

Transforming Organ Donation in America

Appendix A

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List of Appendices

Appendix A: Overview of OPO Funding and Alternative Mechanisms, and Table A: Key Data Points and Table B: Relevant Government Investigations into Organ Procurement Organization Finances

Appendix B: Data on Five Historical OPO Mergers

Appendix C: Data on Historical OPO Leadership Changes

Appendix D: Information to Incentivize Competition and Maintain Continuity of Service

Appendix E: OPO-Specific Factors for Consideration During Selection and Consolidation

Appendix F: Transplant Waitlist by State and Organ

Appendix G: Organ Procurement Organizations (OPOs) Tiered by Centers for Medicare & Medicaid Services (CMS) Final Outcome Measures

Appendix A: Overview of OPO Funding and Alternative Mechanisms

Context

In December 2019, the Department of Health and Human Services (HHS) issued a Notice of Proposed Rulemaking (NPRM) indicating that thousands of potential organs go unrecovered by organ procurement organizations (OPOs) each year.¹²⁹ At the same time, it published data showing the majority of the nation's OPOs were failing to meet the proposed objective outcome measures for organ recovery.¹³⁰ In formal remarks announcing the rule, HHS Secretary Alex Azar noted: "Our broken system of procuring organs and supporting kidney donors costs thousands of American lives each year."¹³¹

Research suggests that, at full potential, there could be as many 28,000 additional organs from deceased individuals per year available for transplant—with OPO practices playing a key role in closing the existing gap.¹³² HHS estimates that just bringing all OPOs into compliance with minimum performance standards would result in an additional 5,000 to 10,000 more lifesaving transplants every year.¹³³

This underlines that the organ procurement system does not currently recover a high enough proportion of viable organs from existing donors and misses many potential donors (e.g., those over 65, after cardiac death, or at hospitals without ICUs). The societal cost is massive, with 33 people dying every day for lack of an organ transplant.¹³⁴ Because there is an insufficient number of kidneys, many people stay on dialysis much longer than would otherwise be necessary, experiencing a reduced quality of life. Medicare spending on patients with kidney failure is \$36 billion a year—almost 1 percent of the entire 2019 federal budget¹³⁵—of which a significant amount could be avoided were more kidneys available for transplant.¹³⁶ The estimated potential organs that go unrecovered each year includes 17,000 kidneys that are not procured or transplanted, which equates to \$40 billion over 10 years in forgone dialysis costs to Medicare and the taxpayer.¹³⁷

129 [Medicare and Medicaid Programs \(NPRM\)...](#), 84 Fed. Reg. 70628.

130 Kindy and Bernstein, "[Trump administration seeks to make thousands more transplant organs available.](#)"

131 "[Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply,](#)" US Department of Health and Human Services.

132 [Reforming Organ Donation in America](#), The Bridgespan Group, January 2019. University of Pennsylvania analysis of 2012–2014 Agency for Healthcare Research and Quality of State Inpatient Databases data; Bridgespan estimate of lives saved, cost savings, and productivity.

133 [Medicare and Medicaid Programs \(NPRM\)...](#), 84 Fed. Reg. 70628.

134 Kindy et al., "[Lives Lost, Organs Wasted.](#)"

135 "[The Federal Budget in 2019: An infographic,](#)" Congressional Budget Office, April 2020.

136 Alex M Azar, "[Remarks to the National Kidney Foundation,](#)" National Kidney Foundation, March 2019.

137 It is important to note that these figures represent the "full potential" of the system, assuming 100-percent donation rates and 100-percent organ utilization. Even achieving a portion of this represents significant lives saved and dialysis costs avoided. Figure on kidneys cited in [Reforming Organ Donation in America](#) (Bridgespan). Cost savings based on Bridgespan analysis and methodology established by Held, McCormick, et al. P J Held, F McCormick, et al., "[A Cost-Benefit Analysis of Government Compensation of Kidney Donors.](#)" *American Journal of Transplantation* (March 16, 2016): 877-85.

While regulatory reforms for OPOs are underway, structural reform of OPO finances offers another, complementary way to align OPO practices with patients' interests. OPO finances have received Congressional attention in recent months from both chambers. In February 2020, the Senate Finance Committee, led by Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR), wrote an oversight letter regarding “concerning allegations of oversight gaps with respect to our nation’s Organ Procurement and Transplantation Network (OPTN), the United Network for Organ Sharing (UNOS), and the network of 58 organ procurement organizations (OPOs) that UNOS monitors. Recent reports of lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted lead us to question the adequacy of UNOS’s oversight of these OPOs.”¹³⁸

In the House, Representatives Katie Porter (D-CA) and Karen Bass (D-CA), chairwoman of the Congressional Black Caucus, wrote to Secretary Azar in July 2020, noting that “there may be up to 28,000 available organs from deceased donors annually which are not procured for transplantation. This results from various problems, ranging from financial impropriety to quality control issues—including leaving transplantable organs on commercial flights—to failure to hire enough staff to respond to all donation cases.”¹³⁹

Overview of OPO reimbursement and financial structure

OPOs are funded on a cost-reimbursement basis, with Medicare and transplant centers covering 100 percent of costs for activities related to organ procurement. This arrangement appears to be unique in US healthcare.¹⁴⁰ In theory, this full-reimbursement model was created to ensure that OPOs always have incentives to recover organs.¹⁴¹ However, this has not always played out in practice, as OPOs may choose not to pursue donors from whom only one or two organs are transplantable.

For example, in 2013, the Association of Organ Procurement Organizations (AOPO) wrote to the White House Office of Management and Budget regarding the previous metrics: “The current system has created a disincentive for OPOs to pursue organ recovery when there may be a lower yield of organs transplanted per donor. ... If an OPO is in jeopardy of decertification ... the OPO is incentivized (for fear of being decertified) to not pursue, or even evaluate the potential for donation of [donors with only 1 or 2

138 Grassley et al., “Letter to Brian Shepard, CEO of UNOS.” February 2020.

139 Representative Katie Porter and Representative Karen Bass, [Letter to the Department of Health and Human Services and Center for Medicare & Medicaid Services](#), July 10, 2020.

140 In our research to identify any major segments of the healthcare system funded in this fashion, the single possible comparable we found was Critical Access Hospitals. “Critical Access Hospital” is a designation given to eligible rural hospitals by CMS, designed to reduce the financial vulnerability of rural hospitals by ensuring costs are covered via a cost-based reimbursement model. See “[What are the benefits of CAH status?](#)”, Rural Health Information Hub.

