

HHS OIG responses to December 18, 2019, questions

1. To what extent has the OIG audited or investigated activities by the 58 nonprofit OPOs that procure organs from recently deceased donors and deliver them to certified transplant centers for critically ill patients in need of an organ transplant? Please identify which OPOs the OIG has audited or investigated since 2009, and provide the dates of each such audit or investigation, a summary of the OIG's findings, any recommendations issued, and the extent to which the OIG's recommendations have (or have not) been implemented.

Since 2009, OIG has issued five audit reports related to OPOs that procure organs from recently deceased donors and deliver them to certified transplant centers for critically ill patients in need of an organ transplant. These five reports examined whether the selected OPO overhead costs and administrative and general costs complied with Federal requirements or the OPO's reporting of organ statistics. These audits consisted of the following:

- *Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs (A-09-08-00033)* issued January 2010.
- *Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs (A-09-09-00087)* issued October 2010.
- *Donor Network of Arizona Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics and Related Costs in Its Fiscal Year 2009 Medicare Cost Report (A-09-11-02035)* issued April 2012.
- *LifeCenter Northwest Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics in Its Fiscal Year 2009 Medicare Cost Report (A-09-11-02039)* issued November 2012.
- *Medicare Could Have Saved Millions if Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs as Two Organs (A-09-12-02085)* issued December 2013.

Detailed information on the findings, recommendations, and implementation status for each report is included in Attachment A.

OIG has no closed cases regarding OPOs. Also, as you know, we are not able to confirm or deny that there are any current investigations.

2. In light of recent research, which suggests the vast majority of OPOs are underperforming, with organ recovery rates of less than 50%, has the OIG identified practices, such as enhanced cost reporting, that could be imposed to identify reasons for poor performance or underperformance? If so, which OPOs should be subjected to enhanced reporting requirements?

HHS-OIG has not conducted work to identify practices that could be imposed to identify reasons for poor performance or underperformance.

3. To ensure that OPOs are focused on achieving their mission of organ recovery, regular fiscal oversight is necessary, but nearly a decade has elapsed since the OIG identified misuse of taxpayer dollars by OPOs in four reports spanning a two-year period. What other efforts has the OIG initiated in this area since 2012? Also, in light of recent investigative reports questioning OPO practices, is the OIG auditing (or planning to audit) or taking other actions to identify unallowable or unsupported expenses by the other 54 OPOs across the country? Please explain.

HHS-OIG does not have any work currently planned on this topic.

- a. For example, has the OIG ever audited or investigated LiveOnNY, which has been flagged for decertification by CMS on multiple occasions since 2013, and yet, still had its contract renewed by CMS in 2019? If so, what were the findings of the audit or investigation? Please explain.

HHS-OIG has not audited LiveOnNY. OIG has no closed cases regarding OPOs. Also, as you know, we are not able to confirm or deny that there are any current investigations.

- b. Has OneLegacy reimbursed the Medicare program for its \$76,686 in unallowable expenditures on lobbying, deferred compensation, gifts, donations, dining, entertainment, and alcohol, or reimbursed the Medicare program for some or all of its \$85,645 in expenditures on the Rose Bowl and the Rose Parade? Because OneLegacy has appealed the OIG's reimbursement decision and its initial appeal hearing is scheduled to take place next month, please provide documentation of the OPO's public education costs, including, but not limited to its expenditures on the Rose Bowl and Rose Parade in calendar years 2007 through 2019.

In our audit report, we recommended that OneLegacy submit a revised FY 2006 Medicare cost report to correct the estimated Medicare overstatement of \$296,502, which included \$76,686 in unallowable expenditures for lobbying, deferred compensation, gifts, donations, dining, entertainment, and alcohol and \$85,645 in expenditures on the Rose Bowl and the Rose Parade.

Based on information we received from Palmetto, the Medicare administrative contractor, OneLegacy reimbursed Medicare \$286,643 on March 9, 2011. The \$286,643 that was reimbursed included the unallowable expenditures listed above.

As a result of the reopening of OneLegacy's FY 2006 Medicare cost report, the total calculated overstated amount was determined to be \$286,643 instead of \$296,502. We consider this matter closed as OneLegacy has fully implemented our recommendation to correct the Medicare overstatement based on actual amounts. HHS-OIG is not aware of an appeal related to our audit of OneLegacy's FY 2006 Medicare cost report.

