shall be the cost actually incurred, excluding costs found to be unnecessary in the efficient delivery of needed health services. Reasonable costs do not include costs for entertainment (including tickets to sporting and other entertainment events) or costs for gifts and donations (the Act §§ 1861(v)(1)(A) and (v)(8)).

The Medicare cost report must provide a complete accounting of costs that an OPO incurs in providing covered services, the total number of Medicare enrollees who received those services, and any other data necessary to enable the MAC to determine the reasonable cost of covered services provided to Medicare enrollees (42 CFR § 413.420(e)).

Payments to OPOs must be based on costs related to patient care and must be reasonable and allowable (42 CFR § 413.402). Reasonable costs include all necessary and proper costs incurred (42 CFR §§ 413.9(a), (b), and (c)(3)). In addition, an OPO's cost information must be accurate and in sufficient detail to support payments made for services provided (42 CFR §§ 413.24(a) and (c)).

CMS's *Provider Reimbursement Manual* (the Manual), Pub. No. 15-1, part 1, chapter 21, describes costs that are not related to patient care (i.e., nonreimbursable costs) and applies to various types of providers. Costs not related to patient care are costs that are not appropriate or necessary and proper in developing and maintaining the operation of patient care facilities and activities (the Manual, part 1, § 2102.3). The Manual, Pub. No. 15-1, part 1, chapter 31, explains how Medicare reimburses for organ acquisition costs of covered transplants. The Manual, Pub. No. 15-2, part 2, chapter 33, provides instructions specific to OPOs for completing the Medicare cost report. CMS stated that these Manual provisions are interpretive of the longstanding reasonable cost principles found in the statute and regulations.⁸

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$101.6 million of professional and public education overhead costs (with Medicare payments of \$50.9 million) reported in the 50 independent OPOs' most recently

⁸ The statute and regulations include the Act § 1861(v)(1)(A) and 42 CFR §§ 413.5 and 413.9. CMS also noted that there is an administrative appeals process for resolving cost report disputes.

finalized Medicare cost reports as of August 13, 2021.^{9, 10} The finalized cost reports had FY end dates from May 31, 2015, through June 30, 2019.¹¹

We used a multistage random sample for this audit:

- For the first stage of our random sample, we randomly selected 10 of the 50 independent OPOs operating at the start of our audit. Next, we reconciled the 10 OPOs' general ledgers (i.e., accounting records) with the OPOs' finalized Medicare cost reports, with FY end dates ranging from June 30, 2017, to December 31, 2018. While reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we identified unallowable education overhead costs. We reviewed these costs separately and did not include them for possible selection in our random sample.
- For the second stage of our random sample, we randomly selected for review 30 general ledger transactions for education overhead costs from each of the 10 OPOs selected in the first stage. The 300 sampled costs totaled \$294,692, with Medicare payments of \$124,661.^{12, 13}

We reviewed supporting documentation (such as invoices, receipts, and employee expense reports that the 10 sampled OPOs provided) to determine whether the sampled education overhead costs met Medicare requirements and to confirm the findings we identified while reconciling the OPOs' general ledgers with their cost reports.

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.

¹¹ The 50 independent OPOs had varying FY end dates. An OPO with an FY ended May 31, 2015, reported costs incurred from June 1, 2014, through May 31, 2015. An OPO with an FY ended June 30, 2019, reported costs incurred from July 1, 2018, through June 30, 2019. Our audit covered costs from only 1 FY for each OPO.

¹² See Appendix D for information about the types of education overhead costs included in our audit.

⁹ When we started our audit (June 1, 2021), there were 57 OPOs (50 independent and 7 hospital-based OPOs). Therefore, our audit covered all 50 independent OPOs.

¹⁰ The \$101.6 million of professional and public education overhead costs included costs from only 1 FY for each of the 50 independent OPOs. The Medicare share of education overhead costs varied for each OPO. Our analysis determined that the Medicare share ranged from 41 percent to 72 percent of the costs reported by the OPOs.

¹³ With the exception of the statistical estimate (i.e., projection) based on our sample results, the Medicare payment amounts included throughout this report are estimates based on a Medicare share ratio specific to each OPO. To calculate that ratio, we divided the OPO's reimbursable overhead costs by the total overhead costs recorded in the Medicare cost report. To calculate the Medicare payment amount, we multiplied the Medicare share ratio by the education overhead costs.

Appendix A describes our audit scope and methodology, Appendix D describes our statistical sampling methodology, and Appendix E contains our sample results and estimates.

FINDINGS

Not all professional and public education overhead costs reported by independent OPOs met Medicare requirements. Of the 300 sampled education overhead costs, 264 costs met Medicare requirements. The remaining 36 costs, totaling \$15,852 (with Medicare payments of \$6,423), did not meet Medicare requirements and were therefore unallowable.

