

Transforming Organ Donation in America

Serving Patients by Expanding High- Performing Organ Procurement Organizations

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Forewords

Patients Deserve Accountability

Organ transplants are a modern medical miracle. Almost 40,000 transplants were performed in the United States in 2019, and many Americans are alive today because of the efforts of medical professionals, organ donors, families, caregivers, nonprofits, and government.ⁱ

Yet the demand for organs far outstrips supply. Today, approximately 110,000 patients are on the transplant waitlist. Each day 33 people die while waiting for an organ transplant.ⁱⁱ COVID-19 has increased the urgency of reforming the transplant system; kidney patients are crowded into dialysis centers, unable to socially isolate, and the coronavirus is ravaging organs of patients who previously did not have organ failure.

Patients deserve an accountable, high-functioning system. Reforming America's deceased donation system is central to the aims of the Executive Order on Advancing Kidney Health, which seeks to double the number of kidneys available for transplant by 2030. According to the Department of Health and Human Services (HHS), "The main approach for achieving this ambitious goal is to increase the number of deceased donors."ⁱⁱⁱ

As long-time advocates for organ donation who have seen the consequences of system failures for patients firsthand, we were encouraged to see this long-overdue focus on increasing organ recovery rates, as well as the explicit recognition that overcoming the most central barrier to improvement would mean implementing much-needed accountability for the organizations working on the frontlines of this field—organ procurement organizations (OPOs).

At the heart of the proposed rule are the basic ideas that federal contractors should be evaluated based on objective data, and that they be held accountable for the life and death consequences of how well they do their work. In December 2019, HHS flagged the majority of the nation's OPOs as failing proposed outcome measures, highlighting that if low performers met even minimum compliance there would be an additional 5,000 lifesaving transplants every year for patients in need.^{iv}

It is easy to see why these common sense reforms have been welcomed by patient advocacy groups and bipartisan lawmakers—with support including the Chair of the

i [Organ Donation Statistics](#), [Organdonor.gov](#).

ii This figure differs from the oft-cited HRSA statistic of 22 deaths per day because it also includes those who were removed from the waitlist after having become too sick to transplant. Kimberly Kindy, Lenny Bernstein, and Dan Keating, "Lives Lost, Organs Wasted," *Washington Post*, December 20, 2018.

iii [Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#), 84 Fed. Reg. 70628, (December 23, 2019).

iv *Ibid.*

House Appropriations Committee, both Chairs of the Kidney Caucus and the Diabetes Caucus, the Chair of the Congressional Black Caucus, and members of the Freedom Caucus.^v

What’s more, because failures in the organ donation system disproportionately harm people of color, reform is a key health care equity issue. It’s also a key cost containment issue since the economics of kidney transplants mean that a lifesaving intervention for patients also has the ability to save Medicare and the taxpayer up to \$40 billion over the next 10 years.^{vi}

Policymakers have every reason to act—both in the form of regulatory reforms (which must be finalized by the Administration) and in Congress (where bipartisan oversight is happening but more is sorely needed).

In the almost 40 years since the passage of the National Organ Transplantation Act (NOTA), no OPO has ever lost a government contract for poor performance, despite massive variability in organ recovery across the country of up to 470 percent, and numerous reports detailing tens of thousands of potential organs going unrecovered each year.^{vii} This is as alarming as it is fixable.

Earlier work by The Bridgespan Group, a 501(c)3 nonprofit consulting firm, highlighted that approximately 28,000 additional available organs each year from deceased donors do not get procured or transplanted due to breakdowns in the system.^{viii} The research has been cited by the White House, HHS, and lawmakers of both parties to underscore the dire state of underperformance. With this report, Bridgespan brings decades of expertise in nonprofit management and strategy (including in the field of public health), as well as an understanding of the field of organ donation in particular, to present a roadmap for how increased accountability and proven leadership can drive performance improvements—and save lives.

In response to new objective and enforceable proposed regulations, some OPOs submitted public comments to HHS arguing—without evidence—that such accountability should not be enforced because decertifying underperforming OPOs would cause disruption. With support from Arnold Ventures and Schmidt Futures, Organize engaged Bridgespan to evaluate the logic and merit of those claims. Based on this research, we believe that enforcing accountability need not cause any disruptions in service and is, unequivocally, in the best interests of the patients that the system is meant to serve. In fact, through its proposal to use recertification cycles to open up all territories to

v Representative Max Rose, et al., [Letter to the US Department of Health and Human Services](#), August 26, 2020.

vi Bridgespan Group analysis of the costs to Medicare and the taxpayer of kidney transplants compared to dialysis care, October 2020.

vii The NPRM states, “We found a wide range of donation rates (1.65 to 6.45 donors per 100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants per 100 inpatient deaths),” a 470 percent difference between highest and lowest transplantation rates. [Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#), 84 Fed. Reg. 70628, (December 23, 2019).

viii [Reforming Organ Donation in America](#), The Bridgespan Group, January 2019.

competition from high-performing OPOs, the Centers for Medicare & Medicaid Services can ensure that patients are served by the very best organizations around the country, further increasing organs available for transplant.

The facts in the report speak for themselves: leadership matters, and ensuring that OPOs across the country are held accountable is critical so that all patients are served by high-performing organizations. The cost of not pursuing these reforms—either through a weakened rule or delayed implementation—is immense: thousands of organs per year will go unrecovered, meaning thousands of lives lost and untold wasted Medicare spending on dialysis.

Patients deserve an accountable system—and policymakers who will make sure government contractors who have such a critical, lifesaving function are held to the highest possible standards. Lives depend on it.

Donna Cryer

President and CEO, Global Liver Institute

Paul Klotman, MD, FACP

President and CEO, Baylor College of Medicine

Greg Segal

CEO, Organize

Bryan Sivak

US Department of Health and Human Services, 2012-2015

Abe Sutton

White House Domestic Policy Council and National Economic Council, 2017-2019

Perspectives from the Field

I have been an organ recovery transplant coordinator since 1978, five years before the scientific breakthrough of the immunosuppressive drug cyclosporine jump-started our field and saved countless lives. In the ensuing decades, I have watched transplants advance from a medical rarity to mainstream practice, as transplant surgeons have pioneered ways to safely transplant organs from donors with conditions from hepatitis C to HIV, truly delivering miracles to patients in need.

Over that same time, however, I've also watched the OPO industry stagnate and the outside world pass us by. It's hard to believe, but while surgeons perform medical marvels in the operating room, some OPOs still rely on fax machines for donation referrals and to share critical information. An industry frozen in amber.

The government helped build the infrastructure of an industry from scratch, and then walked away for decades and let it atrophy. Much of the problem stems from historically unenforceable regulations, leading to a situation in which no OPO has ever lost its government contract for underperformance, no matter how many patients die waiting.^{ix}

OPOs have tried to create concern around, "What happens if the government decertifies an OPO?" The more important question really is: "What happens to patients if they don't?" Unfortunately, we already know that answer.

Since 2009, after adjusting for an increased donor pool resulting from improvements in transplant science and from the opioid epidemic, the number of transplants has not even kept pace with population growth.^x Why? Because OPOs have systematically underinvested in talent and innovation.

As the *Washington Post* editorial board wrote: "In a system in which these [OPOs] have an effective monopoly on organ recovery within their zones, there are few incentives for them to improve unless decertification is a serious possibility."^{xi}

Study after study has found that the strongest predictor of organ donation rates is—quite intuitively—the quality of the donor family experience.^{xii} And yet OPO frontline staff are systematically understaffed, under-supported, and, sadly, treated as disposables.

Working with donor families has been the most rewarding experience of my life. But it has also, without question, been the most challenging. Often OPO coordinators will work 24+ hour shifts, and the nature of the work can be emotionally devastating and isolating. But in a context in which OPOs have not had systemic pressure to perform well, they have routinely under-supported frontline staff, even and especially as resources flowed

ix Kimberly Kindy and Lenny Bernstein, "[Despite low performance, organ collection group gets new federal contract](#)," *Washington Post*, February 4 2019.

x Seth J. Karp, Greg Segal, and D.J. Patil, "[Using Data to Achieve Organ Procurement Accountability-Reply](#)," *JAMA Surgery*, October 7, 2020.

xi "[Many die waiting for organs. The Trump administration could help](#)," *Washington Post*, August 1, 2020.

xii H. M. Traino, A. J. Molisani, and L. A. Siminoff, "[Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation](#)," *American Journal of Transplantation* 17 no. 6 (June 17, 2017): 1620-1627.

unconstrained to unproductive, duplicative, and even vanity expenditures, as well as to lavish management salaries.^{xiii}

OPOs are very well-funded, receiving about \$3 billion annually.^{xiv} The problem has not been a lack of resources but a systemic misallocation of them. As this report shows, holding OPO management accountable to objective performance standards will drive a reallocation of resources to mission critical staffing and programming that will actually increase donations and help the families we are meant to serve, both donor families and transplant recipients.

Patients deserve the very best. To empower frontline staff working with donor families to deliver on that mission, we need sound OPO leadership, held accountable by both HHS and Congress.

Charles Bearden

Organ transplant coordinator for past 42 years

xiii Andrew Conte and Luis Fábregas, “Taxpayers help pay for organ donor groups’ parties, Rose Parade expenses,” Trib Live, October 19 2013.

xiv Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, 84 Fed. Reg. 70628, (December 23, 2019).

Executive Summary

There is an opportunity to save lives through recovering up to 28,000 more organs every year¹ while saving up to \$40 billion in healthcare costs from foregone dialysis over 10 years²—all by simply increasing the donation and transplantation of organs from deceased donors.

A critical component of the organ donation system is the network of organ procurement organizations (OPOs), which lead the work with hospitals and donor families to recover organs and transport them to patients in need. But there is a wide range of effectiveness among the country's 58 OPOs, contributing to the gap between the system's current level of donation and its potential.

To address this gap, the Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rulemaking (NPRM) in December 2019 that institutes accountability for underperforming OPOs. The proposal includes new outcome measures to objectively assess OPO effectiveness and catalyze improvement, noting a 470 percent difference in the number of organs recovered between the best- and worst-performing OPOs.³ Under the proposed rule, OPOs with high-performing leadership will be able to serve an expanded community by extending their operations into the territories of poor-performing OPOs.

The response of OPOs should be to meet, if not exceed, this new standard, and indeed, the example of higher-performing OPOs shows such outcomes are possible. In this report, The Bridgespan Group has distilled—from interviews with OPO leaders and field experts, as well as from the Bridgespan team's experience with performance-improvement initiatives in other social sector fields—improvement strategies for OPOs to close performance gaps. One key to high performance is serving all patients, including communities that have historically been underserved by the system, such as communities of color. CMS's new accountability measures will incentivize OPOs to invest in these communities, resulting in a more effective and equitable system.

The NPRM and existing regulations ensure that no geographic area is ever without an OPO or access to organ procurement services. In the event of a higher-performing OPO taking over the service area of a low performer, historical precedents demonstrate continuity of care can be maintained and that recovery rates can quickly improve. In 1984, there were 128 OPOs; now there are 58, and no data suggests these previous mergers and consolidations were disruptive. An analysis of the five most recent mergers,

1 [Reforming Organ Donation in America](#), The Bridgespan Group, January 2019.

2 Bridgespan Group analysis of the costs to Medicare and the taxpayer of kidney transplants compared to dialysis care, October 2020.

