Department of Health and Human Services
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September 2026 | OAS-25-07-124

Conflicting CMS Guidance and Federal Statutory Requirements Cost Medicare $380 Million Over a 6-Year Period for Organs Not Transplanted Into Medicare Enrollees

REPORT HIGHLIGHTS

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Conflicting CMS Guidance and Federal Statutory Requirements Cost Medicare $380 Million Over a 6-Year Period for Organs Not Transplanted Into Medicare Enrollees

Why OIG Did This Audit

- Medicare reimbursed Certified Transplant Centers (CTCs) for organ acquisition costs on a cost basis, which included more than $3 billion for about 39,000 organs in 2023. Federal statute limits Medicare's reimbursement to the cost of acquiring organs used in Medicare-covered transplants (Medicare usable organs).
- Medicare guidance to CTCs is based on the assumption that any organ that a CTC surgically removes and then furnishes to an Organ Procurement Organization or other CTC will be used for a Medicare transplant; however, this is not always the case. Accordingly, Medicare currently shares in the organ acquisition costs for some organs that are not transplanted into Medicare enrollees.
- This audit determined whether Medicare reimbursed CTCs in accordance with Federal statutory and regulatory requirements for the costs of acquiring organs that CTCs reported as Medicare usable organs between 2017 and 2022. We determined the cost to Medicare of reimbursing CTCs for the cost of acquiring organs that were not transplanted into Medicare enrollees.

What OIG Found

Medicare did not, in some instances, reimburse CTCs for organ acquisition costs for organs that CTCs reported as Medicare usable organs in accordance with Federal statutory and regulatory requirements.

- Of the 180 reported Medicare usable organs in our sample, Medicare reimbursed CTCs a total of $2.8 million for 43 organs that were not used in Medicare-covered transplants and 12 organs that were not transplanted at all. Based on Federal statutory requirements, Medicare should not have reimbursed the costs for these 55 organs. CMS guidance conflicts with Federal statutory requirements.
- On the basis of our sample results, we estimated that Medicare paid CTCs about $380 million for the costs of acquiring organs that were not used in Medicare-covered transplants during our 6-year audit period.

In addition, two CTCs could not provide any documentation to support a total of five organs, totaling $154,210 in unallowable Medicare reimbursement, that they reported as Medicare usable organs.

What OIG Recommends

We recommend that CMS direct the Medicare administrative contractors to recover the $154,210 paid to the two CTCs that lacked supporting documentation and that CMS revise Medicare guidance to align with Federal statutory requirements to count and report as Medicare usable organs only those organs transplanted into Medicare enrollees. The full recommendations are in the report.

CMS concurred with our first recommendation and did not specifically concur or nonconcur with our second recommendation.

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INTRODUCTION

WHY WE DID THIS AUDIT

Medicare reimbursed Certified Transplant Centers (CTCs) more than $3 billion for the acquisition of approximately 39,000 organs in calendar year (CY) 2023 (the most recent year for which these data are available).[1] Medicare reimburses CTCs for the cost of acquiring viable human kidneys, livers, hearts, lungs, pancreases, and intestines. Federal statute limits Medicare's reimbursement to the cost of acquiring organs that are transplanted into Medicare enrollees (Medicare usable organs). When a CTC submits its annual Medicare cost report, Medicare's share of organ acquisition costs is calculated by multiplying the CTC's total accumulated organ acquisition costs by the ratio of Medicare usable organs to total usable organs. Those costs are then reduced by the revenue that the CTC receives from transferring organs to Organ Procurement Organizations (OPOs) or other CTCs.

Medicare guidance to CTCs is based on the assumption that any organ that a CTC surgically removes and subsequently furnishes to an OPO or other CTC will be used for a Medicare transplant. Accordingly, nearly all organs transferred are counted as Medicare usable organs when calculating the CTC's Medicare reimbursement, even though some organs could be transplanted by another CTC into patients who are not covered by Medicare.[2] As a result, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare enrollees. The Centers for Medicare & Medicaid Services (CMS) proposed a rule in May 2021 that would change the way that Medicare organs are counted to eliminate this practice, but it did not finalize the rule.[3]

We conducted this audit to determine the cost to Medicare of reimbursing CTCs for the cost of acquiring organs that were not transplanted into Medicare enrollees.[4]

OBJECTIVE

Our objective was to determine whether Medicare reimbursed CTCs in accordance with Federal statutory and regulatory requirements for organ acquisition costs for organs that CTCs reported as Medicare usable organs.