Furthermore, while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we determined that OPOs reported an additional \$132,898 of education overhead costs (with Medicare payments of \$65,785) that did not meet Medicare requirements and were therefore unallowable. We refer to these additional findings as "reconciliation findings" in this report.¹⁴

On the basis of our sample results and the reconciliation findings, we estimated that \$664,295 of the \$50.9 million paid for education overhead costs was unallowable.¹⁵

The OPOs reported unallowable costs because: (1) they misunderstood Medicare requirements and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements.

SOME SAMPLED PROFESSIONAL AND PUBLIC EDUCATION OVERHEAD COSTS DID NOT MEET MEDICARE REQUIREMENTS

Of the 300 sampled education overhead costs, 36 sampled costs, totaling \$15,852 (with Medicare payments of \$6,423), did not meet Medicare requirements. Table 1 on the following page shows the unallowable costs we identified, by the type of cost. (The total number of unallowable sampled costs exceeds 36 because 1 sampled cost did not meet more than 1 requirement.)

¹⁴ We identified these unallowable costs before we selected our random sample, and they were not included for possible selection in the random sample. The Medicare payment amounts associated with the reconciliation findings were not based on a statistical estimate.

¹⁵ The total estimated Medicare savings of \$664,295 consisted of an estimated \$598,510 based on our sample results and \$65,785 for our reconciliation findings.

Type of Cost	Number of Unallowable Sampled Costs	Amount of Unallowable Reported Costs	Medicare Payments for Unallowable Reported Costs
Meals	20	\$4,637	\$1,797
Donations and gifts	7	2,703	1,118
Entertainment	5	3,211	1,412
Costs not incurred	2	4,291	1,642
Lobbying	2	247	98
Seminars	1	763	356
Total	37	\$15,852	\$6,423

Table 1: Sampled Professional and Public Education Overhead CostsThat Did Not Meet Medicare Requirements

Unallowable Costs for Meals

All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of Medicare enrollees (42 CFR § 413.9(a)). The cost of meals for other than provider personnel is unallowable because it is not related to patient care (the Manual, part 1, § 2105.2). Twenty sampled professional and public education overhead costs (reported by eight OPOs), totaling \$4,637, were for meals provided to non-OPO employees, with Medicare payments of \$1,797.

For example, one OPO reported as professional education overhead costs \$633 for dinner during a clinical managers and hospital directors' meeting for seven people, of whom four were non-OPO employees. Of this amount, \$362 was unallowable. The dinner averaged \$90 per person.

Unallowable Costs for Donations and Gifts

Reasonable costs do not include costs for gifts or donations (the Act § 1861(v)(8)). Seven sampled professional and public education overhead costs (reported by four OPOs), totaling \$2,703, were for donations and gifts, with Medicare payments of \$1,118. The unallowable costs of \$2,703 consisted of \$1,550 incurred for donations to a nonprofit association and \$1,153 incurred for gifts (e.g., gift cards or gift baskets) to non-OPO employees.

For example, one OPO reported unallowable costs of \$1,550 for a donation that sponsored a State Coroner's Association Symposium. These funds covered the cost of attending the Symposium, which included a cocktail reception at which alcohol was served, lunch and dinner at a museum, and raffle prizes.

Unallowable Costs for Entertainment

Reasonable costs do not include costs for entertainment, including tickets to sporting and other entertainment events (the Act § 1861(v)(8)). Five sampled public education overhead costs (reported by four OPOs), totaling \$3,211, were for entertainment, with Medicare payments of \$1,412. The unallowable costs of \$3,211 consisted of \$1,000 for a photo booth and \$2,211 for tickets to various sporting events (i.e., hockey, basketball, and baseball games) and to a winter holiday parade.

Costs Not Incurred

The reasonable cost of any services must be the cost actually incurred (the Act § 1861(v)(1)(A)). In addition, all payments to providers of services must be based on reasonable costs, which include all necessary and proper costs incurred (42 CFR §§ 413.9(a), (b), and (c)(3)). Two sampled public education overhead costs (reported by one OPO), totaling \$4,291, were for costs not incurred, with Medicare payments of \$1,642. The unallowable costs of \$4,291 consisted of \$411 for an advertising commission fee and \$3,880 for publishing advertisements when these items were donated by the vendor (an in-kind contribution).