3 The NPRM states, "We found a wide range of donation rates (1.65 to 6.45 donors per 100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants per 100 inpatient deaths)," a 470 percent difference between highest and lowest transplantation rates. [Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#), 84 Fed. Reg. 70628, (December 23, 2019).

which occurred between 1997 and 2001, showed that donations increased over the five-year period following each merger, with no evidence of disruption to organ procurement in the process.⁴ Redundant resources at lower-performing organizations can also be redirected toward increased organ recovery to achieve better outcomes, particularly for vulnerable populations.

There is a clear roadmap for how CMS, together with higher-performing OPOs, can drive improvement in the system by expanding best practices used in one region into underperforming regions, all to the benefit of countless patients as well as the American taxpayer. Additionally, reform of OPO reimbursement structures can align OPO financial incentives with new regulatory incentives to guide OPO resource allocation toward expenditures most likely to lead to increased organ recovery.

4 Data on donations retrieved from [Organ Procurement Transplantation Network \(OPTN\)](#).

Introduction

Among the remarkable successes in medicine achieved over the past century, organ transplantation stands out for having brought the visionary imaginings of history into real-life hospitals, saving countless lives and extending so many others. Even so, the demand for organs far outstrips supply, and many people die while waiting for a transplant. It doesn't have to be this way.

Several factors contribute to the long-standing challenges around organ supply. This paper looks at one essential part of that system—organ procurement organizations (OPOs). In the United States, there are 58 nonprofit OPOs across the country that manage the procurement and recovery process for organs from deceased donation as government contractors granted monopoly status in their regions. Based on interviews and data analyses conducted over several months, we assessed ways in which the OPO system might be improved to increase the supply of organs for transplant, thus reducing the number of people who die while waiting for one. While this analysis is inevitably technical in places—focusing on organizational management, quality improvement, cost structures, and government regulations—the bottom line is that a more effective OPO system could both reduce costs and bring life and new hope to many more thousands of people each year, as well as to their families and communities across the United States.

Waiting for a Transplant

An organ shortage continues in the United States: the number of people on the waiting list for a transplant remains larger than the numbers of both donors and available transplants.⁵ The US government reports that approximately 109,000 people are on the official waiting list for a transplant (as of October 2020), and that every nine minutes another person is added to the list.⁶ On average, since 2015 more than 12,000 people per year died waiting for a transplant or were removed from the waiting list after becoming “too sick to transplant.”⁷ And the COVID-19 crisis has made the need for organ transplants even more critical, with patients on dialysis at higher risk of contracting COVID-19⁸ and an increased need for organ transplants.⁹

As bad as the situation is overall, it's worse for people of color. While 48 percent of white patients on the waiting list received a transplant in 2019, the proportion of Hispanic patients on the list who received a transplant was only 29 percent¹⁰, and only 26 percent

5 Additionally, growth in the number of deceased donors over the last 10 years has been driven by advances in transplant science, center behavior, and public health trends, not OPO practices. Seth J. Karp, Greg Segal, and D J Patil, “Using Data to Achieve Organ Procurement Accountability-Reply” *JAMA Surgery*, October 7, 2020.

6 [Organ Donation Statistics](#), [Organdonor.gov](#).

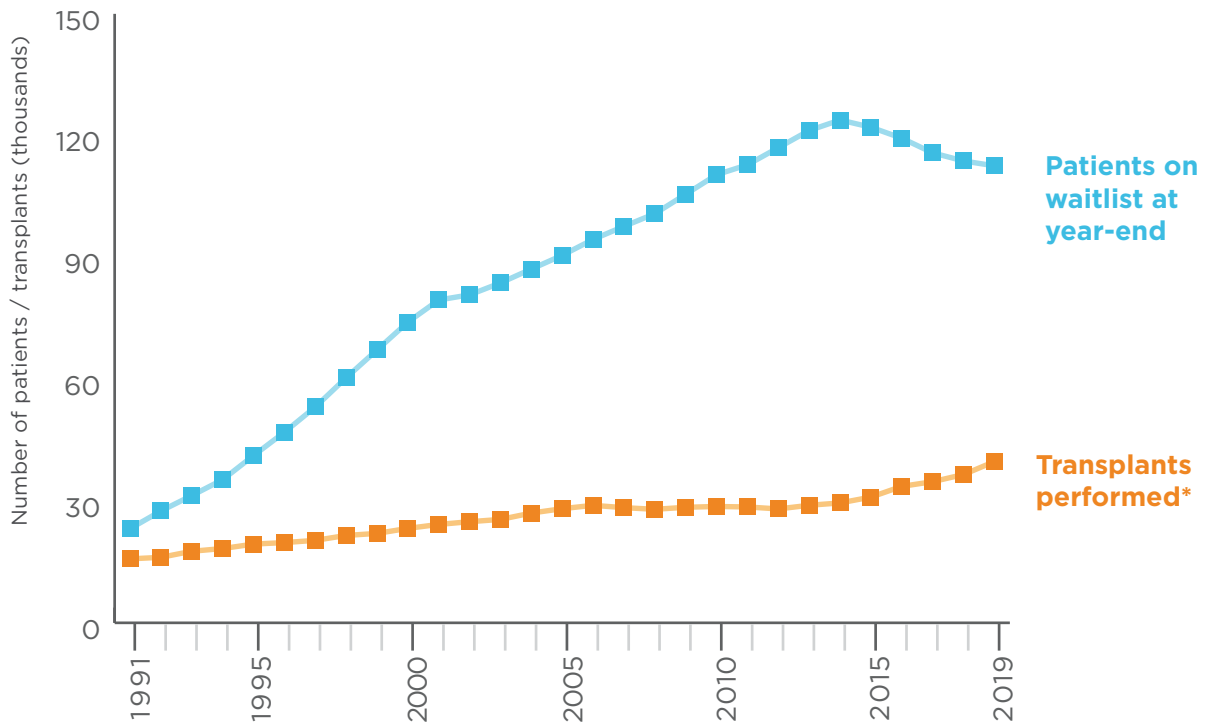
7 Data on waitlist mortality retrieved from OPTN.

8 Giuseppe Rombola and Francesca Brunini, “COVID-19 and dialysis: why we should be worried,” *Journal of Nephrology* 33, 401-403 (2020).

9 Lenny Bernstein and Martine Powers, “Surgeons perform first known US lung transplant for covid-19 patient,” *Washington Post*, June 11 2020.

10 [Organ Donation and Hispanic Americans](#), US Department of Health and Human Services, Office of Minority Health.

Exhibit 1: The demand for organs far outstrips supply



*Transplants performed include donations from both deceased donors and living donors.

Source: OPTN data from organdonor.gov.

for Black patients.¹¹ Yet the need for transplants is especially acute among Black and Hispanic people. Black people are almost four times more likely to suffer from end-stage renal disease than white people.¹² Hispanic men and women have a chronic liver disease rate that is twice that of the white population, and they are almost twice as likely to die from the disease.¹³ Further, there is a so-called “shadow waitlist” of patients who need a transplant but never get listed for one,¹⁴ and this is estimated to impact hundreds of thousands of patients,¹⁵ disproportionately people of color.¹⁶

11 [Organ Donation and African Americans](#), US Department of Health and Human Services, Office of Minority Health.

12 [Race, Ethnicity, and Kidney Disease](#), National Kidney Foundation.

13 [Chronic Liver Disease and Hispanic Americans](#), US Department of Health and Human Services, Office of Minority Health.

14 Venodhar Julapalli, Jennifer Kramer, and Hashem El-Serag, “[Evaluation for liver transplantation: Adherence to AASLD referral guidelines in a large veterans affairs center](#),” *Liver Transpl.*, (November 11, 2005): 1370-8, doi: 10.1002/lt.20434.

15 Frank McCormick, Phillip Held and Glen Chertow, “[The Terrible Toll of the Kidney Shortage](#),” *The Journal of the American Society of Nephrology*, (December 29, 2018): 2775-2776.

16 Jennifer Gander et al., “[Racial Disparities in Preemptive Referral for Kidney Transplantation in Georgia](#),” *Clinical Transpl.*, (September 24, 2018).; Arnold Epstein et al., “[Racial Disparities in Access to Renal Transplantation—Clinically Appropriate or Due to Underuse or Overuse](#),” *The New England Journal of Medicine* (November 23, 2000): 1537-1544.

In a recent op-ed,¹⁷ Ben Jealous, former president and CEO of the NAACP, hits back at arguments offered by some OPOs that these racial inequities in organ transplants are primarily the result of people of color failing to donate organs, noting: “While donation rates are lower among people of color versus white communities, it’s not because of some inherent lack of generosity; the real problem is that too often these government contractors do not engage with our communities.”

There is potential to dramatically increase the number of organs available for transplant—which would save lives and taxpayer dollars. A 2017 report from Bridgespan,¹⁸ conducted with Penn Medicine at University of Pennsylvania and Organize, found that up to an additional 28,000 organs could be transplanted per year by reforming the organ-donation system. This includes 17,000 kidneys that are not procured or transplanted. A 2020 update of our analysis equates those 17,000 kidneys to potential savings of \$40 billion over 10 years in forgone dialysis costs to Medicare and the taxpayer.¹⁹

Other analyses have suggested an even higher potential for organ donation. In an in-depth 2018 story, the *Washington Post* analyzed 2.7 million death records from 2016, finding that “as many as 27,000 people met established criteria for organ donation—more than twice the number of actual donors that year.”²⁰ The *Post* concluded, “at its current average of about three organs per donor, the industry could have produced more than 75,000 organs for transplant that year—enough to put the nation on pace to wipe out the waiting lists within a few years.” And the largest donor potential estimate actually came from the Organ Procurement and Transplantation Network (OPTN) itself, which authored the 2013 Deceased Donor Potential Study, concluding there may be as many as 35,000–40,000 potential organ donors per year (compared to approximately 8,000 organs recovered from deceased donors per year at the time of the study).²¹

The Performance of Organ Procurement Organizations Varies Widely

Nationally, 58 OPOs manage the organ procurement and recovery process in designated service areas (DSAs). They operate as federally granted monopolies, regulated by the Centers for Medicare & Medicaid Services (CMS). Their responsibilities include maintaining relationships with donor hospitals, obtaining next-of-kin authorization for all deceased donors, and managing the logistical transition of organs between donor hospitals and transplant centers. All 58 OPOs are nonprofits and have their expenses compensated through a cost-reimbursement contract with CMS and per-organ fees from

17 Ben Jealous, “Don’t let the COVID-19 crisis delay reforms to our organ transplant system,” *Roll Call*, July 9, 2020.

18 *Reforming Organ Donation in America*, The Bridgespan Group, January 2019.

19 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, doi: 10.1111/ajt.13490.

20 Kimberly Kindy, Lenny Bernstein, and Dan Keating, “Lives Lost, Organs Wasted,” *Washington Post*, December 20, 2018.

21 *OPTN Deceased Donor Potential Study (DDPS)*, Organ Procurement and Transportation Network, March 2015.

transplant centers. This payment system is important, and this report will have more to say about it below.