141 Jerry Mande, former legislative aide to Al Gore during the drafting of the National Organ Transplant Act (NOTA), wrote in a letter to Secretary Azar: “Our goal in writing the legislation [NOTA] was to create a system that would ethically pursue every transplantable organ each time one might be available, leading to as many viable organ recoveries as possible, significantly and equitably increasing the number of successful organs transplanted to improve and save lives. Unfortunately, the infrastructure we put in place has not yet achieved its intended goal and, historically, HHS, CMS, and HRSA have been largely responsible for this shortcoming. The system has enabled systemic OPO underperformance through an over-reliance on government contractors operating with limited oversight.” See Jerry Mande, “[Letter to Secretary Alex Azar](#),” August 12, 2019.

organs available for transplant]. This practice results in fewer organs being transplanted, and more lives lost.”¹⁴²

The recent HHS proposed rule notes: “There were concerns about the donor yield outcome measure. ... We are concerned that potentially transplantable organs may be wasted, exacerbating the organ shortage problem.”¹⁴³ While the proposed changes to OPO performance metrics may address some of this regulatory disincentive, it is clear that the OPO full-reimbursement model has been insufficient to drive its intended goal of ensuring OPOs pursue all donation opportunities. Alternative financing models could better align incentives, as well as harmonize with a new regulatory framework.

OPOs are reimbursed based on self-reported costs—passing these costs along to the Centers for Medicare & Medicaid Services (CMS) and transplant centers—regardless of performance. The current OPO payment model does not give OPOs an incentive to reallocate resources in order to increase the number of organs available for transplant, and it reimburses OPOs for costs that may not, in fact, help produce the desired outcomes. This may have contributed to a historical increase in industry costs overall. An analysis of Medicare cost report data found that between 1996 and 2014, total costs for organ acquisition reported by US hospitals with at least one Medicare-certified transplant program increased by 253 percent, compared to the volume of transplants and donors increasing by just 45 percent and 57 percent, respectively.¹⁴⁴ OPO organ acquisition revenues nationally total approximately \$3 billion annually.¹⁴⁵

Costs by Organ

There are **special rules for kidneys**, established due to the unique way Medicare covers end-stage renal disease. Because there are substantial taxpayer cost savings from kidney transplants through avoided dialysis costs, CMS tries to ensure OPOs are never financially disincentivized from recovering kidneys.¹⁴⁶ OPOs are guaranteed reimbursement for kidneys on the condition that they submit a cost report to detail their kidney procurement costs and calculate the related charge to Medicare, known as the standard acquisition charge (SAC). A 2020 paper on kidney costs published in the *American Journal of Transplantation* reported a range between \$24,000 and \$56,000 across different OPOs over a three-year period.¹⁴⁷

At the end of each fiscal year, if an OPO’s kidney-recovery expenses exceed its total Medicare kidney reimbursements, Medicare will pay the difference via an additional payment—even if the OPO generates positive margins in other lines of business (e.g., tissue procurement, other organ categories) that could cover these costs. If the Medicare reimbursement exceeds the OPO’s allowable kidney-recovery expenses, the

142 “Unaddressed Implications of the Proposed Changes to the Conditions of Coverage for Organ Procurement Organizations (HHS/CMS Rule 0938-AR54),” APOPO, October 2013.

143 *Medicare and Medicaid Programs (NPRM)*..., 84 Fed. Reg. 70628.

144 Brigitte Sullivan, “Maximizing Medicare Cost Report Reimbursement.” Presentation and analysis available on the [Organ Donation Alliance website](#).

145 *Medicare and Medicaid Programs (NPRM)*..., 84 Fed. Reg. 70628.

146 P.J. Held, F. McCormick, A. Ojo, and J.P. Roberts, “A cost-benefit analysis of government compensation of kidney donors,” *American Journal of Transplantation* 2016; 16: 877-885.

147 P.J. Held et al., “The cost of procuring deceased donor kidneys: Evidence from OPO cost reports 2013-2017,” *American Journal of Transplantation* 2020; 20 (4): 1087-1094.

OPO is required to repay Medicare the excess amount. While this attempts to drive cost neutrality, in practice kidney recoveries occur in conjunction with recovery of other organs in a majority of cases, so it can be difficult to isolate the costs specific to kidneys, especially overhead and other operating expenses.¹⁴⁸

The 100 percent reimbursement for kidney costs creates incentives for cost-shifting, as OPOs have a financial interest in showing Medicare that their kidney-recovery costs exceed their reimbursements. Particularly for indirect costs (e.g., overhead, management), OPOs have the incentive to allocate as many costs as possible to kidney recovery rather than spreading them across multiple organ categories. This may impact the actual clinical practices of organ procurement, as some costs can be allocated to kidneys prior to recovery so long as there is an initial intent to procure one (even if those kidneys are not in fact suitable for donation).

For other organs, OPOs charge transplant centers a preset SAC, which is typically calculated based on the OPO's related costs and the number of organs procured in the previous year. SACs include both direct costs (e.g., operating room time) and indirect costs (e.g., management salaries, travel, marketing, and overhead). Indirect costs that might rightly be incurred by procurement of non-renal organs may in fact end up allocated to kidneys, driven by the practice of Medicare covering 100 percent of kidney procurement costs. In our review of published CMS guidance (e.g., the Provider Reimbursement Manual, Chapter 31), we did not find an exhaustive list of specific, prohibited, or allowed indirect expenses (a partial list is offered on page 31-18) or detailed guidance of how to allocate allowable indirect expenses across organs.

While transplant centers technically can negotiate SACs with OPOs, it is important to understand the context in which these negotiations occur. OPOs are geographic monopolies and subject only to limited financial disclosure requirements, leaving the transplant center with limited visibility into OPO costs and little negotiating power. As transplant centers have no other means under the law of acquiring organs, they are ultimately billed for organs at the discretion of the OPOs, experiencing price variation dependent on the macroeconomic environment as well as absorbing operating costs that OPOs have no structural pressures to contain. The cost-reimbursement system means that OPOs can pass through all expenses to payors with little accountability and with limited incentive to allocate resources efficiently. In cases where a transplant center receives an organ from an OPO outside of its designated service area (DSA), it is responsible for paying the OPO's additional transportation costs, with minimal transparency into these costs or the extent to which they increase SAC fees.