Unallowable Costs for Lobbying Activities

All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of Medicare enrollees (42 CFR § 413.9(a)). The costs of lobbying activities are unallowable (the Manual, part 1, § 2139.2). Two sampled professional education overhead costs, totaling \$247 (reported by one OPO), were for membership dues paid to a hospital and health care association (which used 27 percent of these dues for lobbying activities), with Medicare payments of \$98.¹⁶

Unallowable Costs for a Seminar

All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of Medicare enrollees (42 CFR § 413.9(a)). Medicare does not cover the costs of OPO-sponsored seminars that provide continuing education credits (the Manual, part 1, § 3108.C).¹⁷ One sampled professional education overhead cost (reported

¹⁶ The OPO reported an additional \$4,091 of professional education overhead costs related to these membership dues, of which \$1,111 (with \$443 of Medicare payments), or 27 percent, was used for lobbying activities and was not allowable. The OPO divided the total membership dues and reported the cost in its general ledger over 11 months. Membership costs for 2 of the 11 months were included in our sample. The unallowable lobbying costs of \$1,111 for the remaining 9 months were not included in our sample; therefore, we did not include these costs when calculating the estimated amount that Medicare could have saved.

¹⁷ CMS codified this provision at 42 CFR § 413.402(d)(2)(v), effective Feb. 25, 2022 (86 Fed. Reg. 73416 (Dec. 27, 2021)).

by one OPO), totaling \$763, was for sponsoring a seminar at which continuing education credits were provided to participants (with Medicare payments of \$356).

ADDITIONAL PROFESSIONAL AND PUBLIC EDUCATION OVERHEAD COSTS DID NOT MEET MEDICARE REQUIREMENTS

While reconciling the 10 randomly sampled OPOs' general ledgers with the OPOs' Medicare cost reports, we identified additional costs, totaling \$132,898 (with Medicare payments of \$65,785), that did not meet Medicare requirements and were therefore unallowable.¹⁸ Table 2 shows these additional unallowable professional and public education overhead costs, by type of cost.

Type of Cost	Amount of Unallowable Reported Costs	Medicare Payments for Unallowable Reported Costs
Inaccurately Reported Costs	\$80,164	\$40,874
Seminars	52,734	24,911
Total	\$132,898	\$65,785

Table 2: Additional Professional and Public Education Overhead CostsThat Did Not Meet Medicare Requirements

Inaccurately Reported Costs

OPOs' cost information must be accurate and in sufficient detail to support payments made for services provided (42 CFR §§ 413.24(a) and (c)). Three OPOs reported unallowable costs, totaling \$80,164 (with Medicare payments of \$40,874). Specifically, the OPOs used inaccurate reclassification percentages or erroneously included unallowable costs:

- Two OPOs used lower reclassification percentages than those supported by their records when reclassifying or reallocating a portion of the education overhead costs from worksheet A of the Medicare cost report to the tissue cost center.¹⁹ The OPOs' use of incorrect percentages resulted in the OPOs overstating their education overhead costs by \$78,483.
- One OPO erroneously reported as professional education overhead costs \$1,681 of unallowable costs related to coroner and medical examiner liaison costs.

¹⁸ We did not include these additional costs for possible selection in our random sample, nor when we calculated the statistical estimate of unallowable Medicare payments based on our random sample.

¹⁹ OPOs may reclassify nonreimbursable education overhead costs related to tissue recovery by reallocating a percentage of those costs to the tissue cost center on Worksheet A of the cost report.

Unallowable Costs for a Seminar

All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of Medicare enrollees (42 CFR § 413.9(a)). Medicare does not cover the costs of OPO-sponsored seminars that provide continuing education credits (the Manual, part 1, § 3108.C). One OPO reported \$52,734 of unallowable seminar costs as professional education overhead costs incurred for a symposium (or seminar) held in 2017 to educate health care professionals on organ and tissue donation (with Medicare payments of \$24,911). The OPO provided continuing education credits to symposium participants.

ORGAN PROCUREMENT ORGANIZATIONS RECEIVED UNALLOWABLE PAYMENTS FOR PROFESSIONAL AND PUBLIC EDUCATION OVERHEAD COSTS

OPOs reported \$15,852 of unallowable education overhead costs (with Medicare payments of \$6,423) for 36 sampled costs that did not meet Medicare requirements. Furthermore, while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we identified an additional \$132,898 of unallowable professional and public education overhead costs (with Medicare payments of \$65,785). On the basis of our sample results and the reconciliation findings, we estimated that \$664,295 (consisting of an estimated \$598,510 based on our sample results and \$65,785 for our reconciliation findings) of the \$50.9 million paid for education overhead costs was unallowable. Table 3 shows the estimated Medicare payments to OPOs for unallowable education overhead costs.