We do not have documentation of the OPO's public education costs extending past our audit period, which covered January 1 to December 31, 2006.

- c. Has California Donor Network reimbursed the Medicare program for \$33,431 in unallowable expenditures, including nearly \$19,000 to host a retirement party as well as other entertainment, lobbying, and dining-related expenditures? Additionally, has California Donor Network reimbursed the Medicare program for \$51,304 in unallowable and unsupported costs?

In our audit report, we recommended that California Transplant Donor Network (CTDN) submit a revised FY 2007 Medicare cost report to correct the estimated Medicare overstatement of \$84,735, which included \$33,431 in unallowable expenditures and \$51,304 in unsupported costs.

Based on information we have received from Palmetto, CTDN reimbursed Medicare \$82,461 on June 6, 2011. The amount reimbursed includes the unallowable expenditures listed above.

As a result of the reopening of CTDN's FY 2007 Medicare cost report, the total calculated overstated amount was determined to be \$82,461 instead of \$84,735. We consider this matter closed as CTDN has fully implemented our recommendation to correct the Medicare overstatement based on actual amounts.

- d. Has LifeCenter Northwest reimbursed the Medicare program \$88,205, after deficiencies were identified by the OIG in the OPO's organ procurement reports and organ statistics?

Based on information we have received from Palmetto, LifeCenter Northwest reimbursed Medicare, \$86,562 on May 23, 2013.

As a result of the reopening of LifeCenter Northwest's FY 2007 Medicare cost report, the total calculated overstated amount was determined to be \$86,562 instead of \$88,205. We consider this matter closed as LifeCenter has fully implemented our recommendation to correct the Medicare overstatement based on actual amounts.

- e. Has Donor Network of Arizona reimbursed the Medicare program \$8,455, after deficiencies were identified by the OIG in the OPO's organ procurement reports and organ statistics?

Based on information we have received from Palmetto, Donor Network of Arizona reimbursed Medicare \$8,341 on August 22, 2012.

As a result of the reopening of Donor Network of Arizona's FY 2007 Medicare cost report, the total calculated overstated amount was determined to be \$8,341 instead of \$8,455. We consider this matter closed as Donor Network of Arizona has fully implemented our recommendation to correct the Medicare overstatement based on actual amounts.

- f. What reforms have been adopted since the issuance of the OIG's four reports on OPOs to ensure that reported expenses in Medicare Cost Reports are reasonable and focused on the OPO's mission of organ recovery?

Other than the clarifying language that CMS added on the methodology for counting organs in Chapters 31 and 33 of the Provider Reimbursement Manual Parts 1 and 2, respectively, we are not aware of any reforms adopted since the issuance of OIG's four reports.

- i. Please rank each OPO according to the amount of executive compensation received by its chief executive officer. For each such CEO, also provide detailed information on annual salary, bonuses, and additional sources of OPO-related compensation, such as compensation derived from OPO partner organizations (e.g., tissue processors, cornea banks, and funeral homes).

We are not able to rank each OPO according to the amount of executive compensation received by its chief executive officer because we do not have detailed information on annual salary, bonuses, and additional sources of OPO-related compensation for all of the OPOs.

4. Has the OIG audited or investigated any OPOs, such as Indiana Donor Network, that purchased airplanes for organ procurement purposes?

HHS-OIG has not audited Indiana Donor Network and is not aware of which entities have purchased airplanes for organ procurement purposes. OIG has no closed cases regarding OPOs. Also, as you know, we are not able to confirm or deny that there are any current investigations.

- a. Has the OIG identified any OPOs that submitted reimbursement claims to cover the cost of flights that were not directly related to an OPO's charitable mission? If so, did the OPO reimburse the Medicare program for any unallowable expenditures? Please explain and provide documentation.
 - b. What measures are in place to provide sufficient transparency to ensure that these airplanes are not used for personal travel and then billed to taxpayers?
5. UNOS, the only entity to ever have the OPTN contract, is tasked with conducting audits and oversight of all 58 OPOs. Due to concerns, dating back to 1999, that UNOS exercises a monopoly in this area, has the OIG ever audited or investigated UNOS? If so, when? If not, why not?