CMS is charged with reviewing OPOs and certifying them every four years based on whether they meet the federally mandated Conditions for Coverage, including outcome measures (broadly speaking, how many organs were recovered) as well as process-performance measures (broadly speaking, how OPOs did their jobs in the process of organ recovery).²² According to the regulations, if an OPO fails to meet the requirements for certification, it must be decertified.²³ However, **despite dramatic variations in performance, CMS has never successfully decertified an OPO for poor performance.**²⁴ One of the key elements that has limited CMS's ability to hold OPOs accountable up to this point is self-reported data used to evaluate OPOs on the outcome measures. (The process-performance measures receive less attention.)

In December 2019, CMS proposed new, objective outcome measures in an effort to bring accountability to OPOs as directed by the 2019 Executive Order on Advancing American Kidney Health, which broadly seeks to improve treatment for people suffering from kidney disease and expand access to transplants from living and deceased donors.²⁵ The proposed outcome measures include the organ donation rate and the transplantation rate for each OPO.

Many observers have characterized the overall system as woefully underperforming. In 2019, the *New York Times* editorial board argued that “an astounding lack of accountability and oversight in the nation’s creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks.”²⁶ And in 2020, the *Washington Post* editorial board wrote: “Some 33 Americans die every day for lack of transplantable organs to save their lives. Many more wait, crowding into dialysis centers and other healthcare offices in the midst of a pandemic. Much of this death and waiting is unnecessary, because the organs would be available if those responsible for collecting and transporting organs did a better job. It is past time the government demanded it of them.”²⁷

This large performance variance by OPOs has attracted the concern of elected leaders, government officials, and patient advocates, with the NPRM highlighting a 470 percent variability in organs recovered as a percentage of potential between the best- and the worst-performing OPOs.²⁸ Yet this variance also suggests a reason for optimism. If OPOs

22 [Fact Sheet: Organ Procurement Organization \(OPO\) Conditions for Coverage Proposed Rule: Revisions to Outcome Measures for OPOs](#), Centers for Medicare & Medicaid Services, December 17, 2019.

23 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: De-certification and Re-certification](#). 71 Fed. Reg. 486.312 (May 31, 2006, as amended at 82 FR 38515, Aug. 14, 2017).

24 Based on interviews with US Department of Health and Human Services civil servants and longtime organ procurement coordinators.

25 [Executive Order on Advancing American Kidney Health](#), WhiteHouse.gov, July 10, 2019.

26 “She Beat Cancer. Now, She’s in Another Fight for Her Life,” *New York Times*, August 20, 2019.

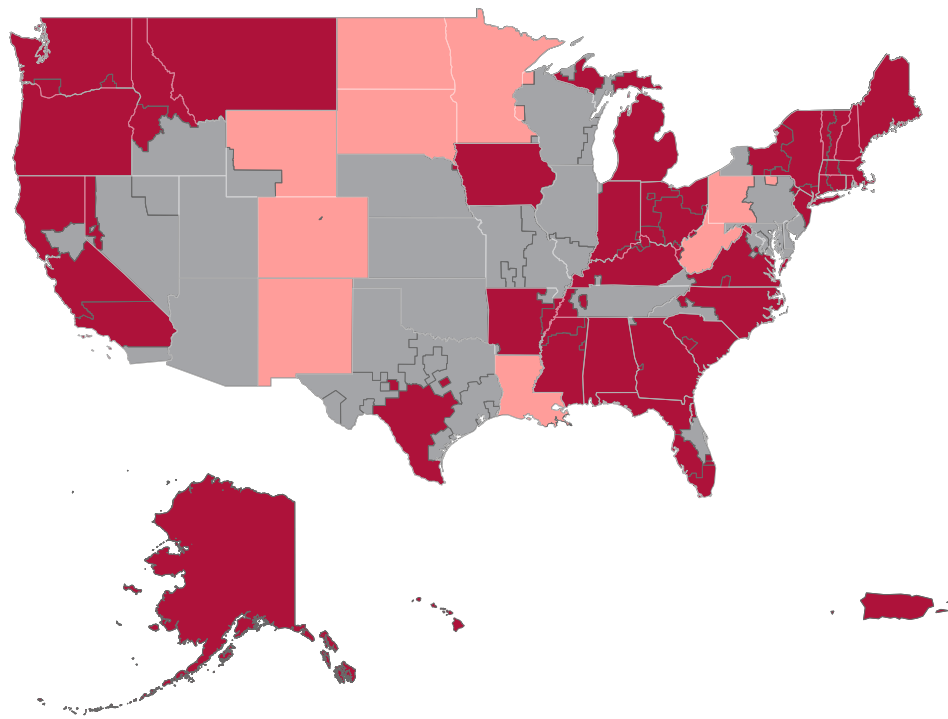
27 “Many die waiting for organs. The Trump administration could help,” *Washington Post*, August 1, 2020.

28 As noted above, the NPRM states, “We found a wide range of donation rates (1.65 to 6.45 donors per 100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants per 100 inpatient deaths),” a 470 percent difference between highest and lowest transplantation rates. [Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#), 84 Fed. Reg. 70628, (December 23, 2019).

were performing at similar levels, it would be challenging to know how to improve organ donation rates and bring more people off the transplant waiting list, or whether such improvements would even be possible. But this is not the case.

The top quartile of OPOs includes OPOs in both urban and rural regions across the US, as well as OPOs with both large and small service areas and OPOs serving a diverse mix of communities and patient populations. Indeed, the wide variance in performance across OPOs cannot be explained by local factors. Publicly available information from CMS about compliance with the proposed new federal standards gives a snapshot of this wide variance in performance.²⁹ Exhibit 2 shows OPOs that are close to each other geographically but at the extremes of the outcome measures proposed by CMS.

Exhibit 2: Organ procurement organizations (OPOs) by compliance with Centers for Medicare & Medicaid Services (CMS) proposed outcome measures



- OPO at or above proposed outcome measures** (listed in compliance by CMS in Notice of Proposed Rule Making (NPRM) on both the donor metric and organ transplant metric)
- OPO below proposed outcome measures on one metric** (listed in noncompliance by CMS in NPRM on either the donor metric or organ transplant metric)
- OPO below proposed outcome measures on both metrics** (listed in noncompliance by CMS in NPRM on both the donor metric and organ transplant metric)

Note: According to Notice of Proposed Rule Making (NPRM), OPOs must pass at least one proposed outcome measure to be recertified.

Source: CMS proposed rule December 2019 ([Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#)), Table 3 and Table 4 (pp. 57-60; 62-65). Tables based on 2017 data.

29 The 2019 Notice of Proposed Rulemaking from CMS included a snapshot of OPO performance under the proposed measures based on data from 2017. Data can change from year to year (which would be expected if the new measures drive changed practices and improved outcomes).

Examples of the variation between neighboring OPOs based on the proposed donation rate outcome measure include:

- **New York State:** One of New York’s OPOs, Finger Lakes Donor Recovery Network, was the worst-performing OPO in the country based on the proposed outcome metrics, with 91 percent estimated improvement required to be in compliance with the new donation rate standard. A nearby New York OPO, Upstate New York Transplant Services (also called ConnectLife), was judged to require no improvement to meet proposed measures and was in the top-performing quartile of OPOs nationwide.
- **Tennessee:** Tennessee Donor Services was within the top-performing quartile nationally (no estimated improvement required). In contrast, Mid-South Transplant Foundation was out of compliance and required an estimated improvement of 15 percent.
- **Alabama and Kentucky:** OPOs in these two states on either side of Tennessee contrast sharply in performance with Tennessee Donor Services. The Alabama Organ Center (now called Legacy of Hope) was the second-worst ranked OPO in the country (82 percent estimated improvement rate required to be in compliance) and Kentucky Organ Donor Affiliates was the fourth-worst ranked OPO (76 percent estimated improvement required to be in compliance).
- **California:** Two contiguous and large urban Southern California OPOs—LifeSharing (of San Diego) and OneLegacy (of Los Angeles)—have radically different outcomes. As Representative Katie Porter (D-CA) noted in a 2019 letter to HHS: “Despite having similar patient demographics and challenges, the San Diego OPO recovered 65 percent more donors [than the Los Angeles OPO].”³⁰ LifeSharing was the second-best performing OPO in the country, while OneLegacy was 37th (and out of compliance).

This point was reiterated when CMS, in the December 2019 Notice of Proposed Rulemaking (NPRM), noted: “We examined the characteristics of the DSAs among the top 25 percent performing OPOs and found that they include geographic areas representative of all parts of the US and diverse racial and ethnic populations. Despite this seemingly broader definition of potential organ donors, we did not notice any particular geographic patterns (including urban vs. rural) distinguishing the top-performing OPOs from the rest of the cohort, leading us to conclude that our broad definition ... appropriately describes the donor potential in a DSA and that the primary factors for differences in OPO performance using these measures are within the control of the OPOs to change.”³¹ This suggests that higher OPO performance is possible anywhere in the country; if average performance across the system could reach that of the top quartile, we could see a dramatic increase in the number of donated organs and related outcomes for patients. In fact, HHS highlighted that minimum compliance with proposed standards would mean 5,000–10,000 additional organ transplants per year.³²

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

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

32 The NPRM projects an increase of 4,903 organs per year if all OPOs reached minimum compliance standards (see Table 4), as well as a higher projection of 10,000 additional organ transplants annually if OPOs also improve donor-management practices: “If the number of donors at the lower-performing OPOs were to reach what is now the 75th percentile of achievement, the number of donors would increase ... by as many as 10,000 by 2026.”

These projections point to the importance of accountability to improve OPO performance and patient outcomes. In addition to finalizing the new outcome measures, a key issue to be resolved is when these new outcome measures will take effect. Congressional leaders have cast the need for reform in urgent terms. Representatives Porter and Karen Bass (D-CA), in a July 2020 letter to HHS Secretary Alex Azar and CMS Administrator Seema Verma, noted the Association of Organ Procurement Organizations (AOPO) “has advocated that the December Proposed Rule not come into effect until the 2026 certification cycle. ... We cannot consign 20,000 or more patients to die waiting for organ transplants while federal contractors are not held accountable, and therefore urge you to use the new standards in the next recertification cycle.”³³

Accountability in the OPO System

Because OPOs are reimbursed for 100 percent of costs deemed allowable by Medicare or included in fees to transplant centers, there is little fiscal pressure for OPOs to improve performance. When the OPO recovers organs from deceased donors, the organs are sent to a transplant center. Depending on who the patient is, the ultimate payor for the costs of procuring and transporting that organ could be either Medicare, Medicaid, or private insurance. For kidneys, patients become eligible for Medicare,³⁴ which reimburses OPOs directly based on an established rate between it and the OPO. At the end of the year, OPOs can receive additional Medicare reimbursement for any direct or indirect costs associated with kidneys not covered by these reimbursements.

For other organs, the corresponding transplant center reimburses the OPO according to a preset, organ-by-organ standard acquisition charge (SAC).³⁵ “Standard” is a misnomer, however, because SACs vary widely by OPO as well as by organ—sometimes by 100 percent across OPOs for the same organ.³⁶ Because OPOs are regional monopolies, setting their SAC fees based on annual costs and the number of organs recovered, transplant centers have little to no negotiating power and must pay SAC fees even if patients’ insurance will not cover the cost (or forego transplantation due to insufficient reimbursement; see [Appendix A](#) for additional detail).³⁷

OPOs are federally regulated, so improving existing federal regulations is an obvious component of any strategy to move the performance of the overall system toward matching that of its strongest performers. In the December 2019 NPRM, CMS tied

33 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. The House Appropriations Committee similarly called for immediate finalization and implementation of proposed OPO reforms: “The Committee supports the goal of significantly increasing kidney transplants, established by the President’s Executive Order on Advancing American Kidney Health, and supports efforts to establish objective outcome measures for Organ Procurement Organizations (OPOs) as well as efforts to decertify underperforming OPOs at the conclusion of the current contract cycles.” [House of Representatives Committee Appropriations Report](#), July 2020.