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[1] Medicare reimbursement of organ acquisition costs increased from $1.27 billion in CY 2011 to $3.31 billion in CY 2023, a 160 percent increase, while the number of organs for which Medicare paid acquisition costs increased from approximately 22,000 to approximately 39,000, a 77 percent increase.

[2] This is a decades-old presumption that most procured kidneys were transplanted into Medicare enrollees. See 86 Fed. Reg. 25070, 25656-25676 (May 10, 2021); 86 Fed. Reg. 73416, 73484-73493 (Dec. 27, 2021).

[3] See 86 Fed. Reg. 25070, 25656-25676 (May 10, 2021); 86 Fed. Reg. 73416, 73484-73493 (Dec. 27, 2021).

[4] We are conducting several other audits of OPOs and CTCs, including an audit to determine whether CTCs are including only allowable costs for organ acquisition on their Medicare cost reports.

BACKGROUND

Medicare Reimbursement of Organ Acquisition Costs at Certified Transplant Centers

CTCs, also referred to as "transplant hospitals," are certified by CMS to transplant one or more types of organs, such as kidneys, hearts, lungs, and other solid organs. CTCs also provide other medical and surgical specialty services that are necessary for the care of transplant patients. As of this report's publication, there are approximately 250 CTCs certified by CMS to transplant organs. Medicare reimburses CTCs for the reasonable and necessary costs incurred in the acquisition of an organ.[5]

CTCs incur organ acquisition costs when surgically removing organs or when acquiring organs from an OPO or other CTC for transplantation. A CTC's allowable organ acquisition costs generally include the amount that the CTC paid for an organ acquired from an OPO or other CTC, organ transportation costs, costs for tissue typing services, operating room and other inpatient ancillary costs, physician costs associated with surgical removal of the organ, and indirect costs associated with transplant coordinators and administrators.

Section 1861(v)(1)(A) of the Social Security Act (the Act) states that "the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs." Under this statutory provision, Medicare will not pay for services provided to non-Medicare enrollees. This provision is referred to as the "anti-cross-subsidization principle."[6] Therefore, the costs of acquiring an organ are reimbursable by Medicare only when the organ has been acquired for use in a Medicare-covered transplant.[7] Although CMS guidance instructs CTCs not to count certain organs as Medicare usable organs, such as those used for research, the guidance also instructs CTCs to count *any* organ that is furnished to another OPO or CTC as a Medicare usable organ.[8]

Medicare's share of organ acquisition costs is calculated separately for each type of organ. The CTC's total accumulated organ acquisition costs are multiplied by the ratio of Medicare usable organs to total usable organs for that type of organ. Any organs that are determined to be

[5] A CTC must abide by the rules of the Organ Procurement and Transplantation Network (OPTN) and meet certain requirements for ensuring that it can perform organ transplants and provide quality patient care. The OPTN is a private organization under Federal contract with the Department of Health and Human Services, Health Resources and Services Administration (HRSA) to maintain a national registry for organ matching.

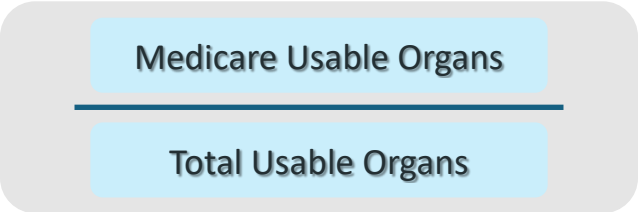
[6] See 68 Fed. Reg. 6682, 6683 (Feb. 10, 2003) for an example of the anti-cross subsidization principle.

[7] 42 CFR § 413.203. A Medicare-covered transplant is one for which Medicare paid the costs of an organ transplant into a Medicare enrollee.

[8] Medicare *Provider Reimbursement Manual–Part 1* (PRM-1), ch. 31, § 3115.

unusable are not included in the Medicare usable organ ratio.[9] The ratio of Medicare usable organs to total usable organs can be expressed as a fraction, as shown in Figure 1.

Figure 1: Ratio of Medicare Usable Organs to Total Usable Organs



Medicare's share of a CTC's organ acquisition costs is then reduced by the revenue that the CTC receives from furnishing organs to OPOs or other CTCs, as shown in Figure 2.