There is also wide variability in SACs, both in the total amount and how they are calculated:¹⁴⁹ kidney costs reportedly range between \$24,000 and \$56,000 across

148 While the exact percentage of kidney donations that occur in the context of multi-organ donors (vs. kidney-only donors) is not readily available, multiple studies have relied on samples showing that in a majority of cases kidneys are recovered with other organs. Estimates in three studies had a range of 68 percent to 80 percent of all kidney donations from deceased donors coming from multiple-organ donors. Giana Katsaros et al., "Nationwide Outcomes after Renal Transplantation from Kidney-Only versus Multiple-Organ Deceased Donors," *American Surgery* 85 no. 9 (September 1, 2019): 1066-1072. H. Cholewa et al., "Early and Long-Term Outcomes of Kidney Grafts Procured From Multiple-Organ Donors and Kidney-Only Donors," *Transplantation Proceedings* 48 no. 5 (June 2016): 1456-60. D. Castello et al., "Does multiorgan versus kidney-only cadaveric organ procurement affect graft outcomes?" *Transplantation Proceedings* 45 no. 3 (April 2013): 1248-50.

149 P.J. Held et al., "The cost of procuring deceased donor kidneys: Evidence from OPO cost reports 2013-2017," *American Journal of Transplantation* 2020; 20 (4): 1087-1094.

different OPOs, for example.¹⁵⁰ As three OPO executives wrote in a 2015 paper on pancreas transplants (“The Economic Aspects of Pancreas Transplant: Why Is the Organ Acquisition Charge So High?”), “although often referred to as a ‘standard acquisition charge’ (SAC), it is better named an OAC [organ acquisition charge] as its components vary from organ to organ and from OPO to OPO. There is very little standard about it.”¹⁵¹

Higher SAC fees may carry real financial consequences for transplant centers, which are typically reimbursed by commercial payors for the transplant admission, including organ charges, under a fixed case rate (i.e., a fixed payment inclusive of services for the case from admission to the point of discharge). The financial burden of these commercial cases that exceed the case rate is, in most cases, shifted to the transplant center, contributing to overall transplant center costs and impacting the center’s bottom line. As a result of such increased SAC fees, transplant centers have fewer resources available to invest in other key programming. Additional transparency around SAC fees would allow government and researchers to determine if, and to what extent, increased SAC fees correlate with organ discard rates.

Additional Activities That May Increase the Costs to Procure Organs

“Unallowable” and “unsupported” costs. Officials in both the legislative and executive branches have also suggested that the current system allows OPOs to build in costs that are unrelated to saving lives. As referenced in a 2019 letter from Senators Grassley and Todd C. Young (R-IN) to the HHS Office of the Inspector General (HHS OIG), previous HHS OIG audits have found OPOs billing taxpayers for “unallowable” and “unsupported” costs.¹⁵² Senators Grassley and Young noted:

*Six years have elapsed since the Office of Inspector General (OIG) issued a report unearthing unallowable Medicare reimbursement claims and highlighting other oversight deficiencies in the organ procurement and transplantation system. That 2013 report indicates that selected OPOs improperly billed the Medicare program for alcohol and entertainment expenses as well as lobbying-related expenditures. Earlier OIG reports also discuss expenditures by OPOs on public education, which in some cases have included football game tickets, sponsorship of a golf tournament, a retirement party, a New Year’s Eve celebration, a parade float, professional musical entertainment, and blocks of hotel rooms amounting to over \$70,000 for a single event.*¹⁵³

Senators Grassley and Young went on in their 2019 letter to request the OIG respond to a number of questions regarding the extent to which the office has pursued additional audits of “unallowable or unsupported expenses,” given the examples surfaced in earlier investigations.

In recent years, some OPOs have established foundations to conduct a range of activities, including those with expenses CMS does not consider allowable for OPOs

150 P.J. Held et al., “The cost of procuring deceased donor kidneys: Evidence from OPO cost reports 2013-2017.” *American Journal of Transplantation* 2020; 20 (4): 1087-1094.

151 Richard S. Luskin, Dara L. Washburn, and Susan Gunderson, “The Economic Aspects of Pancreas Transplant: Why Is the Organ Acquisition Charge So High?” *Current Transplantation Reports* 2(2), June 2015

152 “Review of OneLegacy’s Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs,” US Department of Health and Human Services, Office of Inspector General, January 2020.

153 2019 oversight letter, United States Senate, December 18, 2019.

under Medicare cost-reporting rules. As Rep. Porter noted in her 2019 letter to HHS regarding the OPO in her district: “According to the [Los Angeles OPO OneLegacy] foundation’s most recently available tax filings, the foundation received \$20–30 million in OPO funds in 2016. This money, rather than going to patients in need, now funds many of the same expenses that the OIG deemed impermissible, such as costs related to the Rose Bowl.”¹⁵⁴

Additional expenditures. The cost-based model for organs allows for annual increases in indirect costs. Our own interviews with organ procurement experts reveal expenditures, particularly at the end of a year, that drive up reimbursable costs. The extent and magnitude of such practices is unknowable without transparency into OPO finances, but we have not identified any disincentives that would discourage such a practice.

Because executive salaries can be allocated as indirect costs to per-organ cost-based reimbursements, the July 2020 oversight letter from Reps. Porter and Bass stressed the need for HHS to ensure that taxpayer dollars are not spent on overly generous compensation for board members or organization leadership.¹⁵⁵ Currently, executive salaries do not correlate with whether an OPO is considered passing or failing according to new proposed OPO outcome measures (see [Appendix A](#), a compendium of OPO executive salaries and other key financial information).

For-Profit Tissue Recovery and Oversight of OPO Finances

SACs and Medicare reimbursements represent the entirety of OPO revenue for organ recovery. However, OPOs are also compensated by tissue-processing partners (some of which are for-profit corporations) for procuring tissue, cornea, bone, and skin—recovering these from donors by virtue of their government monopoly status to recover organs.

Unlike organ donation, which is overseen by CMS, tissue donation is governed by regulations within the Food and Drug Administration, although such oversight is confined to clinical regulation rather than financial or business practices. The *Los Angeles Times* found that tissue recovery is a “multibillion-dollar global business” and that “a single body can supply raw materials for products that sell for hundreds of thousands of dollars.”¹⁵⁶ Unlike SACs for organs, prices for tissue and non-organ body parts are subject to market forces, meaning increased demand can increase prices and bring additional revenue for every incremental tissue recovery. Consequently, OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.