Type of Finding	Amount of Unallowable Reported Costs	Medicare Payments for Unallowable Reported Costs	Estimated Medicare Payments
Findings From Sample (Projectable)	\$15,852	\$6,423	\$598,510
Findings From Reconciliation of Medicare Cost Reports	132,898	65,785	65,785
Total	\$148,750	\$72,208	\$664,295

Table 3: Estimated Medicare Payments for UnallowableProfessional and Public Education Overhead Costs

ORGAN PROCUREMENT ORGANIZATIONS MISUNDERSTOOD MEDICARE REQUIREMENTS

The OPOs reported unallowable costs because: (1) they did not understand how CMS requirements applied to them and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements.

Of the 36 unallowable sampled costs, 25 were reported by OPOs because they misunderstood Medicare requirements. Some of the Medicare requirements that apply to OPOs do not

address OPOs specifically.²⁰ For example, Federal regulations and the Manual, part 1, chapter 21, address reimbursement for the care of patients in settings such as hospitals, nursing homes, home health agencies, and hospices. These regulations and the Manual state that all payments to providers of services must be based on the reasonable cost of services and be related to "patient care." The Manual, part 1, chapter 21, describes unallowable costs that are not related to "patient care." However, OPOs do not treat patients or provide the same kind of care as traditional providers of patient care services; OPOs' core purpose is to procure organs for transplant. Because Federal regulations and the Manual are not specific to OPOs, the OPOs misunderstood how the requirements applied to them when reporting education overhead costs.

Some OPOs informed us that the definitions of unallowable costs not related to patient care in the regulations and the Manual are not applicable to them. These OPOs maintained that unlike traditional providers, the OPOs care for patients by increasing the number of registered organ donors and coordinating the organ donation process. Therefore, the OPOs consider all education overhead costs as categorically allowable under the requirement that costs be reasonable and related to patient care.

For example, section 1861(v)(8) of the Act states that costs for entertainment, including tickets to sporting and other entertainment events, are not related to patient care. However, one OPO maintained that costs incurred for tickets to a baseball game were allowable and related to patient care because the OPO was promoting organ and tissue donation at the baseball game. In addition, the Manual, part 1, section 2105.2, states that the cost of meals for other than provider personnel is unallowable because it is not related to patient care. However, some OPOs maintained that the cost of meals provided to hospital staff during meetings on organ donation and management was a professional education overhead cost that was related to patient care and was therefore allowable. The OPOs added that the Manual, part 2, chapter 33 (which provides instructions to OPOs for completing Medicare cost reports) does not instruct OPOs to exclude meal costs associated with professional education meetings but to include all meeting costs. Furthermore, the Manual, part 2, chapter 33, does not specifically define which types of education overhead costs are not related to patient care and therefore unallowable.

The remaining 11 unallowable sampled costs were reported because: (1) staff at 5 OPOs (for 8 sampled costs) made administrative errors when they recorded costs in OPOs' general ledgers and Medicare cost reports and (2) staff at 2 OPOs (for 3 sampled costs) were not aware that costs did not meet Medicare requirements. Some OPOs explained that they accidentally reported unallowable costs, and one OPO informed us that it was not aware that a portion of the membership dues that the OPO paid to a hospital and health care association financed lobbying activities.

²⁰ Federal regulations and CMS manuals that apply to OPOs, but do not address OPOs specifically, include the Act § 1861(v)(8), 42 CFR § 413.9, and the Manual—Part 1, Pub. No. 15-1, chapter 21.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- instruct Palmetto GBA to recover \$72,208 in unallowable Medicare payments by adjusting the applicable OPOs' cost reports to correct the \$148,750 of unallowable professional and public education overhead costs reported, consistent with relevant laws and the agency's policies and procedures; and
- update applicable Medicare requirements to clarify which types of professional and public education overhead costs are unallowable (e.g., clarify whether the costs of meals provided to non-OPO employees for professional education and the costs of tickets to entertainment events purchased for the purpose of public education are unallowable), which could have saved Medicare an estimated \$664,295 for professional and public education overhead costs during our audit period.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described actions that it planned to take to address our recommendations. For the first recommendation, CMS stated that it will instruct Palmetto GBA to recover unallowable payments from the applicable OPOs in accordance with the agency's policies and procedures, as appropriate. For the second recommendation, CMS stated that it is currently reviewing its regulations and guidance and will make updates, as needed, to ensure that OPOs have the tools they need to determine allowable costs for reporting purposes.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included in their entirety as Appendix F.

OTHER MATTERS: MEDICARE REIMBURSEMENT FOR NONKIDNEY ORGANS

In 1973, Medicare was expanded to cover kidney transplants, including acquisition costs; however, coverage was not expanded to cover transplants of nonkidney organs. After a series of policy changes, Medicare added coverage for the procurement and transplantation of nonkidney organs, such as hearts, pancreases, intestines, lungs, and livers. Although Medicare covers the costs associated with transplants of nonkidney organs, the Medicare cost report used by independent OPOs was not updated to allow for the reimbursement to OPOs for nonkidney organs or the settlement of those costs (i.e., determining amounts due to or from OPOs after reconciling any underpayments or overpayments resulting from the total payments that OPOs received from transplant hospitals).