Figure 2: Calculation of Medicare's Reimbursement for Each Type of Organ Acquired

Medicare Cost Reports

Hospitals (including those with CTCs) submit Medicare cost reports (Form CMS-2552-10) to their respective Medicare administrative contractors (MACs) annually.[10] Each cost report is based on that hospital's financial and statistical records and, among other purposes, serves as the mechanism for the hospital to report costs. Accordingly, hospitals' Medicare cost reports record, among other things, the CTCs' organ acquisition costs. After receiving a cost report, the MAC performs a tentative settlement, then performs a desk review of the cost report and conducts an audit, as appropriate, before finalizing the cost report.[11, 12] CMS uses the financial and statistical data reported in the cost reports to set Medicare payment rates and calculate

[9] PRM-1, ch. 31, § 3116. Total organ acquisition costs include the cost of organs that are determined to be unusable, because Medicare continues to share in these costs.

[10] A MAC is the primary operational contact between the Medicare fee-for-service program and the health care providers (including CTCs) enrolled in the program. MACs perform many administrative duties, including desk reviews and audits of cost reports.

[11] Generally, cost reports may be reopened and revised within 3 years after the final settlement date. However, cost reports may be reopened and revised at any time if it is established that the final settlement of that cost report was procured by fraud or similar fault (42 CFR § 405.1885(b)).

[12] We have recently published several audit reports reviewing the desk review, audit, and reopening processes. These audit reports are published on the OIG website.

reimbursements for provider spending on organ acquisition, as well as medical education, uncompensated care, low-income patients, and high-cost Medicare cases.

HOW WE CONDUCTED THIS AUDIT

We used data from CMS's Healthcare Cost Report Information System (HCRIS) to identify all Medicare cost reports for hospitals with CTCs that had provider cost reporting periods ending between CYs 2017 and 2022 (audit period).[13] We included only those reports with Notice of Program Reimbursement (NPR) dates in CYs 2022 or 2023 that claimed Medicare reimbursement for organ acquisition costs.[14] We then conducted a multistage random sampling process (detailed in Appendices A and C), which resulted in a total sample of 180 Medicare usable organs that were reported on the hospitals' Medicare cost reports, with associated Medicare reimbursement totaling $12,288,194 to 12 CTCs.

To develop our sampling frame for the second stage of our sample, we obtained lists of Medicare usable organs from the 12 CTCs and reconciled the numbers of organs on the lists to what the CTCs reported on the selected Medicare cost reports. We removed from the sampling frame any organs for which the CTC could not provide documentation to support the number of Medicare usable organs reported on its cost report; we reviewed these organs separately.

For the 180 reported Medicare usable organs that we randomly selected, we reviewed the CTCs' documentation to determine whether any of the organs that were transplanted at the CTCs were used in a Medicare-covered transplant (footnote 7). For organs that were furnished to other CTCs or to OPOs, we matched data provided by the Department of Health and Human Services, Health Resources and Services Administration (HRSA) (footnote 5) to Medicare claims data to determine whether each organ in our sample was used in a Medicare-covered transplant. For any organs that were used in transplants that were not covered by Medicare, we identified the resulting Medicare reimbursement after calculating the CTCs' Medicare usable organ ratio by removing those organs from the Medicare usable organs.[15] For any organs that were not used in transplants, we identified the resulting Medicare reimbursement after calculating the CTCs' Medicare usable organ ratio by removing those organs from both the Medicare usable organs and the total usable organs (footnote 9).

[13] The HCRIS is a database maintained by CMS that stores annual cost reports submitted by Medicare-certified health care providers, such as hospitals and skilled nursing facilities. It collects and organizes data on a provider's financial performance, including costs, charges, utilization, and Medicare settlement information, to provide a comprehensive picture of health care costs and to aid in policy analysis, research, and financial management.

[14] After each provider's MAC reviews and optionally audits a provider's Medicare cost report, the MAC issues a final cost report settlement accompanied by an NPR. We used the date of issuance of the NPR in our methodology and included only NPR dates in CYs 2022 or 2023 to allow the cost reports to be reopened and revised (footnote 11) based on our audit findings.

[15] For the purpose of our audit, a transplant not covered by Medicare is either: (1) a transplant provided to a recipient who was not enrolled in Medicare or (2) a transplant into a Medicare enrollee for which the enrollee's primary health insurance coverage, other than Medicare, paid the full cost of the transplant.