While OPOs may argue that recovering tissue increases OPO revenue, affording them more resources to invest in organ recovery activities, this may not always play out in practice. For example, LifeNet Health, a national tissue processor that operates the Virginia OPO, reports spending \$392,472,519 on “tissue processing” compared with only \$22,397,590 on “organ procurement” in its most recent tax filings (2018). The Virginia

154 Representative Katie Porter, [Letter to the Department of Health and Human Services and Centers for Medicare and Medicaid Services](#), October 7, 2019.

155 Representative Katie Porter and Representative Karen Bass, [Letter to the Department of Health and Human Services and Centers for Medicare & Medicaid Services](#), July 10, 2020.

156 Melody Petersen, [“In the rush to harvest body parts, death investigations have been upended,”](#) *Los Angeles Times*, October 13, 2019.

OPO was flagged as failing CMS’s proposed metrics, an indication that a large pool of tissue-related profits do not guarantee improvements in organ recovery.

This dynamic has become a line of oversight inquiry from the Senate Finance Committee. In 2019¹⁵⁷ and 2020,¹⁵⁸ the committee began investigations into OPO oversight and the extent of potential financial conflicts of interest around tissue procurement and processing in particular. Key issues raised by the committee include:

- The effectiveness of oversight provided by UNOS, the nonprofit contractor that has held the role of federal watchdog for the field since 1986, and the extent to which UNOS’s activities have been independently audited by the HHS Office of the Inspector General.
- The effectiveness of oversight of OPO performance, including how underperformance is identified and addressed, overall accuracy of data, use of best practices, efforts to address organ loss and discards, and efforts to ensure patient safety.
- The effectiveness of oversight of OPO financials, including the extent of audits to ensure OPO costs are in line with regulations as to what is “reasonable,” “necessary,” “proper,” and “allowable”; levels of CEO and board member compensation; potential conflicts of interest for OPOs and OPO leaders with investments in for-profit tissue-processing companies (and the extent to which these may conflict with their mandate to recover as many transplantable organs as possible).

The committee’s inquiry identifies two areas, in particular, where there is a lack of publicly available information that pertains to the overall topic of structural OPO financing reform: the accuracy and effectiveness of OPO cost reporting, and potential conflicts of interest related to tissue procurement. The extent of these problems today is not fully known, nor is the effectiveness of existing regulatory bodies to address them, in part due to a lack of publicly reported data and transparency. For example, while OPO executives make decisions about dedicating resources to organ recovery versus tissue recovery, CMS does not require OPO executives and board members to disclose personal financial relationships with tissue processors or other partner entities. The Senate Finance Committee’s 2020 oversight letter inquired into potential conflicts of interest, noting that “multiple OPOs recover tissue and some operate tissue banks,” raising questions about ties to for-profit firms from both OPOs and OPO executives.¹⁵⁹ A currently unanswered question in the committee’s 2020 oversight letter on this topic reads, “given that multiple OPOs recover tissue and some operate tissue banks, on what mechanisms does UNOS rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?”¹⁶⁰

This lack of transparency around potential conflicts of interest regarding tissue may also affect the experience of donor families. Research shows that while 73 percent of families say it is “not acceptable for donated tissue to be bought and sold, for any purpose,” only 18 percent of donor families report being told that their tissue donation might go to a for-profit company.¹⁶¹

157 [2019 oversight letter](#), United States Senate, December 18, 2019.

158 [2020 oversight letter](#), United States Senate, February 10, 2020.

159 Ibid.

160 Ibid.

161 Joseph Shapiro and Sandra Bartlett, “[Calculating The Value Of Human Tissue Donation](#),” NPR, July 17, 2012.

Alternative OPO Reimbursement Models

The ultimate goal of OPO financing reform is not to reduce costs, per se, but rather to increase the number of lifesaving organs available for transplant. A payment system that increases transparency, standardizes reimbursements, and rewards OPOs for safely using every available organ in their given DSAs might be a step toward achieving this goal. The most effective system is likely to be one in which financial incentives align with organ recovery and encourage OPOs to reallocate spending into investments that can safely and sensitively increase the volume of successfully procured lifesaving organs, such as frontline staff.

Over the past several decades, the healthcare system as a whole has evolved from retrospective, cost-based reimbursement to prospective, fee-for-service reimbursement, and now toward value-based care, largely driven by reforms from CMS. For instance, from 1967 to 1984, Medicare employed a cost-based reimbursement system similar to the current OPO financing mechanism. This led to significant inflation of hospital budgets, which was curtailed by adoption of a prospective payment system in which prices for certain bundles of services were defined upfront.¹⁶² Since the early 2000s, value-based reimbursement has gained in popularity, further catalyzed by the Affordable Care Act in 2010. OPO financing is now the only major area of healthcare that continues to be financed entirely on a cost-reimbursement basis.¹⁶³

Both fee-for-service and value-based-care paradigms can provide valuable principles for OPO financing reform.

Fee-for-service payment models: Within the fee-for-service system, a prospective payment is based on fee schedules set by Medicare. These are used to pay Medicare rates and often as the basis for payor-negotiated rates. These fee schedules provide transparent and consistent pricing based on reasonable and pre-defined sources of variation (for instance, for regional density in ambulance fee schedules). These fee-for-service models incentivize volume of healthcare services delivered. While in much of healthcare there is concern that volume does not lead to value, in organ procurement, increased volume would address the overall shortage of organs, multiyear waitlists, and billions of dollars spent on dialysis.¹⁶⁴

Value-based-care payment models: Alternative or value-based-care payment models seek to tie reimbursement to the quality or the value of the service provided.¹⁶⁵ These alternative payment methods include mechanisms that connect payment to the quality of services provided (e.g., Medicare Quality Bonus Payments, Hospital Readmission Reduction Program), bundle together related services to incentivize coordination and cost management (e.g., Comprehensive Joint Replacement bundle) or incentivize providers based on total cost of care (e.g., Medicare ACOs, ESCOs). The principles around linking payment to quality or outcomes metrics could be applied in OPO financing reform.

162 [Medicare Hospital Prospective Payment System How DRG Rates Are Calculated and Updated](#), Office of the Inspector General, August 2001.

163 As noted above, the single possible comparable part of healthcare still funded on a cost-reimbursement basis appears to be Critical Access Hospitals.

164 Lawton R Burns and Mark V Pauly, “Transformation of the Healthcare Industry: Curb Your Enthusiasm?” *The Milbank Quarterly* 96 no.1 (2018): 57-109.