HHS-OIG has not audited UNOS nor have any specific concerns related to this entity been brought to our attention. OIG has no closed cases regarding UNOS. Also, as you know, we are not able to confirm or deny that there are any current investigations.

6. The OIG's 2013 report indicates that 44 of 58 OPOs incorrectly reported lung procurement statistics (resulting in unnecessary government expenditures of over \$8,000,000). Has the OIG's

recommendation that CMS resolve this issue by updating the Provider Reimbursement Manual (PRM) been implemented?

Yes, on April 1, 2016, CMS issued PRM transmittal 471 and MLN Matters guidance to providers informing them of changes to the policy manual section 3115 on the methodology for counting organs.

The Provider Reimbursement Manual Part 1, Chapter 31 has been created to update, reorganize, and clarify Medicare's payment policy regarding organ acquisition costs, formerly found in Chapter 27. Section 3115 of Chapter 31 clarifies the methodology for counting organs, including those procured and transplanted "en bloc." In addition, Provider Reimbursement Manual Part 2, Chapter 33, Sections 3303 and 3306 also include clarifying language related to organs procured and transplanted "en bloc." Specifically, the sections include language that "organs procured and transplanted "en bloc" are counted as one organ for allocation purposes.

Below are links to PRM 471 and the MLN Matter's Guidance:

- Medicare Provider Reimbursement Manual Part 1 – Chapter 31 Organ Acquisition Payment Policy Transmittal 471 - <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R471pr1.pdf>
 - MLN Matters Number: 1608 <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1608.pdf>
- a. Please provide a list of the 44 OPOs that incorrectly reported lung procurement costs during fiscal year 2011.
- HHS-OIG will follow up with your staff in response to this question.
- b. Since 2013, has the OIG conducted additional oversight of the 44 OPOs that incorrectly reported lung procurement costs in Medicare Cost Reports? If so, what were the OIG's findings? If the OIG identified unallowable claims as a result of this additional oversight, to what extent was the Medicare program overbilled by each such OPO in each of the last eight fiscal years? Please provide documentation.

There have been no additional audits related to the 44 OPOs.

7. As noted by the OIG in a 2001 report, some OPOs that operate tissue banks are not accredited by the American Association of Tissue Banks (AATB), and may not have adequate mechanisms to avoid conflicts of interest. What financial incentives do OPOs have to prioritize tissue recovery over organ procurement, and under what circumstances do such financial incentives create a conflict of interest?

HHS-OIG has not addressed this issue in our reviews.

- a. How many OPOs currently operate tissue banks that are accredited by the AATB? Please provide a list of these OPOs and the date on which they completed the AATB's accreditation program.
 - b. How many OPOs operate tissue banks that are not accredited by the AATB? Please provide a list of these OPOs.
8. Are mechanisms in place to ensure that financial assets controlled by OPOs, including OPO endowments and OPO foundations, are used to advance the mission for which the OPO was granted non-profit status?

HHS-OIG has not addressed this issue in our reviews. We would refer you to CMS for additional information on this question.

9. Internal Revenue Service 990 filings indicate that some OPOs have transferred financial assets to their private foundations. Given this, has the OIG investigated whether OPO foundations then use these resources for purposes that the OIG had previously deemed impermissible for OPOs?

HHS-OIG's work in this area has consisted only of examining compliance issues associated with OPOs seeking Federal reimbursement.

Attachment A—Detailed information on the findings, recommendations, and implementation status for five OIG audit reports related to OPOs