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 details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Medicare did not, in some instances, reimburse CTCs for organ acquisition costs for organs that CTCs reported as Medicare usable organs in accordance with Federal statutory and regulatory requirements. We determined that 125 of the 180 sampled organs that CTCs reported as Medicare usable organs were used in Medicare-covered transplants. However, 55 of the 180 sampled organs were not used in Medicare-covered transplants (footnote 7) or were not transplanted at all even though they were reported on Medicare cost reports as Medicare usable organs, which resulted in $2,847,855 in Medicare reimbursement to CTCs.[16] More specifically, of the 55 organs, 43 organs were used in transplants that were not covered by Medicare and 12 organs were not transplanted at all.

Medicare reimbursed these amounts because it applied the provisions of relevant CMS guidance that conflict with the Act. CMS guidance instructs CTCs to count *any* organ that is furnished to another OPO or CTC as a Medicare usable organ (Medicare *Provider Reimbursement Manual–Part 1* [PRM-1], ch. 31, § 3115). However, Medicare payment for the procurement of organs not transplanted into Medicare enrollees is not aligned with the anti-cross-subsidization principle set forth in section 1861(v)(1)(A) of the Act.[17]

On the basis of our sample results, we estimated that Medicare paid CTCs approximately $379.9 million for the costs of acquiring organs that were not used in Medicare-covered transplants during our 6-year audit period.[18]

Furthermore, while developing our sampling frame, we found that two CTCs could not provide any documentation to support that a total of five organs were Medicare usable organs, as claimed on their Medicare cost reports. Because these CTCs did not maintain adequate documentation to support their claims, we determined that these five organs should not have been reported as Medicare usable organs on the two cost reports. The incorrect inclusion of

[16] Because the sampled CTCs were following CMS guidance when counting these organs as Medicare usable organs, we are not recommending that CMS recover this Medicare reimbursement.

[17] See 86 Fed. Reg. 73416, 73486-73487 (Dec. 27, 2021).

[18] Specifically, we estimated the Medicare reimbursement for organs that were not used in Medicare-covered transplants to be $379,895,793, with a two-sided 90-percent confidence interval of $220,433,069 to $539,358,518.

these organs on the two Medicare cost reports resulted in unallowable Medicare reimbursement totaling $154,210.

SOME SELECTED USABLE ORGANS REPORTED BY CERTIFIED TRANSPLANT CENTERS WERE NOT USED IN MEDICARE-COVERED TRANSPLANTS

We determined that 125 of the 180 sampled organs that CTCs reported as Medicare usable organs were used in Medicare-covered transplants. However, 55 of the 180 sampled organs were not used in Medicare-covered transplants or were not transplanted at all even though they were reported on Medicare cost reports as Medicare usable organs, which resulted in a total of $2,847,855 in Medicare reimbursement to CTCs (footnote 16). More specifically, 43 organs were used in transplants that were not covered by Medicare and 12 organs were not transplanted at all.

Organs Were Reported as Medicare Usable Organs but Were Used in Transplants That Were Not Covered by Medicare

Under the statutory provision referred to as the anti-cross-subsidization principle (the Act § 1861(v)(1)(A)), Medicare will not pay for the costs of services provided to non-Medicare enrollees.

Contrary to the anti-cross-subsidization principle of the Act, for 43 sampled organs that CTCs reported as Medicare usable organs, the CTCs used the organs in transplants that were not covered by Medicare. Forty-two of these sampled organs were furnished to another CTC or OPO and were then used in transplants that were not covered by Medicare. By reporting these 42 organs—which were not used in Medicare-covered transplants—as Medicare usable organs, the selected CTCs received $2,460,116 in Medicare reimbursement. All 12 of our sampled CTCs had at least 1 sampled organ that was used in a non-Medicare-covered transplant.

With respect to the other sampled organ (of the 43) that a CTC reported as a Medicare usable organ, the organ was transplanted at the selected CTC to a recipient who was enrolled in Medicare (with Medicare as that individual's secondary insurer). PRM-1, chapter 31, § 3104, instructs that providers must submit a bill to Medicare when payment from the primary insurance is insufficient to cover the entire cost of the transplant. If the provider accepts the primary insurance payment as payment in full, a bill to Medicare is not required and the organ is not counted as a Medicare usable organ. In this case, the CTC billed only the recipient's primary insurance and did not bill Medicare for this transplant. The CTC said that because of staff turnover, it could not explain why Medicare was not also billed for the transplant. Because Medicare was not also billed for the transplant, the CTC could not demonstrate that Medicare bore any additional cost for the acquisition of the organ. Accordingly, by reporting this organ as a Medicare usable organ, this selected CTC received $105,602 in Medicare reimbursement.