165 Anne Lockner, and Chelsea Walcker, “Insight: The Healthcare Industry’s Shift from Fee-for-Service to Value-Based Reimbursement,” *Bloomberg Law*, September 26, 2018.

Options for Financial Reform

Changing OPO reimbursement models. There are at least two non-statutory ways to implement reimbursement reform for organ procurement. First, CMS can use its waiver authority under Section 1115A of the Social Security Act to design and launch a demonstration project (via the Center for Medicare & Medicaid Innovation) to test alternative methods of reimbursement. It has conducted similar demonstration projects in a variety of areas, such as the mandatory comprehensive joint replacement program which has successfully lowered costs.¹⁶⁶ These mechanisms could be an effective way to pilot a new payment system for OPOs.

Second, CMS can change the current regulation governing payments to OPOs (42 CFR 413.200) by issuing a new regulation with a reformed financing mechanism that is fair and transparent and provides incentives to drive higher volumes of organ procurement, helping more patients access transplants.

Increasing transparency of overall costs. There are options to improve transparency of organ procurement costs alongside financing reform. CMS could work to reform OPO financing and collect better data under the current financing mechanism to promote transparency and advise new organ-reimbursement rates. CMS currently provides instructions on cost reporting and a fee calculator (in Provider Resource Manual [PRM] 15-1, Chapter 31, or PRM 15-2, Chapter 33). It can issue new guidance on calculating SACs or enact new regulations to reform cost reporting to ensure the OPOs are allocating costs transparently and accurately. Given that OPOs operate as monopolies, unlike other stakeholders in the field of transplantation, CMS could impose transparency requirements above and beyond those for transplant centers and donor hospitals, which are already subject to market pressures to contain costs.

One potential cost-reporting reform would be to require OPOs to publicly report annual SACs by organ type for all organs, along with number of organs recovered and a detailed description of which costs are included in the fee and how they were allocated (potentially in the form of detailed financial statements that outline allocation of direct and indirect costs by line item).

Increasing transparency regarding potential conflicts of interest. Additionally, CMS could require disclosures of financial relationships between OPOs/OPO leaders and partner entities (such as tissue processors and private jet service companies), or even prohibit OPO leaders from engaging in financial relationships with partner entities (as it does for Medicare-funded physicians under Stark Law).¹⁶⁷

Adoption of these reforms could protect against instances of spending that have been the subject of a series of investigations and inquiries. [Table B](#) contains a listing of those inquiries previously or currently conducted by various government entities, including the HHS Office of the Inspector General, the Senate Finance Committee, and members of the House of Representatives.

166 [Understanding Medicaid Section 1115 Waivers: A Primer for State Legislators](#), National Conference of State Legislatures.

167 "A Roadmap for New Physicians: Fraud and Abuse Laws," Office of the Inspector General.

Table A: Key data points by OPO

The table below comprises key financial and other data points for each OPO from the most recent publicly available IRS Form 990, the CMS 2019 Notice of Proposed Rulemaking, and the Small Business Association. OPOs failing both proposed outcome measures are highlighted in dark red; OPOs failing one proposed outcome measure are highlighted in light red.

OPO	DESIGNATED SERVICE AREA	FAILING/ PASSING CMS PROPOSED OUTCOME MEASURES	ADD'L DONORS NEEDED	ADD'L ORGANS NEEDED	PAYCHECK PROTECTION PROGRAM FUNDS RECEIVED	CEO	CEO COMPEN- SATION	PAID BOARD MEMBERS	OPO ASSETS	OPO FOUND- ATION ASSETS
Legacy of Hope	AL	Failing both metrics	141 (82%)	551 (106%)	\$0	Christopher Meeks	Data unavailable	Data unavailable	Data unavailable	N/A
Arkansas Regional Organ Recovery Agency	AR	Failing both metrics	44 (81%)	178 (109%)	\$1-2M	Alan Cochran	\$251,689	No	\$13M	N/A
Donor Network of Arizona	AZ	Passing	0 (0%)	0 (0%)	\$0	Timothy Brown	\$538,071	Yes	\$90M	N/A
OneLegacy	CA - Los Angeles	Failing both metrics	44 (10%)	210 (14%)	\$150-350K (including funds received by Foundation)	Tom Mone	\$904,293	Yes	\$86M	\$36M
Sierra Donor Services	CA - North Central	Passing	0 (0%)	0 (0%)	\$0	Sean Van Slyck	Data unavailable	Data unavailable	Data unavailable	N/A
Donor Network West	CA - Northern; NV - Northern	Failing both metrics	29 (9%)	80 (7%)	\$5-10M	Cynthia Siljestrom*	\$415,721	No	\$45M	N/A
LifeSharing	CA - Imperial, San Diego	Passing	0 (0%)	0 (0%)	\$0	Lisa Stocks	Data unavailable	Data unavailable	Data unavailable	N/A
Donor Alliance	CO; WY	Failing one metric	0 (0%)	31 (7%)	\$2-5M	Susan Dunn*	\$579,221	No	\$85M	\$5M
LifeChoice Donor Services	CT; MA - Franklin, Hampden, and Hampshire Counties	Failing both metrics	29 (41%)	131 (64%)	\$0	Alexandra Glazier	\$589,303	No	\$5M	N/A
New England Organ Bank	CT; MA; ME; NH; RI; VT	Failing both metrics	43 (14%)	219 (23%)	\$5-10M	Alexandra Glazier	(since covered above)	No	\$36M	N/A
Washington Regional Transplant Community	DC; MD; VA	Passing	0 (0%)	0 (0%)	\$1-2M	Lori Bringham	\$514,979	No	\$26M	N/A
OurLegacy	FL - Eastern	Passing	0 (0%)	0 (0%)	\$0	Ginny McBride	Data unavailable	Data unavailable	Data unavailable	N/A
LifeQuest Organ Recovery Services	FL - Northern	Failing both metrics	21 (147%)	112 (25%)	\$0	Danielle Balbis	Data unavailable	Data unavailable	Data unavailable	N/A
Life Alliance Organ Recovery Agency	FL - Southern	Failing both metrics	5 (2%)	119 (22%)	\$0	Sam Salama	Data unavailable	Data unavailable	Data unavailable	N/A
LifeLink of Florida	FL - West	Failing both metrics	3 (1%)	82 (12%)	\$0	Jean A. Davis	Data unavailable	Yes	Data unavailable	N/A