OPOs use a standard acquisition charge (SAC) when billing transplant hospitals for the costs of procuring organs. The transplant hospitals then report in their own Medicare cost report (Form

CMS-2552) the costs of acquiring the organs from the OPOs. Medicare in turn reimburses the transplant hospitals for the organ acquisition costs. The SAC is developed for each organ based on costs expected to be reasonably and necessarily incurred in the acquisition of that organ. Because independent OPOs are reimbursed by Medicare for the costs of acquiring only kidneys, the SAC for kidneys is established and approved by Palmetto. However, because OPOs establish their own SACs for nonkidney organs and Palmetto does not review these SACs, there is an incentive for independent OPOs to include costs that are not reasonable and necessary as part of their nonkidney SACs.

Additionally, because Medicare reimburses independent OPOs for the costs of acquiring only kidneys, which include organ acquisition overhead costs that are allocated to kidneys based on a calculated ratio of kidneys to nonkidney organs, there is an incentive for OPOs to maximize their Medicare reimbursement by shifting the costs of procuring nonkidney organs to kidneys. Procuring more nonkidney organs would decrease the amount of overhead costs allocated to kidneys and the OPOs' potential Medicare reimbursement. There is also an incentive for independent OPOs not to procure available nonkidney organs to maximize their Medicare reimbursement.

Because of the method that Medicare uses to reimburse independent OPOs, Palmetto has expressed concerns that opportunities and incentives exist for OPOs to: (1) inflate their SACs for nonkidney organs, (2) misallocate overhead costs between reimbursable and nonreimbursable costs, and (3) not work actively to recover all available organs. These concerns not only negatively affect the Medicare trust fund but also negatively affect people in need of organ transplants. CMS should consider reviewing these concerns when determining whether opportunities exist for cost savings and improved efficiencies in the procurement of nonkidney organs. Additionally, CMS should consider updating the Medicare cost report for independent OPOs to allow for the review and settlement of organ procurement costs of all eligible organs, not just kidneys.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$101,593,498 of professional and public education overhead costs (with Medicare payments of \$50,884,292) reported in the 50 independent OPOs' most recently finalized Medicare cost reports as of August 13, 2021.²¹ The finalized cost reports had FY end dates from May 31, 2015, through June 30, 2019.²²

We used a multistage random sample for this audit:

- For the first stage of our random sample, we randomly selected 10 of the 50 independent OPOs operating at the start of our audit. Next, we reconciled the 10 OPOs' general ledgers (i.e., accounting records) with the OPOs' finalized Medicare cost reports, with FY end dates ranging from June 30, 2017, to December 31, 2018. While reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we identified unallowable education overhead costs. We reviewed these costs separately and did not include them for possible selection in our random sample.²³
- For the second stage of our random sample, we randomly selected for review 30 general ledger transactions for education overhead costs from each of the 10 OPOs selected in the first stage. The 300 sampled costs totaled \$294,692, with Medicare payments of \$124,661.²⁴

We did not perform an overall assessment of CMS's internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective. Specifically, we: (1) interviewed CMS and Palmetto officials to obtain an understanding of their oversight of OPOs' Medicare cost reports and (2) contacted officials at the 10 sampled independent OPOs to obtain an understanding of their internal controls, such as their policies and procedures for ensuring that education overhead costs included on Medicare cost reports met Medicare requirements.

We conducted our audit from June 2021 to May 2023.

²¹ The \$101,593,498 of professional and public education overhead costs included costs from only 1 FY for each of the 50 independent OPOs. The Medicare share of educational overhead costs varied for each OPO. Our analysis determined that the Medicare share ranged from 41 percent to 72 percent of the costs reported by the OPOs.

²² The finalized Medicare costs reports for the 50 independent OPOs included costs incurred during the period June 1, 2014, through June 30, 2019.

²³ The Medicare payment amounts associated with the reconciliation findings were not based on a statistical estimate but were calculated based on the Medicare share ratio specific to each OPO.