Organs Were Not Used in Transplants but Were Reported as Medicare Usable Organs

Contrary to the anti-cross-subsidization principle of the Act, as well as the provisions of PRM-1, chapter 31, §§ 3115 and 3116, four CTCs reported a total of 12 sampled organs as Medicare usable organs that were not transplanted at all. These 4 CTCs stated that all 12 of these organs were associated with deceased donors and were furnished to OPOs for surgical removal by the OPOs. For each of these 12 organs, though, the OPOs either used the organs for research, discarded them, or never surgically removed the organs.[19, 20] Each of these four CTCs told us that it had followed CMS guidance when reporting these organs as Medicare usable organs. As a result, these four CTCs received a total of $282,137 in Medicare reimbursement for the cost of acquiring organs that were not used in Medicare-covered transplants.

Selected Certified Transplant Centers and Medicare Administrative Contactors Followed CMS Guidance That Conflicts With Federal Statute

Medicare reimbursed these amounts because CMS applied the provisions of its guidance (PRM-1, ch. 31, § 3115) that conflict with the anti-cross-subsidization principle set forth in section 1861(v)(1)(A) of the Act.

This discrepancy between the Act and CMS guidance has its roots in decisions that were made beginning more than 50 years ago. When Medicare added the end-stage renal disease (ESRD) benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare enrollees receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.[21] As Medicare added benefits for transplantation of nonrenal organs and added provisions for the reimbursement of costs to acquire nonrenal organs, Medicare guidance (PRM-1, ch. 31, § 3115.A) retained this earlier presumption that the ultimate transplant recipient was unknown but was likely a Medicare enrollee. Accordingly, guidance in PRM-1 does not instruct the CTCs or MACs to determine whether the organs that are furnished to other CTCs or OPOs are then used in Medicare-covered transplants.

CMS has formally acknowledged that allowing CTCs to count *all* organs sent to other CTCs or OPOs as Medicare usable organs is contrary to the anti-cross-subsidization principle of the Act. In the Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) proposed notice-and-comment rulemaking, CMS summarized the current guidance, noting that the guidance

[19] We identified several instances in which a CTC furnished the body of a deceased donor to an OPO that then surgically removed multiple organs.

[20] In one case, the OPO did not surgically remove the organ because it determined that the donor was not deceased, but the CTC still reported the organ as a Medicare usable organ on its Medicare cost report.

[21] Discussion of this presumption may be found in 54 Fed Reg. 5619 (Feb. 6, 1989) regarding the promulgation of 42 CFR § 413.179 (governing OPOs and CTCs), which was later moved to and split between 42 CFR §§ 413.202 (OPOs) and 413.203 (CTCs) (62 Fed. Reg. 43657 (Aug. 15, 1997)). See also Part A Intermediary Letter No. 74-23, "Determining Costs Associated with the Renal Disease Provisions of P.L. 92-603" (July 1974).

requires CTCs to presume that organs sent to other CTCs or OPOs will be transplanted into Medicare enrollees, "even if they are not" (86 Fed. Reg. 25070, 25664 (May 10, 2021)). CMS added that "[a]s a result, through unintended consequences, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare [enrollees]" (86 Fed. Reg. at 25665).

Accordingly, in May 2021, CMS proposed to add a new regulation that would explicitly require CTCs to accurately count and report Medicare usable organs in their Medicare cost reports, "to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare" (86 Fed. Reg. at 25667). The proposed new regulation would require CTCs to count and report as Medicare usable organs only those organs transplanted into Medicare enrollees (86 Fed. Reg. at 25702). However, in the FY 2022 IPPS Final Rule, CMS stated that it did not finalize these new regulations because of public comments that expressed concerns over the potential loss of revenue that some providers (e.g., children's hospitals) might experience because of this change.[22]

Thus, with respect to the organ acquisition costs that we reviewed for our audit period, CMS guidance in PRM-1 remains in conflict with the anti-cross-subsidization principle of the Act. The CTCs with which we communicated for this audit generally told us that they adhered to the guidance in PRM-1 when counting and reporting Medicare usable organs. In turn, the MACs told us that they also followed CMS guidance in PRM-1 when reviewing the Medicare cost reports submitted by the CTCs.