34 [Medicare Guide for End-Stage Renal Disease](#), Medicare.gov.

35 Standard acquisition charge fees are set in the previous year by the OPO.

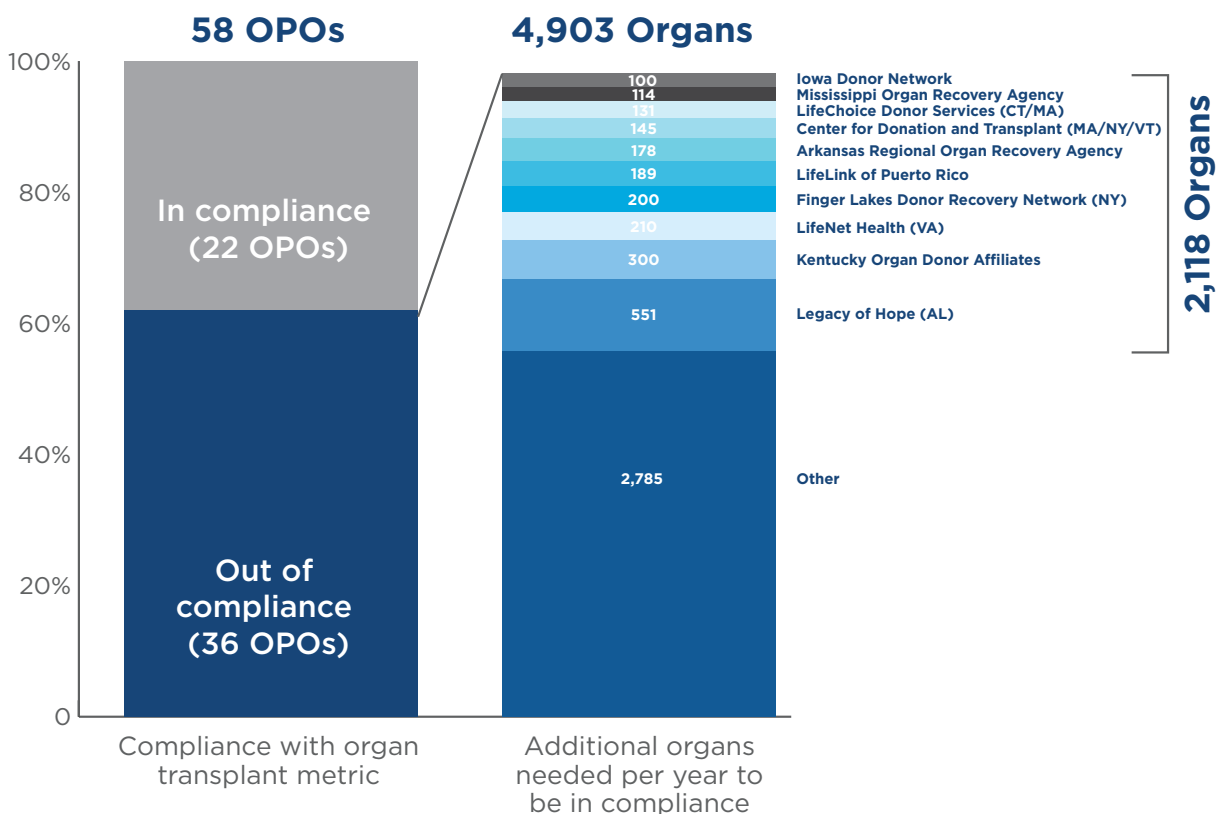
36 P.J. Held et al., “[The cost of procuring deceased donor kidneys: Evidence from OPO cost reports 2013–2017](#),” *American Journal of Transplantation* 2020; 20 (4): 1087–1094.

37 OPO finances are further complicated by their presence in tissue recovery, the for-profit portion that separately sells tissue, corneas, etc., with some OPOs reporting as much as 45 percent of funds flowing from for-profit tissue operations based on analysis of OPO tax filings.

together both the need to increase deceased donation and the regulatory strategy to do so, writing, “we know that the HHS goal for increasing kidney donation and transplantation cannot be met without a substantial increase in performance.” It added: “Our new performance measures would create an organizational survival issue. The future of an OPO depends largely on its performance in obtaining donors and on utilization of those organs for transplantation.”³⁸ To be clear, the NPRM points to a strategy of improving OPO performance to help more patients access transplants, creating clear standards and transparency so that underperforming OPOs either improve or those communities are served by higher-performing OPOs.

Exhibit 3: Meeting compliance standards would mean 4,903 more organs transplanted per year

Bringing the 10 worst-performing OPOs (by estimated improvement required) into compliance would mean 2,118 more transplants per year.



Note: “In compliance” means listed as in compliance by CMS in the NPRM on organ transplant metric. “Out of compliance” means failing at the organ transplant metric.

Source: CMS proposed rule December 2019 ([Revisions to the Outcome Measure Requirements for Organ Procurement Organization](#)), Table 3 and Table 4 (page 57-60; 62-65). Tables based on 2017 data.

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

Note, as well, that CMS writes in the December 2019 NPRM that it does not expect to incur substantial costs: “The data collection required for enforcement of the proposed standards already exists and can readily be used to assess performance,” and “[t]he number of affected facilities is also small compared to the number of facilities that CMS works with on a regular basis. Regardless, these oversight activities are unlikely to require more than three or four additional person-years of effort, with annual costs of one million dollars or less.”³⁹

Under federal law, CMS certifies OPOs based on whether they meet the Conditions for Coverage, including outcome and process measures.⁴⁰ If an OPO is decertified, the corresponding DSA is opened to competition from OPOs whose track records suggest they would better serve patients. CMS would then assign one or more higher-performing OPOs to serve all or part of the decertified OPO’s DSA.⁴¹ However, despite dramatic variations in performance, CMS has never successfully decertified an OPO for poor performance.⁴² As government-granted monopolies who pass through their expenses, OPOs do not face significant market incentives to perform well; the fact that no OPO has ever been decertified suggests that OPOs have not faced effective regulatory incentives either.

Further strengthening the case for decertifications: there is no evidence to suggest that HHS’s alternatives have ever been successful. Specifically, in 2012, HHS placed an underperforming OPO on a “performance improvement plan” in lieu of decertification, in hopes that such a governmental plan would lead the OPO to turn around. As noted in the *Washington Post*, since 2012, CMS has required the OPO to submit at least three “corrective action plans.” Despite such plans, for at least the past eight years, the OPO “has consistently registered one of the poorest performances in the nation,” and “ranked as the country’s second-worst OPO [in 2017].”⁴³ In their July 2020 letter to Secretary Azar, Representatives Porter and Bass criticized CMS’s reliance on performance improvement plans, writing, “patients do not have years to wait,” and “there is no reason to have confidence that performance improvement plans actually lead to OPO improvement or better results for patients.”⁴⁴

The lowest-performing OPOs play a big role in the mixed performance of the OPO system in providing enough organs to reduce the transplant waiting list. Even modest steps to improve the lowest-performing OPOs could produce significant improvement. Minimum compliance with proposed measures translates to 4,903 more organs transplanted, and if just the 10 worst-performing OPOs (according to the estimated

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

40 [Fact Sheet: Organ Procurement Organization \(OPO\) Conditions...](#), Centers for Medicare & Medicaid Services.

41 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Re-certification and Competition Processes](#). 71 Fed. Reg. 486.312 (May 31, 2006, as amended at 78 FR 75199, Dec. 10, 2013; 84 FR 61492, Nov. 12, 2019).

42 Based on interviews with US Department of Health and Human Services civil servants and longtime organ procurement coordinators.

43 Larry Bernstein and Kimberly Kindy, “[New York organ collection agency, nation’s second-largest, threatened with closure](#),” *Washington Post*, July 11 2018.

44 Representative Katie Porter, et al., [Letter to the Department of Health and Human Services and Centers for Medicare & Medicaid Services](#).

amount of improvement required to meet proposed CMS standards) were brought into compliance with the standards, our analysis finds that there would be approximately 2,100 more organs transplanted per year—saving over 1,900 lives and hundreds of millions of dollars in dialysis costs annually.^{45,46}

Given the implications of underperformance of organ recovery for patients in need of transplants, the idea that OPOs should be held accountable—and face real consequences for underperformance—has been forcefully argued by expert observers, members of Congress, and, now, by federal regulators themselves.

Recent comments from government officials in both parties reflect their concern with the current system. In HHS’s formal remarks announcing the proposed rule, Secretary Azar noted: “Our broken system of procuring organs and supporting kidney donors costs thousands of American lives each year. ... We’re going to stop looking the other way while lives are lost and hold OPOs accountable.”⁴⁷ Senator Todd Young (R-IN) told the *Washington Post*: “We can’t continue to allow [thousands of] Americans to die each year waiting for lifesaving organs that we know are available if only this system were being managed by competent individuals operating in the light of day.”⁴⁸ And, in August 2020, in a letter led by Congressmen Max Rose (D-NY) and Tom Reed (R-NY), which included the co-chairs of the Congressional Kidney Caucus and the Congressional Diabetes Caucus, 25 bipartisan Congressional representatives wrote to Secretary Azar regarding “serious, widespread problems in our organ transplant system including OPOs self-reporting and grading themselves on their performance,” which “has led to grave consequences,” noting that “this incompetence has also cost tremendous amounts of taxpayer dollars.”⁴⁹

A critical element of this accountability is the system of metrics by which outcomes are measured. Up to this point, self-reported metrics have limited CMS’s ability to hold underperforming OPOs accountable on behalf of patients.⁵⁰ DJ Patil, former chief data scientist of the United States, has called the current data for OPOs “functionally useless.”⁵¹ The Association of OPOs wrote to the White House Office of Management and Budget in 2013, critiquing the performance metrics then in use: “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. This is in direct conflict with the mission

45 The difference between organs transplanted and lives saved is accounted for by the frequency of multiple organ transplants (e.g., combination kidney and liver); assumes 1.1 organs transplanted per recipient on average, based on historical data.

46 We note the expressed intention of CMS to publish new data each year in an effort to improve transparency and accountability, so the list of OPOs in or out of compliance can be expected to change.

47 “[Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply](#),” US Department of Health and Human Services, December 17, 2019.

48 Kindy et al., “[Lives Lost, Organs Wasted](#).”

49 Representative Max Rose, et al., Letter to the US Department of Health and Human Services, August 26, 2020. Of note, the members explicitly acknowledge and reject OPO arguments related to the NPRM: “We are disturbed that OPOs are now asking that the proposed accountability measures in this upcoming rule be delayed because of the COVID-19 pandemic. We strongly urge that you issue the rule without delay and that it is not watered down to appease the OPOs.”