²⁴ See Appendix D for information on the types of education overhead costs included in our audit.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed officials at CMS and Palmetto to obtain an understanding of: (1) their oversight of the OPOs' cost reports, including any controls and system edits for costs reported in the Medicare cost reports, and (2) the types of education overhead costs they consider allowable, reasonable, and related to patient care;
- obtained from Palmetto the most recently finalized Medicare cost reports as of August 13, 2021, for the 50 independent OPOs operating at the start of our audit;
- analyzed the 50 Medicare cost reports and determined for each OPO the Medicare share ratio and the Medicare payment amount for education overhead costs;
- for the first stage of our multistage sample, selected a random sample of 10 of the 50 independent OPOs;
- contacted officials at the 10 sampled independent OPOs to obtain an understanding of how costs are reported and the internal controls they have for ensuring that only allowable costs are reported;
- obtained the most recently finalized Medicare cost reports, general ledgers, and supporting documentation from the 10 sampled OPOs;²⁵
- reconciled the 10 sampled OPOs' general ledgers with the OPOs' Medicare cost reports and identified unallowable education overhead costs;
- created a sampling frame of 5,141 education general ledger transactions (or costs), with Medicare payments totaling \$2,547,508, that were reported in the 10 sampled OPOs' general ledgers and finalized Medicare cost reports;
- for the second stage of our multistage sample, selected a random sample of 30 education overhead costs from each of the 10 OPOs selected in the first stage;
- reviewed supporting documentation (such as invoices, receipts, and employee expense reports that the 10 sampled OPOs provided) to determine whether the sampled education overhead costs met Medicare requirements and to confirm the findings we identified while reconciling the OPOs' general ledgers with their cost reports;

²⁵ The documents obtained from each OPO pertained to the same FY as the most recently finalized Medicare cost report provided by Palmetto for that OPO.

- informed the OPOs of our findings and requested that the OPOs provide a reason for reporting unallowable costs;
- calculated the unallowable Medicare payments for education overhead costs included in our sample and the additional costs associated with the reconciliation findings;
- estimated the amount that Medicare paid OPOs for education overhead costs that did not meet Medicare requirements (i.e., unallowable costs); 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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Medicare Could Have Saved Millions if Organ		
Procurement Organizations Had Correctly Reported	<u>A-09-12-02085</u>	12/31/2013
Procurement of Double Lungs as Two Organs		
LifeCenter Northwest Did Not Fully Comply With		
Medicare Requirements for Reporting Organ Statistics in	<u>A-09-11-02039</u>	11/15/2012
Its Fiscal Year 2009 Medicare Cost Report		
Donor Network of Arizona Did Not Fully Comply With		
Medicare Requirements for Reporting Organ Statistics	A-09-11-02035	4/13/2012
and Related Costs in Its Fiscal Year 2009 Medicare Cost	<u>A-03-11-02033</u>	
Report		
Review of California Transplant Donor Network's		
Reported Fiscal Year 2007 Organ Acquisition Overhead	<u>A-09-09-00087</u>	10/1/2010
Costs and Administrative and General Costs		
Review of OneLegacy's Reported Fiscal Year 2006 Organ		
Acquisition Overhead Costs and Administrative and	<u>A-09-08-00033</u>	1/28/2010
General Costs		

APPENDIX C: WORKSHEET A OF THE MEDICARE COST REPORT

OPOs record their costs on Worksheet A of the Medicare cost report, where the costs are grouped into cost categories (i.e., cost centers) based on the type of costs. Professional education overhead costs are reported on line 10, and public education overhead costs are reported on line 11. Generally, costs related to tissue recovery are reported on line 25. OPOs use column 4 to record reclassifications and column 6 to record adjustments.

06-19)		Form CMS-	216-94					3390 (Cont.)
RECLASSIFICATION AND ADJUSTMENT OF TRIAL		Provider CCN:		REPORTING F	PERIOD		WORKSHEET A			
	RALANCE OF EXPENSES		_							
	ITCL .	of ExtEnded			TO:					
						RECLASS.	RECLASSIFIED	ADJUSTMENTS	NET COST	
		COST CENTERS (OMIT CENTS)			TOTAL	TO EXPENSES (FROM	TRIAL BALANCE (COL.3	TO COST (FROM	FOR COST ALLOCATION	
		COST CENTERS (OMIT CENTS)	SALARIES	OTHER	(Cols. 1 & 2)	WKST.A-4)	+/- COL.4)	(WKST. A-5)	(COL.5+/-COL.6)	
			1	2	3	4	5	6	7	<u> </u>
		GENERAL SERVICE COST CENTERS		-						
1	0100	Capital CostsBuildings and Fixtures								1
2	0200	Capital CostsMovable Equipment								2
3	0300	Employee Benefits								3
4	0400	Administrative and General (from W/S-A-1, cols. 1 and 2, line 20)								4
5	0500	Operation and Maintenance of Plant								5
6	0600	Housekeeping								6
7	0700	Medical Supplies								7
8		Other Overhead (specify)								8
	0000	ORGAN ACQUISITION OVERHEAD								<u> </u>
9	0900	Procurement Coordinators								9
10	1000	Professional Education								10
11	1100	Public Education								11
12	1200	Other Acquisition (specify)								12
	1200	REIMBURSABLE COST CENTERS								
13	1300	Kidney Acquisitions (from W/S A-2, cols. 1 and 2, line 23)								13
14	1400	Tissue Typing Laboratory (W/S-A-3, cols. 1 and 2, Line 11)								14
	1.00	NON-REIMBURSABLE COST CENTERS								<u> </u>
15	1500	Liver Acquisitions (W/S-A-2, cols. 1 and 2, line 23)								15
16	1600	Heart Acquisitions (W/S-A-2, cols. 1 and 2, line 23)								16
17	1700	Pancreas Acquisitions (W/S-A-2, cols. 1 and 2, line 23)								17
18	1800	Lung Acquisitions (W/S-A-2, cols. 1 and 2, line 23)								18
19	1900	Other Acquisitions (W/S-A-2, cols. 1 and 2, line 23)								19
20	2000	Other Acquisitions (subscript line 19 and do not use line 20)								20
	2100	Research								21
22	2200	Blood Bank								22
23	2300	Laboratory-Non-Tissue Typing								23
24	2400	Dialysis Units								24
25	2500	Other Non-Reimbursable (Specify)								25
26		Total Expenses (sum of lines 1-25), Transfer Column 7 to W/S-B								26
		line 1, or W/S-C, as per instructions								