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OPO	DESIGNATED SERVICE AREA	FAILING/ PASSING CMS PROPOSED OUTCOME MEASURES	ADD'L DONORS NEEDED	ADD'L ORGANS NEEDED	PAYCHECK PROTECTION PROGRAM FUNDS RECEIVED	CEO	CEO COMPEN- SATION	PAID BOARD MEMBERS	OPO ASSETS	OPO FOUND- ATION ASSETS
LifeLink of Georgia	GA; SC - Catoosa, Dade, and Walker Counties	Failing both metrics	42 (14%)	238 (26%)	\$0	Dustin Diggs	Data unavailable	Yes	Data unavailable	N/A
Legacy of Life Hawaii	HI	Failing both metrics	1 (0%)	38 (38%)	\$0	Stephen Kula*	\$142,729	No	\$3M	N/A
Iowa Donor Network	IA; NE - Dakota County	Failing both metrics	21 (34%)	100 (56%)	\$2-5M	Suzanne Conrad	\$350,265	No	\$28M	N/A
Gift of Hope Organ & Tissue Donor Network	IL - Northern/Central; IN - Lake and Porter Counties	Passing	0 (0%)	0 (0%)	\$5-10M	Kevin Cmund	\$636,283	No	\$113M	No data
Indiana Donor Network	IN	Failing both metrics	52 (30%)	121 (19%)	\$0	Kellie Hanner	\$464,033	No	\$43M	\$304K
Midwest Transplant Network	KS; MO - Western	Passing	0 (0%)	0 (0%)	\$0	Jan Finn	\$474,104	No	\$101M	N/A
Kentucky Organ Donor Affiliates	KY; IN - Southern; WV - Western	Failing both metrics	90 (76%)	300 (72%)	\$1-2M	Julie Bergin	\$316,970	No	\$18M	N/A
Louisiana Organ Procurement Agency	LA	Failing one metric	3 (1%)	0 (0%)	\$2-5M	Kelly Ranum	\$344,355	No	\$37M	\$0
The Living Legacy Foundation	MD	Passing	0 (0%)	0 (0%)	\$0	Charles Alexander	\$726,147	No	\$27M	N/A
Organ Procurement Agency of Michigan (Gift of Life Michigan)	MI	Failing both metrics	39 (13%)	255 (28%)	\$2-5M	Ladora Dills	\$453,407	Yes	\$55M	No data
Upper Midwest Organ Procurement Organization (Lifesource MN)	MN; ND; SD; WI - Western	Failing one metric	0 (0%)	16 (2%)	\$2-5M	Susan Raether	\$624,918	No	\$29M	N/A
Mid-America Transplant Services	MO - Eastern; AR - Northeast; IL - Southern	Passing	0 (0%)	0 (0%)	\$2-5M	Diane Brockmeier	\$541,405	Yes	\$87M	\$67M
Mississippi Organ Recovery Agency	MS	Failing both metrics	29 (34%)	114 (42%)	\$1-2M	Kevin Stump	\$305,722	Yes	\$15M	N/A
Carolina Donor Services	NC - Eastern/Central	Failing both metrics	53 (25%)	171 (23%)	\$2-5M	Danielle Niedfeldt	\$333,572	No	\$29M	N/A
LifeShare of the Carolinas	NC - Southwestern and Western; SC - York County	Passing	0 (0%)	0 (0%)	\$0	Michael Daniels	Data unavailable	Data unavailable	Data unavailable	N/A
Nebraska Organ Recovery	NE	Passing	0 (0%)	0 (0%)	\$350K-\$1M	Kyle Herber	\$250,379	No	\$19M	N/A
New Jersey Sharing Network	NJ - Northern/Central	Failing both metrics	2 (1.0%)	91 (15%)	\$0	Joseph Roth	\$611,990	No	\$31M	\$1.7M

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OPO	DESIGNATED SERVICE AREA	FAILING/ PASSING CMS PROPOSED OUTCOME MEASURES	ADD'L DONORS NEEDED	ADD'L ORGANS NEEDED	PAYCHECK PROTECTION PROGRAM FUNDS RECEIVED	CEO	CEO COMPEN- SATION	PAID BOARD MEMBERS	OPO ASSETS	OPO FOUND- ATION ASSETS
New Mexico Donor Services	NM	Failing one metric	0 (0%)	28 (15%)	\$0	Wayne Dunlap	Data unavailable	Data unavailable	Data unavailable	N/A
Nevada Donor Network	NV	Passing	0 (0%)	0 (0%)	\$2-5M	Joseph Ferreira	\$445,693	No	\$27M	No data
Albany Medical Center (Center for Donation and Transplant NYAP)	NY - Eastern; MA - Berkshire County; VT	Failing both metrics	30 (46%)	145 (82%)	\$0	James Barba*	\$1,845,333	Yes	\$10M	No data
Finger Lakes Donor Recovery Network	NY - Central	Failing both metrics	45 (91%)	200 (163%)	\$0	Robert Gruenfelder	Data unavailable	Data unavailable	Data unavailable	N/A
LiveOnNY	NY - Southern (NYC)	Failing both metrics	76 (26%)	323 (34%)	\$2-5M	Helen Irving	\$465,051	No	\$31M	\$1.4M
Upstate New York Transplant Services (ConnectLife)	NY - Western	Passing	0 (0%)	0 (0%)	\$2-5M	Mark Simon	\$436,877	No	\$34M	\$163K
Lifeline of Ohio	OH - Central; WV - Wood and Hancock Counties	Failing both metrics	6 (4%)	46 (11%)	\$0	Kent Holloway	\$299,120	No	\$22M	N/A
Lifebanc	OH - Northeast	Failing both metrics	2 (1%)	52 (10%)	\$2-5M	Gordon Bowen	\$508,718	No	\$36M	N/A
Life Connection of Ohio	OH - Northwest	Failing both metrics	9 (13%)	77 (40%)	\$1-2M	Ron Apswich*	\$276,647	Yes	\$11M	\$172K
LifeCenter Organ Donor Network	OH - Southwest; KY - Northern; IN - Southeast	Failing both metrics	1 (0%)	36 (16%)	\$1-2M	Bary Massa	\$303,419	No	\$10M	\$4M
Lifeshare Transplant Donor Services of Oklahoma	OK	Passing	0 (0%)	0 (0%)	\$2-5M	Jeffrey Orłowski	\$462,721	No	\$26M	\$541K
Pacific NW Transplant Bank	OR; ID - Western; WA - Southwest	Failing both metrics	17 (13%)	107 (27%)	\$0	Craig Van De Walker	Data unavailable	Data unavailable	Data unavailable	N/A
Gift of Life	PA - Eastern; DE; NJ - Southern	Passing	0 (0%)	0 (0%)	\$0	Howard Nathan	\$752,777	No	\$5M	\$44M
Center for Organ Recovery and Education	PA - Western; NY - Chemung County; WV	Failing one metric	0 (0%)	73 (11%)	\$0	Susan Stuart	\$527,845	No	\$96M	N/A
Lifelink of Puerto Rico	PR	Failing both metrics	35 (40%)	189 (81%)	\$0	Guillermo Sanchez	Data unavailable	Yes	Data unavailable	N/A
We Are Sharing Hope SC	SC	Failing both metrics	11 (6%)	26 (4%)	\$1-2M	David Destefano	\$262,280	No	\$18M	N/A
Tennessee Donor Services	TN - Central/Eastern; GA - Northern; KY - Christian County; VA - Southwest	Passing	0 (0%)	0 (0%)	\$0	Jill Grandas	\$305,730	Yes	\$45M	N/A