50 Kindy and Bernstein, “[Despite low performance, organ collection group gets new federal contract](#).”

51 Laura and John Arnold, “[A simple bureaucratic organ donation fix will save thousands of lives](#),” *Stat*, July 24, 2019.

of OPOs to pursue every viable organ for transplant to save even one life.”⁵² Regarding this potential disincentive, CMS noted in the proposed rule, “We are concerned that potentially transplantable organs may be wasted, exacerbating the organ shortage.”⁵³

Under the proposed new rules issued by CMS in December 2019, the number of potential donors and transplantable organs would be independently assessed rather than self-reported. The new outcome measures would use data held by the government to establish how many potential donors each OPO could have pursued in its efforts to recover organs each year. The rule would further set a standard for organs transplanted by each OPO, with a threshold for acceptable performance. Thirty-two OPOs would be out of compliance if the new rules were in place today based on the data published last December, with 37 of the 58 failing on at least one of the two metrics.⁵⁴ Federal officials estimate that the proposed changes could increase organ donation and transplantation “by as many as 10,000 by 2026.”⁵⁵ A statement from the AOPO, the OPO trade group, noted that “an independent, verifiable metric for evaluating OPO performance can be an important tool, helping to identify potential opportunities for growth in OPOs’ quest for continual improvement.”⁵⁶ However, AOPO has since requested that HHS delay finalization of the outcome measures, advocating instead for an alternative metric. Researchers in a *Journal of the American Medical Association* viewpoint, including Patil, described this alternative as “unworkable,” noting that AOPO’s proposal would still “leave the system vulnerable to gaming and inaccuracy” and would represent “a massive unfunded mandate on our nation’s 6,000 hospitals.”^{57,58}

While the proposed new metrics have not yet been finalized, the intention of federal regulators is to use new standards to improve OPO performance and—potentially—put teeth in the heretofore unused decertification process to better serve patients in need of transplants. Increased oversight will likely prompt OPOs to seek to improve their performance, which is highlighted in the December 2019 NPRM itself. Since the executive order announcing the proposed new metrics and increased oversight, data show that OPO performance has already begun to improve, perhaps early evidence of the “Hawthorne effect” (i.e., increased scrutiny and observation by itself drives behavior change that leads to improved outcomes).⁵⁹ That such gains were possible, and yet unmade prior to the executive order, underscores the importance for HHS to institutionalize such regulatory pressure for OPOs to improve performance. As the *Washington Post* editorial board wrote: “In a system in which these nonprofits have an

52 [Unaddressed Implications of the Proposed Changes to the Conditions of Coverage for Organ Procurement Organizations \(HHS/CMS Rule 0938-AR54\)](#), Association of Organ Procurement Organizations, October 2013.

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

54 Ibid.

55 Ibid.

56 [The Association of Organ Procurement Organizations Comments on CMS Rule to Increase Organ Supply](#), Association of Organ Procurement Organizations, December 17 2019.

57 Seth J. Karp, Greg Segal, and D J Patil, “[Fixing Organ Donation: What Gets Measured Gets Fixed](#),” *Journal of the American Medical Association Surgery* 155, no. 8 (2020): 687-688.

58 Ibid. One of the authors of this piece, Greg Segal of Organize, is a Bridgespan client.

59 William Chapman et al., “[Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage; Revisions to the Outcome Measure Requirements for Organ Procurement Organizations](#),” Public Comment to CMS, February 20, 2020.

effective monopoly on organ recovery within their zones, there are few incentives for them to improve unless decertification is a serious possibility.”⁶⁰

Data also suggest that the mere threat of decertification improves performance across all OPOs, which means that mid-performing OPOs will likely work harder to improve to avoid decertification. This further suggests that CMS—and other analysts—are correct that more organs could be transplanted with increased OPO accountability. So while there is documented underperformance across the system, the evidence also suggests that OPOs can improve performance.⁶¹

As two leading OPO CEOs, including the former president of AOPO, wrote to Secretary Azar in October 2020, “If OPOs spent their time and resources, right now, rapidly improving their practice and increasing organ donors, we believe that many—if not all—of our colleagues would not face decertification.” They also advised that HHS should not hesitate to decertify OPOs that prove incapable of meeting performance standards, and that HHS, in fact, has an obligation to patients to do so: “To the extent that an OPO is not able to rise to the challenge of a high CMS standard, the focus of our attention and energy must be on better serving patients on the national waitlist, not on protecting specific OPOs. If we accept that such improvements are possible—and we understand that such improvements are lifesaving—realizing these gains is not simply a policy question, but a social imperative.”

Based on expert interviews, data analysis, and a review of previous experience in the OPO systems, we believe that the likeliest path to OPO improvement is either through responding to increased regulatory pressure to perform or new leadership.

New Leadership Could Drive OPO Performance Improvements

This section looks in detail at the potential for driving improvement within the OPO system through new leadership and provides some suggestions as to how these improvements might best be pursued. It’s been done successfully in the past. For example, at Donor Network West, the San Francisco-based OPO, a new CEO grappled with underperformance across numerous key performance indicators. She sought out stakeholders within and outside the organization and listened to them deeply before taking action. That led her to put in place real-time case review and problem-solving processes during referral and donor management, and before ruling out potential donors. The OPO also improved training on family-approach best practices, increased frontline support, including cutting down back-to-back shifts, and established executive leadership goals and expectations for increased organ recovery volume and lives saved. Largely as a result, Donor Network West increased donations by nearly 30 percent in the first year.

New, enforceable regulatory standards, and, by extension, the threat of decertification for underperformance, might motivate more OPOs to install new leadership (in hopes of improving organ recovery, thereby avoiding decertification) and/or to merge with

60 “Many die waiting for organs...,” *Washington Post*.

61 Diane Brockmeier and Ginny McBride, [Letter to the Department of Health and Human Services](#), October 9, 2020.

another OPO with a track record of better performance. If an OPO does not meet performance standards, CMS may force a change by decertifying the organization, effectively installing new leadership by reassigning a territory to a higher-performing OPO.

Existing OPOs Find New Leadership

In the December 2019 NPRM, CMS noted that the proposed outcome standards provide OPOs with flexibility as to how they go about meeting them, noting: “In addition to all the possible internal reforms that an OPO could make ... OPO boards could replace the executive leadership.”⁶² Recent experience suggests this is apt: while leadership change itself does not guarantee improvement, there is clear evidence that the right leadership can quickly improve performance for stubbornly underperforming OPOs.⁶³ There are several examples of this. In some cases, improvement has occurred as quickly as the first year. In addition to the Donor Network West example noted above, when new leadership took over OPO operations in Washington State (2010), Nevada (2012), and Oklahoma (2012), each OPO sustained gains over a five-year time period that outpaced the corresponding national increases in donors⁶⁴ (see [Appendix C](#) for details on examples of new leadership).⁶⁵ The boards of directors that hire, fire, and provide oversight of OPO CEOs should focus on increased organs procured and transplanted as a key measure of CEO effectiveness, relying on CMS’s new metrics as the measure of success.

New Leadership Through Expansion

The second way new leadership could play out is through existing high-performing OPO leaders assuming responsibility for additional geographies, translating their processes and practices to new DSAs.

Improving patient outcomes via consolidation of OPO service areas is not new. Indeed, the current system of 58 OPOs is the result of several rounds of historical consolidation, with no deliberate design behind the total number of service areas or their borders. In the 1980s, there were 128 OPOs. Driven by a push for greater efficiency, they consolidated to less than half that number. Even though the current system is underperforming, these consolidations did coincide with a general increase in organ recovery and transplantation. Analysis of five recent mergers, which occurred between 1997 and 2001, shows consolidation can occur while maintaining continuity of service.⁶⁶ In four of these five mergers, the OPOs had five-year post-merger growth rates in donors that exceeded the national five-year growth rate. And even in the one merger where the rate of growth lagged the national trend, the combined OPO still recovered more donors per year than the separate entities had prior to the merger, indicating continuity of services throughout the consolidation.

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

63 Elaheh Niroomand, et al., “[Rapid improvement in organ procurement organization performance: Potential for change and impact of new leadership](#),” *American Journal of Transplantation*, May 31, 2020.

64 The national increase in donation during this time period was largely driven by the opioid epidemic; David Goldberg and Raymond Lynch, “[Improvements in organ donation: Riding the coattails of a national tragedy](#),” *Clinical Transplantation* 34, Issue 1 (November 19, 2019).

65 Data on donations retrieved from OPTN.

66 *Ibid.*

In all five cases, there was no evidence of disruption to organ procurement as a result of consolidation. Small year-to-year variations in the number of donors were in line with typical OPO performance. (See [Appendix B](#) for additional data on these past mergers.)⁶⁷ These data support the position of key stakeholders, such as the National Kidney Foundation, which noted in an October 2, 2020, statement: “We believe that any concerns about major, immediate disruption to the transplant system are unfounded.”⁶⁸

Mergers enabled by new OPO regulations will necessarily entail a relatively high-performing OPO assuming responsibility for a geography previously served by a lower performer. Given this, future mergers, implemented intentionally to improve organ recovery rates, could potentially outperform historical mergers. CMS specifically signals this in the December 2019 NPRM, writing: “We believe that OPOs will be held to a high standard of performance under the new proposed outcome measures. This would ensure that any OPO that is seeking to compete for an open service area performs significantly better than the de-certified OPO.”⁶⁹

What’s more, our analysis and interviews with field experts show that higher-performing OPOs taking over responsibility for additional DSAs could help more patients by freeing up duplicative resources that could be effectively dedicated to frontline activities that drive procurement and, in turn, increase the number of transplants.

Performance-Improvement Strategies

A range of initiatives and activities could improve OPO recovery rates, instituting best practices used by higher performers. These can be implemented in the context of a high-performing OPO assuming responsibilities for a new DSA, a leadership transition, or as part of an OPO’s performance-improvement strategy. Keep in mind that there are different points in the procurement process where opportunities for donations are lost:⁷⁰

1. In some cases, a hospital fails to refer a potential donor to the OPO. This could be due to the OPO’s failure to build a strong relationship with the hospital (one of the OPO’s primary responsibilities), or, in a related issue, hospital staff’s belief that the OPO will not respond (often based on experience). In other cases, the referral to the OPO comes so late in the patient-management process that it is difficult for the OPO to respond in time. In the long term, these late referrals can be addressed by improved hospital education by the OPO (e.g., regular rounds by OPO staff and quarterly performance reviews to educate hospital staff on the referral process).

67 A sixth example of an OPO taking on the territory of an underperforming peer and driving improvement—though not technically a merger—occurred in 2017 when the New England Organ Bank in Massachusetts and Connecticut-based LifeChoice Donor Services chose to voluntarily affiliate under the name New England Donor Services (NEDS). Their example further suggests such leadership change can improve outcomes while maintaining continuity of service. With the goal “to increase the number of organs available for transplant and create region-wide financial efficiencies,” NEDS reported success: “Two years into the affiliation, the number of donors and transplants has nearly doubled in the LifeChoice DSA—from 2016 to 2018, the Connecticut OPO experienced a 95 percent increase in donors and a 93 percent increase in transplants from donors.” Sara Moriarty, “[‘Roll up your sleeves’: The hard work of increasing donors and transplants](#),” United Network for Organ Sharing, April 30, 2019.

68 [NKF Statement Regarding the Administration’s Proposed Revisions to the OPO Conditions for Coverage](#), National Kidney Foundation, October 2 2020.