Medicare Reimbursed Organ Acquisition Costs for Organs That Were Not Used in Medicare-Covered Transplants

Fifty-five of the 180 sampled organs were not used in Medicare-covered transplants even though they were reported as Medicare usable organs, which resulted in $2,847,855 in Medicare reimbursement to CTCs. On the basis of our sample results, we estimated that of the $1,406,040,094 in Medicare reimbursement that CTCs received for the cost of acquiring organs during our audit period, CTCs received $379,895,793 for organs that were not used in Medicare-covered transplants.

TWO SELECTED CERTIFIED TRANSPLANT CENTERS COULD NOT PROVIDE DOCUMENTATION TO SUPPORT THE TOTAL MEDICARE USABLE ORGANS THAT THEY REPORTED

Federal regulations state that providers are required to maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare program (42 CFR § 413.20(a)).

When developing our sampling frame for the second stage of our sample, we found that two CTCs could not provide any documentation to support a total of five organs that they reported

[22] 86 Fed. Reg 73416, 73488 (Dec. 27, 2021).

as Medicare usable organs on their Medicare cost reports. We removed these five organs from our sampling frame for the second stage of our sample, and thus these organs are not included in the estimate of Medicare reimbursement for organs that were not used in Medicare-covered transplants during our audit period.

One CTC told us that it believed that it may have incorrectly reported three kidneys that were designated for research—not transplant—as Medicare usable organs. The other CTC told us that it could not determine why it reported two additional pancreases (above and beyond those used for Medicare-covered transplants or furnished to other CTCs or OPOs) as Medicare usable organs. The incorrect inclusion of these five organs on the two Medicare cost reports resulted in unallowable Medicare reimbursement totaling $154,210.

RECOMMENDATIONS

- We recommend that CMS direct the relevant MAC to recover $154,210 in Medicare reimbursement paid to two CTCs that could not provide documentation to support the numbers of Medicare usable organs that they reported on their Medicare cost reports.

- We recommend that CMS revise Medicare guidance to CTCs to align with Federal statutory requirements to count and report as Medicare usable organs only those organs transplanted into Medicare enrollees, which could have saved Medicare $379,895,793 during our audit period.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our first recommendation and stated that it would direct the MAC to recover the associated Medicare reimbursement "consistent with relevant law and [CMS's] policies and procedures."

CMS did not specifically concur or nonconcur with our second recommendation. CMS referred to the public comments it received on the FY 2022 IPPS proposed rule and stated that in the CY 2023 Outpatient Prospective Payment System proposed rule it had requested "information on alternative methodologies for counting organs for purposes of calculating Medicare's share of organ acquisition costs." CMS added that it was reviewing the comments that it received and would continue to explore options that it would propose in future rulemaking. CMS also stated that it would take our recommendation, as well as our findings, into consideration as it determines appropriate next steps and that it would update guidance, including instructions in the *Provider Reimbursement Manual*, as necessary "to ensure alignment with any newly established regulations."

CMS also provided technical comments, which we addressed as appropriate.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We used HCRIS data (footnote 13) to identify all Medicare cost reports for hospitals with CTCs that had provider cost reporting periods ending during our audit period. We included only those reports with NPR dates in CYs 2022 or 2023 that claimed Medicare reimbursement for organ acquisition costs (footnote 14). We further refined our scope to include only Medicare cost reports that reported acquiring more than 10 Medicare usable organs. This resulted in a total of 215 Medicare cost reports, representing 122 unique CTCs, for our sampling frame. Collectively, these CTCs reported acquiring 20,135 Medicare usable organs, with Medicare's share of organ acquisition costs totaling $1,497,205,683 and actual Medicare reimbursement to the CTCs totaling $1,406,040,094.

We then conducted a multistage random sampling process (detailed in the Methodology section below), which resulted in a total sample of 180 reported Medicare usable organs with associated Medicare reimbursement totaling $12,288,194.

For the 180 reported Medicare usable organs that we randomly selected, we reviewed the associated CTCs' records, the records of the other CTCs and OPOs to which the selected CTCs furnished organs, and Medicare claims data to determine whether the organs were used in Medicare-covered transplants (footnote 7).