CIN	Audit Title	Audit Period	Report Issuance Date	Summary of OIG Findings	Recommendations	Status of Implementation of Recommendations
A-09-08-00033	Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs	FY 2006 (1/1 - 12/31/2006)	1/28/2010	<p>OneLegacy did not fully comply with Medicare requirements for reporting selected OPO overhead costs and administrative and general costs in its FY 2006 Medicare cost report. Of the \$3,157,740 of costs we reviewed, \$2,626,280 was allowable. The remaining \$531,460 represents \$290,968 of unallowable costs and \$240,492 of unsupported costs:</p> <ul style="list-style-type: none"> • Contrary to Federal regulations, OneLegacy reported \$290,968 of costs that were not related to patient care or did not comply with other Medicare requirements and therefore were not allowable. This amount included costs incurred for the Rose Parade, deferred compensation, donations and gifts, lobbying, meals, and entertainment. We estimated that Medicare's share of the unallowable costs related to kidney procurement was \$162,331. • Contrary to Federal requirements, OneLegacy reported \$240,492 of costs that were unsupported. For \$26,635 of this amount, no documentation existed to support the reported costs. For the remaining \$213,857, OneLegacy was unable to provide adequate documentation to support the allowability of the reported costs. Based on Federal regulations and the Manual, we considered the unsupported costs to be unallowable for Medicare reimbursement. We estimated that Medicare's share of the unsupported costs related to kidney procurement was \$134,171. <p>OneLegacy did not have procedures to ensure that all OPO overhead costs and administrative and general costs reported in its Medicare cost report were allowable, supportable, and in compliance with Medicare requirements. As a result, OneLegacy overstated its Medicare reimbursement in the FY 2006 Medicare cost report by an estimated \$296,502.</p>	<p>We recommend that OneLegacy:</p> <ul style="list-style-type: none"> • submit a revised FY 2006 Medicare cost report to the fiscal intermediary to correct the estimated Medicare overstatement of \$296,502 and • develop and implement procedures to ensure that costs reported in future Medicare cost reports are allowable, supportable, and in compliance with Medicare requirements. 	See response in 3b

CIN	Audit Title	Audit Period	Report Issuance Date	Summary of OIG Findings	Recommendations	Status of Implementation of Recommendations
A-09-09-00087	Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs	FY 2007 (1/1 - 12/31/2007)	10/1/2010	<p>California Transplant Donor Network (CTDN) did not fully comply with Medicare requirements for reporting selected OPO overhead costs and administrative and general costs in its FY 2007 Medicare cost report. Of the \$1,595,845 of costs we reviewed, \$1,428,781 was allowable. The remaining \$167,064 represents \$65,912 of unallowable costs and \$101,152 of unsupported costs:</p> <ul style="list-style-type: none"> • Contrary to Federal requirements, CTDN reported \$65,912 of costs that were not related to patient care or did not comply with other Medicare requirements and therefore were not allowable. This amount included costs incurred for donations and gifts, a retirement party, entertainment, lobbying, and meals. We estimated that Medicare's share of the unallowable costs related to kidney procurement was \$33,431. • Contrary to Federal requirements, CTDN reported \$101,152 of costs that were unsupported. For \$1,984 of this amount, no documentation existed to support the reported costs. For the remaining \$99,168, CTDN was unable to provide adequate documentation to support the allowability of the reported costs. Based on Federal regulations and the Manual, we considered the unsupported costs to be unallowable for Medicare reimbursement. We estimated that Medicare's share of the unsupported costs related to kidney procurement was \$51,304. <p>CTDN did not have procedures to ensure that all OPO overhead costs and administrative and general costs reported in its Medicare cost report were allowable, supportable, and in compliance with Medicare requirements. As a result, CTDN overstated its Medicare reimbursement in the FY 2007 Medicare cost report by an estimated \$84,735.</p>	<p>We recommend that CTDN:</p> <ul style="list-style-type: none"> • submit a revised FY 2007 Medicare cost report to the Medicare contractor to correct the estimated Medicare overstatement of \$84,735 and • develop and implement procedures to ensure that costs reported in future Medicare cost reports are allowable, supportable, and in compliance with Medicare requirements. 	See response in 3c