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OPO	DESIGNATED SERVICE AREA	FAILING/PASSING CMS PROPOSED OUTCOME MEASURES	ADD'L DONORS NEEDED	ADD'L ORGANS NEEDED	PAYCHECK PROTECTION PROGRAM FUNDS RECEIVED	CEO	CEO COMPENSATION	PAID BOARD MEMBERS	OPO ASSETS	OPO FOUNDATION ASSETS
Mid-South Transplant Services	TN - Western; AR - Eastern; MS - Northern	Failing both metrics	12 (15%)	73 (32%)	\$350K-1M	Kim Van Frank	\$282,411	No	\$7M	N/A
Southwest Transplant Alliance	TX	Passing	0 (0%)	0 (0%)	\$2-5M	Patricia Niles	\$705,285	No	\$43M	No data
LifeGift	TX - Northern and Southeast	Passing	0 (0%)	0 (0%)	\$0	Kevin Myer	\$478,522	No	\$61M	N/A
Texas Organ Sharing Alliance	TX - Southern	Failing both metrics	23 (13%)	73 (12%)	\$1-2M	Joseph Nespral	\$297,424	No	\$21M	\$95K
Intermountain Donor Services (DonorConnect)	UT; ID - Southeastern; NV - Elko; WY - Western	Passing	0 (0%)	0 (0%)	\$0	Tracy Schmidt	\$274,103	No	\$10M	N/A
LifeNet	VA; NC - Currituck County; WV - Northwest	Failing both metrics	56 (36%)	210 (41%)	\$0	Rony Thomas+	\$1,585,890	Yes	\$403M	\$1.6M
LifeCenter Northwest	WA; AK; ID; MT	Failing both metrics	1 (0%)	88 (11%)	\$2-5M	Kevin O'Connor	\$487,512	No	\$26M	N/A
University of Wisconsin Hospital and Clinic	WI; IL - Winnebago County; MI - Northwest; MN - Houston County	Passing	0 (0%)	0 (0%)	\$0	Michael Anderson	Data unavailable	Data unavailable	Data unavailable	N/A
Versiti Organ & Tissue Donation	WI - Southeast	Passing	0 (0%)	0 (0%)	\$0	Chris Miskel+	\$1,001,689	Data unavailable	Data unavailable	N/A

Sources: Financial data from most recent available IRS Form 990; 2018 990s used except for Albany Medical Center, Lifebank, Pacific NW Transplant Bank, and Intermountain Donor Services (all 2017); Form 990 data not available for OPOs based within hospitals; outcomes data based on CMS 2019 Notice of Proposed Rulemaking (based on 2017 data); Paycheck Protection Program funds data from the Small Business Administration.

Notes: CEO name is drawn from most recent 990 or from organization website where 990 not available. * by CEO name indicates CEO from most recent 990 filing no longer serving in role.

+ by CEO name indicates CEO runs a parent organization, such as a hospital system or tissue processor, in which the OPO is housed.

Failing/passing refers to OPO standing in relation to 2019 CMS proposed rule on OPO outcome measures, based on 2017 data.

“Additional donors needed” and “Additional organs needed” reflect improvement required to be in compliance with performance standards in the December 2019 Notice of Proposed Rulemaking. The first number reflects the total number of donors or organs, while the number in parentheses represents the percent improvement required.

“Paycheck Protection Program funds received” indicates whether funds were applied for and dispersed; public data is not available as to whether any funds were ultimately returned. New England Donor Services, which manages two OPOs (LifeChoice Donor Services and New England Organ Bank) received funds, rather than the individual OPO(s). In addition to OPOs, United Network for Organ Sharing (UNOS) and the Association of Organ Procurement Organizations (AOPO) received PPP funds of \$5-\$10M and \$150K-\$350K, respectively.

“Paid Board Members” refers to whether board members are paid by OPO according to IRS Form 990; does not account for separate contracts given to board members or their businesses.

“N/A” for foundation assets indicates OPO does not have a separate foundation according to IRS Form 990 and organization website; “No data” for foundation assets indicates foundation has been legally incorporated (verified through IRS Form 990 and/or organization website) but asset data is unavailable.

Table B: Relevant Government Investigations into Organ Procurement Organization Finances

There have been a number of government inquiries into the financing of organ procurement organizations. Table B is a list of these inquiries.

Investigation	Date	Areas of Inquiry
Office of Inspector General: Review of OneLegacy's Reported Fiscal Year 2006 Organ-Acquisition Overhead Costs and Administrative and General Costs	January 2010	<p>Summary of findings:</p> <p>OneLegacy (Los Angeles OPO) "did not fully comply with Medicare requirements for reporting selected organ procurement organization (OPO) overhead costs and administrative and general costs in its fiscal year (FY) 2006 Medicare cost report. Of the \$3.2 million of costs we reviewed, \$2.6 million was allowable. The remaining \$531,000 represents \$291,000 of unallowable costs and \$240,000 of unsupported costs. As a result, OneLegacy overstated its Medicare reimbursement in the FY 2006 Medicare cost report by an estimated \$297,000."</p>
Office of Inspector General: Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs	October 2010	<p>Summary of findings:</p> <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>
Office of Inspector General: 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	March 2012	<p>Summary of findings:</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> <p>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.</p> <p>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> <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>