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

70 Based on interviews with OPO leaders and industry researchers. [Additional research by Bloom Works has further mapped this process.](#)

2. The OPO receives a referral but does not respond. The OPO might prematurely assess that the referral will not lead to a donation, or an OPO may deprioritize those who can donate single rather than multiple organs. In addition to missing a potential donation, this could damage the relationship with the hospital, affecting future donations. In some cases, an OPO may discount potential organ donations that it believes local transplant centers might not accept, even if other transplant centers outside of the immediate community might do so.
3. The OPO receives a referral, but frontline staff arrive too late to respond (potentially due to staffing problems) so do not have sufficient time to pursue the case (e.g., the potential donor suffers cardiac arrest before the donation process is complete). The *Washington Post* reported on one OPO that was “short-staffed at critical moments, causing transplant coordinators to show up late or not at all to speak with grieving families.”⁷¹
4. The OPO arrives at the hospital to work on the case, but frontline staff do not receive authorization from the donor family. Though in some cases a refusal may be unavoidable based on the family’s wishes, often it results from the poor quality of the OPO interactions and approach.⁷² The *Washington Post* documented one OPO that was “particularly bad at” securing consent, with an “approach [that is] sometimes indelicate, causing families to delay signing consent forms or to refuse to sign them altogether.”⁷³ Moreover, peer-reviewed research has found broad variability in the quality of OPO interactions with donor families, concluding that “national standards for request staff communication training and certification are not established even though the existing evidence points to the critical importance of communication during requests and the success of currently available training options.”⁷⁴
5. The OPO does not allocate the organ in time. This may be related to whether or not the OPO uses all mechanisms available within OPTN policy to fast track so-called marginal organs (i.e., lifesaving organs from older donors) to transplant centers more likely to accept them and use them successfully.⁷⁵
6. The OPO allocates the organ, but inefficient logistics or other challenges in transit lead to eventual discard. A recent Kaiser Health News investigation found a “startling number of lifesaving organs are lost or delayed after being shipped on commercial flights, the delays often rendering them unusable.”⁷⁶
7. The transplant center receives the organ, but it is not transplantable, for reasons including but not limited to damage incurred during transit or too much cold ischemic time (the length of time between when an organ is removed from a donor and a transplant procedure begins) degrading the organ quality, leading to a discard.

71 Kindy, “[Underperforming in New York: Nonprofit struggles to recover transplantable organs.](#)”

72 Laura Siminoff et al., “[Factors Influencing Families’ Consent for Donation of Solid Organs for Transplantation,](#)” *JAMA*, 286 no. 1 (July 4, 2001): 71-77.

73 Kindy, “[Underperforming in New York: Nonprofit struggles to recover transplantable organs.](#)”

74 H. M. Traino, A. J. Molisani, and L. A. Siminoff, “[Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation,](#)” *American Journal of Transplantation* 17 no. 6 (June 17, 2017): 1620-1627.

75 The Organ Procurement Transplantation Network (OPTN) is a public-private partnership established by the National Organ Transplant Act, which manages the national waiting list.

76 JoNel Aleccia, “[How Lifesaving Organs for Transplant Go Missing in Transit,](#)” Kaiser Health News, February 2020.

From interviews with OPO leaders and field experts, as well as from the Bridgespan team's experience with performance-improvement initiatives in other social sector fields, we distilled the following performance-improvement strategies to address one or more of these gaps.

Assess where in the DSA there is untapped potential. One OPO leadership team conducted an analysis of potential donors compared to actual donors within its DSA, identified gaps, and addressed them by increasing staffing. A hospital in the DSA, for example, averaged one to two donors per year, compared to an expected number of donors closer to 15. The team reallocated frontline staff to focus on that hospital; similar changes in staffing and referral responses across the DSA increased referrals by almost 70 percent. This kind of data-informed view of the largest pools of potential donors that do not lead to donation is a good starting point. Four important data sources for identifying these are the CDC WONDER database, Scientific Registry of Transplant Recipients data,⁷⁷ death-record audits for non-heartbeating referrals to the OPO, and referral data currently provided to the OPOs by hospitals. Analyzing county-level death data from WONDER, narrowed by the CALC (Cause, Age, Location-Consistent) donation measure,⁷⁸ provides a realistic view of the total number of potential deceased organ donors in a given year. Comparing these potential figures with actual OPO referrals from hospitals within the same timeframe allows OPOs to identify potential underreporting at a hospital level.

Once an OPO has identified which hospitals in its DSA are underperforming in terms of actual donors compared to potential, it can then take steps to address this underperformance (e.g., improve its hospital process to capture these missed referrals). While some individual OPOs may be more or less proficient with death-record auditing and referral data analysis (e.g., only some OPOs employ full-time data analysts), the required analysis should be feasible, because methods for utilizing CALC data are well known within the industry and they can be replicated by OPO analysts. Some OPOs are already using CALC data to inform new strategic plans to improve performance, and there is no reason the remaining OPOs cannot develop such capabilities in-house or engage external researchers to advise on CALC-data-informed strategies.⁷⁹

Research suggests that the largest pools of untapped potential are likely older donors,⁸⁰ DCD (donation after circulatory death) donors,⁸¹ and donors of color.⁸² One OPO recognized that older donors and DCD donors were a large source of unrealized potential donations, prompting renewed efforts to serve both populations. Simple changes to how this OPO ruled out these donors, and how frontline staff followed up on

77 [WONDER database](#), Center for Disease Control.

78 The Cause, Age, Location-Consistent (CALC) measure is a metric that captures the potential donor supply in a particular area. According to the American Society of Nephrology, the measure is more accurate than the existing metric of "eligible deaths" because it focuses on inpatient deaths from causes that lead to donation. More information on the CALC measure can be found [here](#) and [here](#).

79 Based on interviews with organ-donation professionals who attended organ procurement organization (OPO) presentations at the January 15, 2020, AOPO conference.

80 United Network for Organ Sharing, "[OPTN Deceased Donor Potential Study](#)," Organ Procurement and Transplantations Network, March 2015.

81 Laura Siminoff, Amma Agymang, and Heather Traino, "[Consent to organ donation: a review](#)," *Progress in Transplantation* 23 no. 1 (March 2013): 99-104.

82 Laura Siminoff, Christopher Burant, and Said Ibrahim, "[Racial Disparities in Preferences and Perceptions Regarding Organ Donation](#)," *Journal of General Internal Medicine* 21, no. 9 (September 2006): 995-1000.

these potential cases, resulted in increases in donations, with the OPO now on track to recover close to 20 percent more organs in 2020 than in 2019.⁸³

Invest in frontline staff. Once an OPO has identified the largest areas for improvement, it can bring resources to bear more effectively to pursue these donations. Increasing the number of donors reached and organs transplanted will necessitate aligning frontline staff to this goal, providing them with greater support, and equipping them to better serve underserved donor groups. OPOs employ a range of staffing models and varying degrees of centralization in their service areas, so the exact staffing solutions required will vary based on the OPO's existing approaches as well as the nature of the unrealized potential donations (e.g., some OPOs may need to change coverage models to increase face-to-face approaches to donor families, improve hospital relationships to get more timely and accurate referrals, or adjust staffing to improve referral response times). In many cases, OPOs may be able to more effectively deploy existing staff to pursue potential donors, and in some cases, OPOs may need to increase the number of frontline staff overall. Given that a large portion of unrealized potential donors comes from communities of color, OPOs should make a conscious effort to hire more frontline staff who are people of color. (See the section "Improve Performance with Communities of Color and Other Donor Groups That Have Historically Received Less Engagement," on page 21.)

Support frontline staff to ensure a high level of service to donor families and effective procurement and placement of donations.⁸⁴ Our interviews with OPO stakeholders suggest that OPO frontline staff are typically overworked, underpaid, and under-supported. One OPO leadership team increased donations from a specific hospital after analysis suggested changes to staffing supports would help. In this case, one hospital in the DSA, while close to headquarters, had longer than average frontline response times, leading to a higher incidence of potential donors suffering cardiac arrest before donation could take place. Analysis of the causes of this delay indicated many cases were being responded to in the middle of the night by coordinators working 24-hour shifts. A switch to 12-hour shifts, which allowed frontline staff to more quickly deploy to potential cases, cut response time by close to 50 percent and corresponded with an increase in donations from that hospital. Implementing similar changes in staffing across the DSA resulted in an annual increase of 15 percent in donors.

Research suggests that "lack of any formalized training to perform their job functions likely contributes to the high rates of staff burnout and turnover."⁸⁵ Seventy-five percent of frontline staff in one survey "expressed a desire for more training and education opportunities."⁸⁶ OPO coordinators should be trained in trauma-informed care for approaching difficult cases and be provided with healthy strategies for managing stress

83 "Indiana Donor Network breaks monthly record," *Washington Times Herald*, August 14, 2020.

84 The term "coordinator" is used in the transplant field to refer to a range of frontline roles. We have used the term "frontline staff" and "coordinator" where appropriate and sometimes interchangeably. Primary functions of "coordinators" include: relationship managers who educate hospital staff and respond to referrals at hospitals; requestors who respond to referrals, engage with hospital staff, and engage with families; and clinical coordinators, who respond to referrals, engage with hospital staff, support donor families, and initiate donor management along with managing allocation.

85 Laura Siminoff, Heather Traino, and Maureen Wilson Genderson, "Communicating Effectively About Organ Donation: A Randomized Trial of a Behavioral Communication Intervention to Improve Discussions About Donation," *Transplantation Direct* 1 no. 2 (March 2015): e5.

86 J. Kress et al. "Improving the Recruitment and Retention of Organ Procurement Coordinators: A Survey Study." *American Journal of Transplantation*, 9 no. 6 (June 2009): 1451-1459.

to prevent burnout. Long hours can also affect an OPO coordinator’s ability to make critical decisions. We heard from a consultant who has worked with many OPOs that some coordinators who stay on longer can “develop maladaptive behaviors to cope with that level of stress, trauma, and lack of rest. We tend to hollow out the workforce and then complain when we have these really deplorable conditions.”