CIN	Audit Title	Audit Period	Report Issuance Date	Summary of OIG Findings	Recommendations	Status of Implementation of Recommendations
A-09-11-02035	Donor Network of Arizona Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics and Related Costs in Its Fiscal Year 2009 Medicare Cost Report.	FY 2009 (1/1 - 12/31/2009)	4/13/2012	<p>Donor Network of Arizona (DNA) did not fully comply with Medicare requirements for reporting organ statistics and related costs in its fiscal year 2009 Medicare cost report.</p> <p>DNA did not fully comply with Medicare requirements for reporting organ statistics and related costs in its FY 2009 Medicare cost report:</p> <ul style="list-style-type: none"> Based on our review of 65 donor case files, we determined that DNA reported incorrect kidney and pancreas statistics related to 3 donors. As a result, Medicare's share of organ procurement costs was overstated by an estimated net amount of \$5,855. DNA attributed the incorrect reporting of organ statistics to incorrect information provided by organ procurement staff to the finance department, which generates data reported in the Medicare cost report. DNA did not report proceeds from the sale of research organs as a reduction to its expenses. As a result, Medicare's share of organ procurement costs was overstated by an estimated \$2,600. DNA attributed the omission of research revenues to an inadvertent reporting error in preparing its Medicare cost report. <p>In total, Medicare's share of organ procurement costs was overstated by an estimated \$8,455 in DNA's FY 2009 Medicare cost report.</p>	<p>We recommend that DNA:</p> <ul style="list-style-type: none"> submit a revised FY 2009 Medicare cost report to the Medicare administrative contractor to correct the estimated Medicare overstatement of \$8,455 related to the reporting errors and ensure that the organ statistics and related costs reported in future Medicare cost reports comply with Medicare requirements. 	See response in 3e

CIN	Audit Title	Audit Period	Report Issuance Date	Summary of OIG Findings	Recommendations	Status of Implementation of Recommendations
A-09-11-02039	LifeCenter Northwest Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics in Its Fiscal Year 2009 Medicare Cost Report	FY 2009 (1/1 - 12/31/2009)	11/15/2012	LifeCenter did not fully comply with Medicare requirements for reporting organ statistics in its FY 2009 Medicare cost report. Based on our review of 49 donors, we determined that LifeCenter reported incorrect organ statistics for 15 organs related to 13 donors. Specifically, LifeCenter did not report five imported pancreases that were processed administratively with imported kidneys; three pancreases, two livers, and two kidneys that it attempted to procure for transplant; two pancreases procured for islet cell transplant; and one kidney procured from an adult donor. As a result, Medicare's share of organ procurement costs was overstated by an estimated \$88,205.	<p>We recommend that LifeCenter:</p> <ul style="list-style-type: none"> • submit a revised FY 2009 Medicare cost report to the Medicare administrative contractor to correct the estimated Medicare overstatement of \$88,205 related to the incorrect reporting of organ statistics and • ensure that the organ statistics reported in future Medicare cost reports comply with Medicare requirements. 	See response in 3d

CIN	Audit Title	Audit Period	Report Issuance Date	Summary of OIG Findings	Recommendations	Status of Implementation of Recommendations
A-09-12-02085	Medicare Could Have Saved Millions if Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs as Two Organs	FY 2011 Medicare Cost Reports	12/31/2013	<p>Of the 54 Organ procurement organizations (OPOs) that we reviewed, 44 reported lung statistics incorrectly in their fiscal year 2011 Medicare cost reports.</p> <ul style="list-style-type: none"> • Of the 51 independent OPOs reviewed, 43 incorrectly reported double lungs as 1 organ. Specifically, the OPOs understated the number of lungs procured by reporting 1,691 lungs instead of 3,382 lungs. We estimated that Medicare's share of organ procurement costs was overstated by \$9,039,419. • Of the three hospital-based OPOs reviewed, one incorrectly reported double lungs as one organ. Specifically, the OPO understated the number of lungs procured by reporting 30 lungs instead of 60 lungs. We estimated that Medicare's share of organ procurement costs was understated by \$188,401. <p>Both independent and hospital-based OPOs incorrectly reported lung statistics because they relied on CMS's Provider Reimbursement Manual, which does not provide specific instructions on reporting double lungs. If the 44 OPOs (43 independent OPOs and 1 hospital-based OPO) had reported procurement of 1,721 double lungs correctly, the Medicare program could have saved an estimated net amount of \$8,851,018 during the year.</p>	To help realize future savings for the Medicare program, we recommended that CMS (1) clarify instructions on how independent and hospital-based OPOs should report lung statistics in Medicare cost reports and (2) work with the Medicare contractors to educate OPOs on the correct reporting of double lungs in Medicare cost reports. CMS concurred with our recommendations and provided information on actions that it planned to take to address them.	See response in 6.