FORM CMS-216-94 (06/2019) (INSTRUCTIONS FOR THIS WORKSHEET ARE PUBLISHED IN CMS PUB. 15-2, SECTION 3304)

Rev. 8

APPENDIX D: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame for stage 1 of our multistage sample was a list of 50 independent OPOs operating at the start of our audit.

The sampling frame for stage 2 of our multistage sample was a list of 5,141 general ledger transactions for professional and public education overhead costs, with Medicare payments totaling \$2,547,508 (Medicare share), from the 10 OPOs randomly selected in stage 1. The stage 2 sampling frame consisted of education general ledger debit transactions that were: (1) not salary related, (2) not adjusted (i.e., removed) from the Medicare cost report, (3) not related to credit transactions, (4) over \$35 (Medicare share), and (5) not identified as unallowable costs during our reconciliation of the OPOs' general ledgers with the OPOs' Medicare cost reports.

SAMPLE UNIT

The primary sample unit was an independent OPO.

The secondary sample unit was a general ledger transaction for education overhead costs.

SAMPLE DESIGN AND SAMPLE SIZE

We used a multistage sample. The first stage consisted of a random selection of 10 independent OPOs operating at the start of our audit. The second stage consisted of a simple random selection of 30 general ledger transactions for education overhead costs from the 10 OPOs randomly selected in stage 1.

Therefore, we randomly selected for review a total of 300 education general ledger transactions. (See Table 4 on the following page.)

Randomly Selected OPO	Number of Professional and Public Education General Ledger Transactions in Frame	Medicare Payment	Sample Size
OPO 1	637	\$304,436	30
OPO 2	321	297,837	30
OPO 3	1,099	170,533	30
OPO 4	300	274,053	30
OPO 5	413	175,668	30
OPO 6	903	663,468	30
OPO 7	352	93 <i>,</i> 854	30
OPO 8	613	227,967	30
OPO 9	445	312,736	30
OPO 10	58	26,956	30
Total	5,141	\$2,547,508	300

Table 4: Organ Procurement Organizations in Sampling Frame

Before we selected our sample of 300 education general ledger transactions, we identified unallowable education overhead costs while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports. We reviewed these costs separately and did not include them for possible selection in our random sample.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

For stage 1 of our multistage sample, we sorted the 50 independent OPOs (primary sample units) operating at the start of our audit by provider CMS certification number, and then we consecutively numbered the OPOs. After generating random numbers according to our sample design, we selected the corresponding OPOs for review.

For stage 2 of our multistage sample, we sorted the education general ledger transactions (secondary sample units) for the 10 randomly selected by OPOs by dollar amount (Medicare share) and by a unique identifier, and then we consecutively numbered the general ledger transactions. After generating random numbers according to our sample design, we selected the corresponding general ledger transaction items for review.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the total amount that Medicare paid OPOs for education overhead costs that did not meet Medicare requirements (i.e., unallowable costs). We also identified additional unallowable payments from reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports and added those amounts to the estimate for the statistical sample to obtain the total unallowable payments. (See Appendix E for our estimates.)