This has implications not only for frontline staff performance (e.g., coordinators operating on hour 22, for example, are more likely to make mistakes), but also on retention—with turnover likely to occur around the two-year mark.⁸⁷ The fairly short retention period for staff is particularly striking, given that some OPO directors have mentioned it takes one to two years for new coordinators to get to a high level of proficiency at the job.⁸⁸ This suggests that OPOs are investing significant financial and human resources toward recruiting and training frontline staff who leave just as they’re becoming effective. As one OPO leader noted: “It takes a long time to train a transplant coordinator. When you’ve gotten to the point where they’ve been there for two years [and] they’ve just figured out how to do the job ... it is difficult to have them leaving because now you have to start again.”⁸⁹

Potential ways to better support frontline staff include:

- Move from 24-hour shifts to 12-hour shifts for frontline staff, with a mandatory cap on overall number of hours per month. Recall that one OPO moved to a 12-hour shift and reduced response times to one local hospital by almost 50 percent, because staff were not responding to off-hour calls from home, but rather coming from the office.
- Increase OPO frontline staff salaries. To boost retention and secure talent, OPOs should consider increasing OPO coordinator salary to attract the ideal candidates they are considering. One OPO leader described their efforts to hire critical care nurses with experience managing ICU patients, noting, “[If] we want to have the very best clinicians, we will have to pay a competitive industry salary rate.”
- Assess existing mental health resources and supports for frontline staff and identify initiatives to strengthen support. The OPO coordinator profession is associated with high degrees of emotional, mental, and physical stress. This is especially true given the increase in DCD cases, particularly pediatric DCD cases. Potential initiatives include mandating that frontline teams attend an emotional debrief after a difficult case, or piloting the use of an on-staff counselor and encouraging use of vacation time. As OPOs expand into more DCD cases, these supports will be even more important.
- Provide training and development opportunities to frontline staff. This can be an important factor for retention. Research indicates that among the most likely variables to predict whether a family will donate were the OPO coordinators’ “relational communication skills,” including whether they exhibited “sensitivity and compassion” to the family, or whether the family felt “pressure to donate.” Donor families report stark differences in their experiences with OPOs which, not surprisingly, correlate strongly with OPO performance. Research concludes that this is a “modifiable but largely

87 Kress et al., “Improving the Recruitment and Retention of Organ Procurement Coordinators: A Survey Study.”

88 Ibid.

89 Ginny McBride, “From Burnout to Breakthrough: Strategies to Reduce Coordinator Turnover and Improve Productivity,” Organ Donor and Transplantation Alliance webinar, August 2020.

overlooked factor in organ availability,” and that “initial training is needed to acquire and develop the informational and relational communication skills needed to optimize the likelihood of donation.”⁹⁰

Improve performance with communities of color and other donor groups that have historically received less engagement. If OPOs want to improve their performance, they must serve traditionally underserved communities—especially communities of color. Donors of color are likely to be a key source of unrealized potential donations, and are more likely to be a match for patients on the waitlist with similar ethnic backgrounds.⁹¹ But significant improvements by many OPOs will be needed. As Ben Jealous, former president and CEO of the NAACP, wrote in a July 2020 op-ed: “OPOs are now resorting to blaming others for their failures—and pointing the fingers directly at communities of color. ... The real problem is that too often these government contractors do not engage with our communities. They hire blindly white work forces, and seem completely unwilling or unable to adopt culturally competent practices.”⁹² Indeed, recently published research in the *Journal of Racial and Ethnic Health Disparities* finds that donor families of color, particularly Black families, receive fewer and lower-quality contacts from OPOs than white donor families.⁹³ The authors report that Black families are less likely to have spoken to an OPO representative and were given fewer opportunities to consider the decision with OPO staff. When they are approached about donation, Black families often receive inferior levels of service. The authors conclude that organization-level changes at the OPO level are required to address these disparities: “There is a need to change organ procurement organization attitudes and practices toward black families as potential donor families.”

Staffing is an important element of any potential solution. There is evidence suggesting that OPOs deploying ethnicity-matched requestors for donation has “the potential to increase consent rates among racial and ethnic minorities.”⁹⁴ OPOs acknowledge this: indeed, one OPO executive noted that OPOs “need to find opportunities to recruit, retain, and mentor people of color.” However, interviews with field experts indicate that some OPOs that serve racially diverse populations have a frontline staff that is entirely or almost entirely white. And an OPO executive noted that in terms of increasing the recovery of organs from donors of color, “a big obstacle is that there is a lack of diverse representation in frontline workers and OPO leaders.” A more diverse staff should also be supported in its work by effective outreach to communities of color, including outreach materials that are culturally and linguistically appropriate, partnerships with faith-based and other community organizations, and focus groups with community members to better understand challenges and opportunities in working with these communities.

Beyond hiring diverse staff who reflect the communities they serve, OPOs could also improve their performance with implicit bias and cultural sensitivity training for OPO

90 Traino et al, “Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation.”

91 [Facts about organ donation](#), UNOS.

92 Jealous, “Don’t let the COVID-19 crisis delay reforms to our organ transplant system.”

93 L.A. Siminoff, G. P. Alolod, H.M. Gardiner, et al., “A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation,” *Journal Racial and Ethnic Health Disparities* (June 30, 2020).

94 David Goldberg, Scott Halpern, and Peter Reese, “Deceased Organ Donation Consent Rates among Racial and Ethnic Minorities and Older Potential Donors,” *Critical Care Medicine* 41 no. 2 (February 2013): 496-505.

employees. Implicit bias—the attitudes or stereotypes that unconsciously affect our understanding, actions, and decisions—is an issue across the US healthcare system. A systematic review⁹⁵ of 42 studies indicates that “almost all studies found evidence of implicit biases among physicians and nurses” and concluded that there is “evidence for a relationship between implicit bias and negative effects on clinical interaction.” At present, OPOs are not sufficiently addressing these issues. One OPO executive noted that existing implicit bias and cultural sensitivity training is not very effective, and is typically done in-house or by organizations that do not specialize in the topic. In addition to using tools with documented effectiveness and securing high-quality training, OPOs have the opportunity to learn from others in healthcare who have developed effective training and worked to successfully address issues of implicit bias.⁹⁶

Another key element of improving performance with communities of color is using data to identify specific areas of underperformance. OPOs can compare data on recent donors from the Scientific Registry of Transplant Recipients with their own data on the demographics of their DSA overall to explore whether or not donors are representative of the population they are serving. They can compare conversion rates by race/ethnicity, age, and socioeconomic status to investigate potential bias in practices (i.e., disproportionately ruling out donor referrals by any demographic).

How CMS Can Drive Improvement Throughout the Recertification Cycle

In accordance with the regulations, OPOs are required to develop, implement, and maintain a comprehensive, data-driven quality assessment and performance-improvement (QAPI) program designed to monitor and evaluate performance of all donation services. The QAPI must include objective measures to evaluate and demonstrate improved performance with regard to certain OPO activities. As the regulations emphasize, “The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.”⁹⁷

While QAPI requirements for OPOs were first established in 2006,⁹⁸ underperformance in the OPO system has persisted, with direct implications for patients. Moving forward, CMS has the opportunity to more effectively use the existing QAPI program to help turn around underperforming OPOs and help more patients access transplants. For example, building on the initiatives laid out in this report, as well as best practices laid out by the Organ Donation Breakthrough Collaborative (a 2003 initiative established by HHS to codify and share best practices),⁹⁹ CMS could implement more prescriptive standards for how OPOs should improve performance, including working with OPOs to

95 Chloë Fitzgerald and Samia Hurst, “[Implicit bias in healthcare professionals: A systematic review](#),” *BMC Medical Ethics* 18, (2017): 19.

96 Chris Crawford, “[The EveryONE Project Unveils Implicit Bias Training Guide](#),” American Academy of Family Physicians, January 15, 2020.

97 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Condition: Quality assessment and performance improvement \(QAPI\)](#), 81 Fed. Reg. 486.348 (Sept. 16, 2016, as amended at 84 FR 51830, Sept. 30, 2019).

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

99 [Improvement Stories: Organ Donation Breakthrough Collaborative](#), Institute for Healthcare Improvement.

ensure their QAPIs reflect these practices. CMS could also update the Conditions for Coverage to require OPOs to submit additional data they already collect, such as criteria used by OPOs to screen referrals and outcomes of every onsite medical assessment, including medical rule-outs, with appropriate description and documentation. This could enable CMS and external researchers to diagnose key challenges and opportunities for improvement.

Moreover, as CMS notes in the December 2019 NPRM, “There is no need to wait until the end of the four-year period to take action regarding any OPOs that are underperforming.”¹⁰⁰ Under the proposed rule, an OPO’s performance on the outcome measures will be assessed at least every 12 months and the results publicly disclosed. CMS notes “OPOs who cannot achieve the outcome measures may decide to voluntarily de-certify ... or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA.”¹⁰¹

In the interest of serving patients, CMS could also consider requiring leadership changes for failing OPOs and explore options to decertify failing OPOs on a shorter timeline than four years.¹⁰²

What Is the Best Way for CMS to Decertify, When Necessary?

Decertification of chronically underperforming OPOs should not be an unthinkable option; if it were, then government contracts would be indefinite sinecures, and CMS would be unable to ensure the system worked for patients. As part of CMS’s broader oversight function, decertification is a critical final step in ensuring accountability in patients’ interests. CMS uses decertification elsewhere in healthcare. For example, as part of its regulatory oversight of a wide range of healthcare services (including hospitals, dialysis centers, and home healthcare), CMS issued 43 notices of Medicare termination in the first nine months of 2020.¹⁰³ Though directly touching only a small fraction of healthcare providers, termination underpins the broader process of addressing chronic underperformance by organizations in a regulated industry. It can work for the OPO system, too, where instances of chronic underperformance over the course of many years have been well documented. The fact that CMS’s December 2019 NPRM highlighted that the majority of OPOs were failing proposed objective standards underscores the underperformance that has persisted under previous decades of an unenforced (or unenforceable) regulatory regime.

In fact, in the December 2019 NPRM, CMS notes that “stakeholders increasingly have brought to our attention that the interpretation of ‘eligible deaths’ appears to be inconsistent across ... DSAs, and that ‘all OPO data is unaudited and self-reported’ and therefore, ‘the accuracy and consistency of that data cannot be assured.’”¹⁰⁴ An HHS official told the *Washington Post* that CMS’s existing performance measures are not

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

101 *Ibid.*

102 For example, CMS could clarify or update the definition of “urgent need” to include significant underperformance in organ recovery.

103 [Termination Notices](#), Centers for Medicare & Medicaid Services.

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

rigorous enough to be used to hold OPOs accountable.¹⁰⁵ If CMS indeed moves forward with replacing the current metrics with measures that are “transparent, reliable, and enforceable,” as the President’s executive order calls for,¹⁰⁶ these clearer outcome measures will provide more definitive judgments on performance.

CMS can use decertification to strengthen OPO accountability, replace failing OPOs with higher-performing ones that can better serve patients, and strengthen the organ donation system. In the December 2019 NPRM, CMS also sought “comments on an alternative approach where all OPO service areas would be open for competition at the end of each agreement cycle.” If it pursues such a measure, “[A]ny OPO seeking to renew the agreement could face competition from another OPO that wanted to take over that DSA,” signaling that CMS is again seeking to ensure patients are served by the very best OPOs. The need for increased competition for organ-donation-related contracts was recently highlighted by the House Appropriations Committee, which wrote of the Organ Procurement Transplantation Network that the committee “encourages HHS to promote competition for this contract.”¹⁰⁷

While replacing low-performing OPOs with higher-performing ones may feel like uncharted territory, CMS can tap into the expertise it has developed in other segments of the healthcare system to map out a way to use them within the OPO system in order to maintain continuity of organ donation within a service area.

Below, we have identified three key principles that could help guide the process.

1. Create appropriate incentives to ensure competition among high-performing OPOs for open service areas so that patients’ interests are served. Incentives could play an important role in attracting proposals from high-performing providers for a newly opened service area. They would be equally important for encouraging competition if CMS decides to open the service area of every OPO for competition at the conclusion of every recertification cycle, regardless of whether the OPO met the outcome performance standards for the prior recertification cycle, as it indicated in the proposed rule it is considering.¹⁰⁸ Incentives might include the following.

- **Financial incentives:** While the majority of top-performing OPOs should be able to cover initial start-up expenses,¹⁰⁹ an OPO that expands into a new territory has the opportunity to recoup its costs through the existing financing structure (see [Appendix A](#)). Given that there may also be savings from consolidation, it is not necessarily true that costs will outweigh savings, even in the first year. Additionally, financial reforms proposed in [Appendix A](#) could create incentives for OPOs to grow revenue by pursuing DSA expansion, which could further encourage competition in the OPO system.