We did not perform an overall assessment of CMS's internal control structures. Rather, we limited our review to those controls that were relevant to our objective. We also queried the individual selected CTCs on internal controls they had in place to help ensure that they correctly reported Medicare usable organs on their Medicare cost reports.

We performed audit work from April 2024 through June 2026.

METHODOLOGY

We took the following steps to accomplish our objective:

- Reviewed applicable Federal laws, regulations, and guidance
- Obtained and used CMS's HCRIS data to identify all Medicare hospitals' cost reports that:
    - Covered provider cost reporting periods ending during our audit period
    - Had NPR dates (footnote 14) in CYs 2022 or 2023
    - Reported Medicare-reimbursable organ acquisition costs

- Assessed the reliability of the HCRIS data for these CTCs by comparing them to data from cost reports actually submitted by the CTCs

- Selected a random sample of 12 Medicare cost reports from the 215 cost reports in our sampling frame

- Obtained lists of the Medicare usable organs that the respective CTCs reported on the 12 selected cost reports

- Reconciled the number of organs on the lists of Medicare usable organs to what the CTCs reported on the selected Medicare cost reports

- Randomly selected 15 Medicare usable organs from each of the Medicare usable organ lists provided by the 12 CTCs, which resulted in a total sample of 180 organs

- Obtained and reviewed the selected CTCs' documentation to confirm that any organs that were transplanted at the CTC were used in a Medicare-covered transplant

- Obtained organ tracking data from HRSA (footnote 5) for organs furnished to other CTCs or to OPOs and matched these data on the sampled organs to Medicare claims data to determine whether each organ in our sample was used in a Medicare-covered transplant

- Obtained and reviewed documentation from the OPO or CTC to which each organ was furnished to verify whether the organ was transplanted and to obtain information on the primary health insurance of the organ recipient at the time of transplantation

- Contacted the relevant OPOs to determine the final disposition of organs for which there were no identifiable recipients in the HRSA data

- Recalculated what the CTCs' Medicare reimbursement would have been if the non-Medicare organs in our sample had been properly classified to determine the Medicare reimbursement for organs that were not used in a Medicare-covered transplant

- Estimated the total Medicare reimbursement amount that CTCs received for the cost of acquiring organs during our audit period for organs that were not used in Medicare-covered transplants

- 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: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 215 Medicare cost reports representing 122 unique CTCs. Each of the 215 cost reports included more than 10 Medicare usable organs acquired by the CTCs. Collectively, these Medicare cost reports included 20,135 Medicare usable organs that the 122 CTCs reported, with Medicare's share of organ acquisition costs totaling $1,497,205,683 and actual Medicare reimbursement to the CTCs totaling $1,406,040,094.

SAMPLE UNIT

The primary sample unit was a Medicare cost report. The secondary sample unit was a reported Medicare usable organ.

SAMPLE DESIGN AND SAMPLE SIZE

We used a multistage random sample design that we executed in two stages. The first stage consisted of a simple random sample of 12 Medicare cost reports. The second stage consisted of a simple random sample of 15 reported Medicare usable organs from each of the 12 sampled Medicare cost reports, for a total of 180 sample units (i.e., 180 organs).

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

For the first stage of our sampling process, we sorted the Medicare cost reports in ascending order by the cost report record number and then consecutively numbered the cost reports in the sampling frame. After generating the random numbers according to our sample design, we selected the corresponding frame items for use in the second stage (Appendix C).

For the second stage, we sorted the Medicare usable organs in ascending order by their acquisition date and then consecutively numbered the organs in the sampling frame for each selected cost report. After generating the random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS statistical software to calculate the point estimate and two-sided 90-percent confidence interval for the total amount of Medicare reimbursement with respect

to the acquisition cost that was made for any reported Medicare usable organ in the sampling frame that was not transplanted into a Medicare enrollee (Appendix C).