APPENDIX E: SAMPLE RESULTS AND ESTIMATES

	Number of Professional and Public Education	Value of Medicare Payment in	Size of	Value of Medicare Payment in	Number of Unallowable Costs in	Value of Medicare Payment for Unallowable
OPOs	Costs in Frame	Frame	Sample	Sample	Sample	Costs in Sample
OPO 1	637	\$304,436	30	\$18,831	3	\$634
OPO 2	321	297,837	30	25,965	1	65
OPO 3	1,099	170,533	30	4,024	1	549
OPO 4	300	274,053	30	12,912	2	308
OPO 5	413	175,668	30	14,634	7	850
OPO 6	903	663,468	30	6,957	6	287
OPO 7	352	93,854	30	5,368	3	298
OPO 8	613	227,967	30	8,881	3	1,661
OPO 9	445	312,736	30	15,985	8	1,640
OPO 10	58	26,956	30	11,104	2	131
Subtotal for Statistical Sample	5,141	\$2,547,508	300	\$124,661	36	\$6,423
Additional Costs From Reconciliation [*]		65,785		65,785		65,785
Grand Total	5,141	\$2,613,293	300	\$190,446	36	72,208

Table 5: Sample Details

^{*} The additional unallowable education overhead costs that we identified while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports were not included in our sampling frame for possible selection in our random sample, nor when we calculated the statistical estimate of unallowable Medicare payments based on our random sample. We did not include the number of costs for the reconciliation findings in Table 5 because some of these findings did not always have a specified number of general ledger transactions (e.g., reclassifications are a percentage of all education overhead costs).

Table 6: Estimated Unallowable Payments forProfessional and Public Education Overhead Costs in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

	Estimated Unallowable Payments for the Statistical Sample	Unallowable Payments From Reconciliation	Total Estimated Unallowable Payments
Point estimate	\$598,510	\$65,785	\$664,295
Lower limit	300,687	65,785	366,472
Upper limit	896,333	65,785	962,118

APPENDIX F: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administr	ator	r
Washington,	DC	20201

DATE:	June 21, 2023
то:	Amy Frontz Deputy Inspector General for Audit Services
FROM:	Chiquita Brooks-LaSure Chy & LaS Administrator
SUBIECT	Medicare Paid Independent Organ Procurement Orga

SUBJECT: Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements (A-09-21-03020)

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.

OPOs are non-profit organizations responsible for the procurement of organs for transplantation. They are the entities legally permitted to recover organs from deceased donors and also provide support to donor families, clinical management of organ donors, and professional and public education about organ donation. Other specific tasks include identifying potential organ donors, requesting consent from the families of donors, procuring organs and working with other agencies to identify potential transplant recipients, and ensuring that organs are transferred to transplant hospitals.

Section 1138 of the Social Security Act and 42 USC § 273 provide the statutory qualifications and requirements that an OPO must meet for organ procurement costs to be reimbursed under Medicare and Medicaid. OPOs must also follow regulatory requirements enforced by CMS and submit Medicare cost reports (Form CMS-216-94) to the Medicare Administrative Contractor annually to determine the amounts payable under Medicare associated with procurement of kidneys (42 CFR §§ 413.420 and 413.20(b)). An OPO's Medicare cost report includes direct costs, administrative and general costs, and overhead costs associated with procuring organs.

To assist OPOs in reporting their costs, CMS provides guidance in the *Provider Reimbursement Manual* (Manual), Part 1, Ch 31 and Part 2, Ch 33. For example, Manual Part 2, Ch 33 explicitly lays out instructions for OPOs to fill out their cost report accurately, including instructions related to public and professional overhead costs. CMS is pleased that OIG found that of the 300 sampled professional and public education overhead costs, 264 met Medicare requirements or guidance (88 percent). However, to provide additional clarification on the professional and public education overhead allowable costs for reporting purposes, CMS is in the process of updating our guidance and/or regulations, as appropriate.

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

OIG Recommendation

The Centers for Medicare & Medicaid Services should instruct Palmetto GBA to recover \$72,208 in unallowable Medicare payments by adjusting the applicable OPOs' cost reports to correct the \$148,750 of unallowable professional and public education overhead costs reported, consistent with relevant laws and the agency's policies and procedures.

CMS Response

CMS concurs with this recommendation. CMS will instruct Palmetto GBA to recover unallowable payments from the applicable OPOs in accordance with our agency's policies and procedures, as appropriate.

OIG Recommendation

The Centers for Medicare & Medicaid Services should update applicable Medicare requirements to clarify which types of professional and public education overhead costs are unallowable (e.g., clarify whether the costs of meals provided to non-OPO employees for professional education and the costs of tickets to entertainment events purchased for the purpose of public education are unallowable), which could have saved Medicare an estimated \$664,295 for professional and public education overhead costs during our audit period.

CMS Response

CMS concurs with this recommendation. CMS is currently reviewing our regulations and guidance and will make updates, as needed, to ensure OPOs have the tools they need to determine allowable costs for reporting purposes.