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Investigation	Date	Areas of Inquiry
<p>Office of Inspector General: LifeCenter Northwest Did Not Fully Comply with Medicare Requirements for Reporting Organ Statistics in its Fiscal Year 2009 Medicare Cost Report</p>	<p>November 2012</p>	<p>“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> <p>LifeCenter stated that human error and the manual system it used to track donors caused the incorrect reporting of organ statistics for the 15 organs.”</p>
<p>Office of Inspector General</p>	<p>May 2016</p>	<p>FBI Press Release Summary:</p> <p>“U.S. District Judge R. David Proctor today sentenced the former director of the Alabama Organ Center to 13 months in prison for his role in a scheme to take kickbacks from a funeral home that did business with the organ center, announced U.S. Attorney Joyce White Vance and FBI Special Agent in Charge Patrick J. Maley.</p> <p>Judge Proctor also ordered the defendant, Demosthenes Lalian, 45, to pay \$489,551 in restitution to the University of Alabama Health Services Foundation and to forfeit \$242,344 to the federal government as proceeds of illegal activity. The Alabama Organ Center is a component of the Health Services Foundation and is the federally approved organ procurement organization for the state of Alabama.</p> <p>The judge ordered Lalian to remain on supervised release for three years after completing his prison sentence. As a special condition of that release, if Lalian seeks employment in any occupation involving the rendering of healthcare services, he must inform the prospective employer of his conviction and provide a copy of his plea agreement.</p> <p>Lalian and his co-defendant, Richard Alan Hicks, 40, pleaded guilty in November to one count each of conspiracy to commit healthcare fraud, healthcare fraud, and mail fraud. Hicks’ sentencing is scheduled June 5. Hicks is the former associate director of the Organ Center. He and Lalian will both be responsible for paying the restitution.</p> <p>From about March 2007 until June 2011, Lalian solicited and received kickbacks totaling \$242,344, and Hicks received kickbacks totaling \$256,207 from a local funeral home that did business with the organ center, according to court documents. In exchange for the kickback payments, Lalian and Hicks promoted the funeral home and recommended its hiring by the organ center for services paid for by the Health Services Foundation. Neither Lalian nor Hicks disclosed to the organ center or the foundation that they were receiving payments from the funeral home. Both men falsely represented to the foundation that neither of them had any financial conflicts of interest from customers, suppliers, contractors or competitors, according to court documents.</p> <p>The investigation revealed no evidence that indicated Lalian’s and Hicks’s conduct endangered the public or donors or recipients of organs or tissue.”</p>
<p>Representative Katie Porter (D-CA) letter to the Department of Health and Human Services and CMS on oversight of OPOs</p>	<p>October 2019</p>	<p>Letter regarding implementation of President Trump’s executive order requiring major improvements to the organ transplant system, including addressing “OPO chronic underperformance and financial mismanagement by adjusting regulations, reporting requirements, and performance metrics in order to spur improved OPO outcomes; conducting more frequent and publically accessible audits of OPOs financial management and general effectiveness; and reviewing why CMS has not used its authority to decertify any underperforming OPOs in 20 years.”</p>

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Investigation	Date	Areas of Inquiry
<p>Senators Charles Grassley (R-IA) and Todd Young (R-IN) letter to Office of Inspector General</p>	<p>December 2019</p>	<p>Request that OIG conduct “a comprehensive examination of the adequacy of the organ procurement and transplantation system in the United States,” including:</p> <ul style="list-style-type: none"> • Extent to which OIG has audited OPO finances in last decade and extent of plans to conduct further audits • Extent to which OIG followed up on four documented cases of OPOs billing Medicare for “unsupported” and “unallowable” costs • Reforms to ensure reported expenses in Medicare cost reports and reasonable and focused on the OPO’s mission of organ recovery, including requesting data on OPO CEO executive compensation and additional sources of OPO-related compensation, such as compensation derived from OPO partner organizations (e.g., tissue processors, cornea banks, and funeral homes) • Use of private planes by OPOs (and transparency to ensure that these airplanes are not used for personal travel and then billed to taxpayers) • Whether OIG has ever audited the United Network for Organ Sharing (UNOS) • Whether OIG has followed up on its 2013 investigation of 44 OPOs incorrectly reporting lung procurement cost in Medicare cost reports • Financial incentives OPOs have to prioritize tissue recovery over organ procurement, and under what circumstances do such financial incentives create a conflict of interest? • 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 nonprofit status • Internal Revenue Service 990 filings indicate that some OPOs have transferred financial assets to their private foundation; given this, has the OIG investigated whether OPO foundations then use these resources for purposes that the OIG had previously deemed impermissible for OPOs?
<p>Senators Charles Grassley (R-IA), Ron Wyden (D-OR), Todd Young (R-IN), and Benjamin Cardin (D-MD) letter to United Network for Organ Sharing</p>		<p>Letter inquiring as to oversight gaps of OPOs: “We write today about concerning allegations of oversight gaps with respect to our nation’s Organ Procurement and Transplantation Network (OPTN), the United Network for Organ Sharing (UNOS), and the network of 58 organ procurement organizations (OPOs) that UNOS monitors. Recent reports of lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted lead us to question the adequacy of UNOS’ oversight of these OPOs.”</p>
<p>Representatives Katie Porter (D-CA) and Karen Bass (D-CA) letter to Department of Health and Human Services and CMS</p>	<p>July 2019</p>	<p>Letter urging: finalization of standards in December 2019 NPRM, adoption of new outcomes measures in 2022 certification cycle, and review of OPO use of taxpayer funds</p>
<p>Representatives Max Rose (D-NY), Tom Reed (R-NY), and 23 other representatives letter to the Department of Health and Human Services</p>	<p>August 2020</p>	<p>Letter highlighting earlier research and investigations, urging finalization of rules in December 2019 NPRM for OPO oversight and accountability: “This incompetence has also cost tremendous amounts of taxpayer dollars.”</p>
<p>Senators Charles Grassley (R-IA), Ron Wyden (D-OR), Todd Young (R-IN), and Benjamin Cardin (D-MD) letter to the Department of Health and Human Services</p>	<p>October 23, 2020</p>	<p>Letter inquiring about Department of Health and Human Services oversight of the organ procurement and transplantation system, including:</p> <ul style="list-style-type: none"> • Data on OPO and OPTN oversight by HHS • Oversight of organ acquisition costs and fees for patients to register for the transplant waiting list • Oversight of OPO finances, including financial operations, executive and board member compensation • Oversight of potential conflicts of interest for OPOs operating tissue banks • Oversight of recent cases involving lapses in patient safety • Details on organ procurement and transplantation oversight by the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) • OPO spending on lobbying