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 1: Stage 2 Sample Details and Results

Medicare Cost Report Number	Medicare Usable Organs in Frame	Medicare Reimbursement for Organ Acquisition in Frame	Sample Size	Value of Sample	Number of Medicare Usable Organs Not Used in Medicare-Covered Transplants in Sample	Medicare Reimbursement for the Cost of Acquiring Organs Not Used in Medicare-Covered Transplants in Sample
1	106	$8,223,118	15	$1,110,145	5	$309,331
2	113	7,976,943	15	1,032,805	1	67,752
3	148	11,179,339	15	1,176,733	1	52,649
4	200	10,062,586	15	739,955	4	152,667
5	166	11,570,208	15	1,092,480	4	274,880
6	41	1,682,800	15	653,384	1	42,064
7	76	4,280,250	15	889,196	8	322,597
8	206	25,500,687	15	1,865,748	3	420,444
9	69	7,200,538	15	1,560,965	2	207,991
10	192	5,029,742	15	406,093	8	83,609
11	101	7,224,699	15	1,057,680	7	420,847
12	16	749,767	15	703,010	11	493,024
Totals	**1,434**	**$100,680,677**	**180**	**$12,288,194**	**55**	**$2,847,855**

Table 2: Estimated Value of Medicare Reimbursement for the Cost of Acquiring Organs Not Used in Medicare-Covered Transplants in the Sampling Frame (*Limits Calculated at the 90-Percent Confidence Level*)

Point estimate	$379,895,793
Lower limit	220,433,069
Upper limit	539,358,518

APPENDIX D: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 29, 2026

TO: Megan Tinker
Chief of Staff
Office of Inspector General

FROM: Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Conflicting CMS Guidance and Federal Statutory Requirements Cost Medicare $380 Million for Organs Not Transplanted Into Medicare Enrollees* (OAS-25-07-124)

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.

The Medicare Program supports organ transplantation by providing an equitable means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant and separately reimburses transplant hospitals (THs) on a reasonable cost basis.[1]

A certified transplant center's (CTC's) Medicare cost report includes direct costs, administrative and general costs, and overhead costs associated with procuring organs. To assist CTCs in reporting their costs, CMS provides guidance on organ donation and transplantation reimbursement in the *Provider Reimbursement Manual* (Manual), Part 1, Ch 31. Specifically, § 3115 states that "…CTCs are responsible for accurately counting both Medicare and non-Medicare organs to ensure that costs are properly allocated on the [Medicare cost report] and further defines Medicare usable organs to include "organs transplanted into Medicare beneficiaries…and organs sent to other CTCs…"

In the FY 2022 Inpatient Prospective Payment System (IPPS) proposed rule, CMS proposed a new rule which would have required CTCs to count and report only organs transplanted into Medicare enrollees as Medicare usable organs (86 Fed. Reg. at 25702). Due to the public comments received on the FY 2022 IPPS proposed rule, in the CY 2023 Outpatient Prospective Payment System (OPPS) proposed rule, CMS requested information on alternative methodologies for counting organs for purposes of calculating Medicare's share of organ acquisition costs. CMS is reviewing the comments that were received and continues to explore options to propose in future rulemaking.

[1] 42 CFR 412.2(e)(4) and 412.113(d)

In addition to being committed to reducing health care costs and spending, CMS is also committed to improving patient care. CMS will continue to balance both priorities in accordance with federal rules and regulations.

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

OIG Recommendation 1

The Centers for Medicare & Medicaid Services should direct the relevant MAC to recover $154,210 in Medicare reimbursement paid to two CTCs that could not provide documentation to support the numbers of Medicare usable organs that they reported on their Medicare cost reports.

CMS Response

CMS concurs with this recommendation. CMS will direct the Medicare Administrative Contractor to recover identified reimbursements associated with OIG's audit consistent with relevant law and the agency's policies and procedures.

OIG Recommendation 2

The Centers for Medicare & Medicaid Services should revise Medicare guidance to CTCs to align with Federal statutory requirements to count and report as Medicare usable organs only those organs transplanted into Medicare enrollees, which could have saved Medicare $379,895,793 during our audit period.

CMS Response

Changes regarding requirements for counting and reporting of Medicare usable organs require notice-and-comment rulemaking. As stated above, in the FY 2022 IPPS rulemaking cycle, CMS proposed to revise and codify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries. However, due to the number and nature of the comments received, the proposal was not finalized. Subsequently, CMS included a request for information in the CY 2023 OPPS proposed rule. CMS is reviewing the comments that were received and continues to explore options to propose in future rulemaking. CMS will take this recommendation, as well as OIG's findings, into consideration as we determine appropriate next steps. CMS will update guidance, including Manual instructions, as necessary to ensure alignment with any newly established regulations.

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