105 Quote in reference specifically to LiveOnNY; Kindy et al., “[Despite low performance, organ collection group gets new federal contract.](#)”

106 [Executive Order on Advancing American Kidney Health](#), Whitehouse.gov.

107 House of Representatives (116th Congress), [The Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill, 2021.](#)

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

109 Based on an analysis of the latest available financial data from 990 tax filings, the organ procurement organizations (OPOs) in compliance with both CMS proposed metrics have an average of \$36.4 million in unrestricted net assets, \$15.8 million in investment securities, and \$8.9 million in cash on hand. Note that data is only available for 17 of the 21 OPOs in compliance with both metrics.

- **Increased data transparency:** The regulations indicate that OPOs must maintain data in a format that can be readily transferred to a successor OPO and, in the event of a transfer, must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. These include donor and transplant beneficiary records, and procedural manuals and other materials used in conducting OPO operations.¹¹⁰ At the same time, having access to additional data prior to the competition and selection process could help high-performing OPO leaders determine whether to compete for another DSA or pursue a voluntary consolidation with another OPO, and start planning in advance. [Appendix D](#) lists data points—generated in conversations with OPO leaders—that would help a higher-performing OPO plan to take over additional service areas, and that CMS could explore making available in these cases.

2. Objectively assess OPOs competing for the service area. The December 2019 NPRM proposes that CMS will consider current criteria for selecting an OPO for an open service area, which include an OPO’s success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to the open area.¹¹¹ As part of the competition process, CMS could also consider how well a higher-performing OPO has evaluated a failing OPO’s data to understand the greatest missed organ potential and presented a plan to address those specific gaps, particularly with regard to serving communities of color. In parallel, CMS could also consider a potential successor-OPO’s financials, including SAC fees, exploring any effects those might have on overall system costs and the extent to which higher SAC fees might affect transplant centers and organ acceptance rates.

110 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Condition: Information Management](#), 71 Fed. Reg. 486.330 (May 31, 2006, as amended at 79 FR 27156, May 12, 2014).

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

OPOs Ready to Lead the Way

Some OPOs are already thinking about how they will contribute to system improvements through consolidations under the new rules. Mid-America Transplant Services, for example, serves donor hospitals in eastern Missouri, southern Illinois, and northern Arkansas. As an OPO in compliance with CMS’s proposed new outcome metrics, it could be among the likely candidates for taking over the territory of decertified OPOs. CEO Diane Brockmeier, in speaking about accountability under the new rules, told us, “We have an obligation to get more people transplanted every day. Let’s get our head back in the day-to-day work of saving more lives.”

When it comes to potential consolidations in the near future, the Mid-America Transplant Services team has clear perspectives on what it will take to turn around performance. Many of them are “the simple clinical things that underperforming OPOs have gotten away without doing,” Brockmeier says, pointing to establishing strong relationships with hospitals, ensuring frontline staff pursue every donation opportunity (particularly single-organ donors that other OPOs might pass up and the harder-to-pursue cases of donation after cardiac death), and working aggressively to place organs on the transplant waitlist. A key enabler of this work will be eliminating redundant costs (e.g., back-office functions and duplicative management roles) and, in Brockmeier’s words, “using those dollars to the benefit of patients on the waiting list.”

COO Kevin Lee emphasizes the importance of the basics in turning around performance. “At the end of the day, it’s about how hard you are pedaling to get people off the waiting list. If you are committed to pursuing every donation opportunity, you can’t only respond to referrals when it is convenient. Your team needs to be in all hospitals, consistently building and stewarding relationships.” To Brockmeier and the team at Mid-America Transplant Services, it’s their duty to do this hard work: “We all have to be held accountable for our own improvement. At the end of the day, we are all trying to get people’s lives saved. We have a serious mission. It’s a big deal for one additional organ to get transplanted—we pursue those single-organ donors, and a lot of our contemporaries don’t—for financial reasons, or capability, or they can’t answer as to why or why not. Our obligation is, if the phone rings, we go on site, and [we] have a depth of donor hospital relations to do so.”

Additional considerations include:

- There are notable differences among the 58 OPOs—including the size and geography of the population they serve and their governance structures. In turn, CMS may question whether and to what extent these differences should be accounted for when selecting an OPO to take over an open territory. After exploring these factors with OPO leaders and field experts, we believe OPOs with good leadership, as well as a strong track record of performance and the systems and capacity to quickly and seamlessly establish local operations in the new DSA, can overcome any challenges that these differences may pose. The key point for patients is that any change would entail a higher-performing OPO assuming leadership of an underperforming OPO's service area. Further details on these considerations are included in [Appendix E](#).
- Note that, in adherence with recent OPTN rulings, allocation policy will not be linked to DSAs as of December 2020,¹¹² and the regulations do not require that DSAs merge when a new OPO takes over,¹¹³ so decertification and selection of a new OPO to take over the service area should not affect organ allocation policy.
- In addition, if no OPO applies for the open service area, CMS may select a single OPO to take over the entire service area or may adjust the service-area boundaries of two or more contiguous OPOs to incorporate the open area, according to existing regulation.¹¹⁴

3. Maintain continuity of service during the transition period. One of the core principles of medical ethics is that a practitioner should act in the best interest of the patient.¹¹⁵ As nonprofit organizations certified by CMS, OPOs should abide by this principle. If an OPO is decertified by CMS, it is clearly in the best interest of patients that care continues uninterrupted, requiring the decertified OPO to work with CMS and the successor OPO to ensure a smooth transition. Such smooth transitions are a principle of government contracting in general, so any agreement between CMS and an OPO should include commitments to facilitate transitions in patients' interests and not obstruct future operations. CMS can support such transitions and ensure that the successor OPO gets off to a strong start.

Additional considerations include:

- The regulations require that CMS give written notice of decertification to an OPO at least 90 days before the effective date of the decertification (except in cases of urgent need).¹¹⁶ The regulations also note that, if there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose

112 [Changes to kidney and pancreas allocation to be implemented later this year](#), Organ Procurement and Transplantation Network, September 11 2020.

Note: Allocation policy for organs besides kidney and pancreas is already not linked to DSAs.

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

114 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Condition: Information Management](#). 71 Fed. Reg. 486.316 (May 31, 2006, as amended at 79 FR 27156, May 12, 2014).

115 [Glossary](#), Organ Procurement and Transplantation Network.

116 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: De-certification](#). 71 Fed. Reg. 486.312 (May 31, 2006, as amended at 82 FR 38515, Aug. 14, 2017).

to extend the OPO's agreement with CMS.¹¹⁷ CMS could work with the selected OPO to set a contract start date on which authority to assume operations in that DSA would transfer to the higher-performing OPO, providing sufficient planning time to ensure a smooth transition.

- Note that CMS has stated that “existing regulations ensure a DSA is never without an OPO or access to organ procurement services, especially donated organs.”¹¹⁸
- CMS could support the higher-performing successor OPO in developing and executing a communications plan for relevant stakeholders. Such a plan could include all transplant centers and donor hospitals within the DSA, outline the anticipated benefits of the higher-performing OPO taking over the service area, and highlight key implications for donor hospitals and transplant centers (e.g., unless granted a waiver by CMS, hospitals will enter into new agreements with OPO taking over DSA).
- CMS could also bring in a mergers and acquisitions expert through the Intergovernmental Personnel Act, who could provide necessary guidance to CMS throughout the process.

OPO Best Practices to Improve Performance in a New Service Area

Following decertification of an underperforming OPO and CMS selection of a high-performing successor OPO, there are distinct paths for the successor OPO to take over the decertified territory. For instance, the decertified OPO could choose to enter into a collaborative merger with the successor OPO—a decision that would clearly be in the public's best interests and aligned with the overall mission of OPOs to increase organ transplantation. In cases such as these, the decertified OPO's board could file any necessary legal documentation and obtain state approval as needed, plan for the transition of OPO leadership, and transfer all other OPO staff and assets to the successor OPO.¹¹⁹ The successor OPO could also choose to have some board members from the decertified OPO join the successor OPO's board.

Combining entities (whether by formally merging, sharing governance, or adopting other approaches) is also possible outside the context of decertification—for instance, a poorly performing OPO could merge with a higher-performing OPO to avoid decertification, or OPOs could voluntarily combine to improve efficiency and effectiveness.¹²⁰ In the course of our research, we spoke with multiple OPO leaders who had recently considered, or planned to pursue, a voluntary consolidation, and who were also ready to assume responsibility for additional territories should underperforming OPOs be decertified.

117 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Appeals](#). 71 Fed. Reg. 486.314 (May 31, 2006, as amended at 78 FR 75199, Dec. 10, 2013; 84 FR 61492, Nov. 12, 2019).

118 [Fact sheet. Organ Procurement Organization \(OPO\) Conditions for Coverage Proposed Rule: Revisions to Outcome Measures for OPOs](#), Centers for Medicare & Medicaid Services, December 2019.

119 In an analysis of the most recent 990 tax filings for 46 OPOs (the subset for which such documents are available), total investment assets averaged \$12.7 million (with a maximum of \$64.0 million) and unrestricted net assets averaged \$33 million (with a maximum of \$236.7 million). This does not include the approximately 20 OPOs with separate nonprofit foundations, many of which hold additional assets governed by state-level nonprofit law.

120 CMS could also take steps to support and incentivize this more voluntary form of merger, including by developing stronger procurement volume incentives and developing mechanisms for OPO CEOs and boards interested in exploring a merger to connect with one another.

In all paths outlined above, OPOs will need to have a planning period leading up to the contract start date. What follows are advice and considerations, in line with the mergers and acquisitions guidance outlined above, for OPOs pursuing these different paths.

Collaborative Processes

Exhibit 4 on the next page lays out guidance for higher-performing OPO leaders to consider in a scenario where they subsume a lower-performing OPO, as well as for OPOs pursuing a voluntary consolidation. It outlines high-level steps that cut across the organization and those specific to key areas of OPO operations (clinical services, hospital development, and public engagement). While not exhaustive, this list includes both management best practices for mergers in general and organ procurement-specific activities critical to increasing donations.

At a high level, in a collaborative process (whether a merger, consolidation, or where the higher-performing OPO assumes responsibility for the geography of a lower-performing OPO that ceases operations), the organization's objectives at each step in the process should be as follows:

- Before taking responsibility for new geographies:
 - » Plan and prepare for a seamless integration of operations and staff on Day 1 of the consolidation, including securing necessary approvals, aligning on organizational structure, and conducting outreach to key internal and external stakeholders.
- Day 1:
 - » Immediately rectify the most glaring inefficiencies in the lower-performing OPO's processes to stop loss of potential donors, implementing the higher-performing OPO's donor evaluation, triage, and donor-management processes.
 - » Formally combine entities.
- First month:
 - » Begin deploying frontline coordinators (e.g., increasing staffing as needed, shifting from 24-hour to 12-hour shifts) based on analysis of untapped potential donors in the DSA.
 - » Standardize processes across the OPO (e.g., hospital reporting, death-records review to ensure continuous improvement).
- First 100 days:
 - » Integrate remaining operations (focused on areas that might be integrated on Day 1, but could also be staged to occur later with no disruption to service), implementing practices of higher-performing OPO.

Exhibit 4: Guidance for high-performing OPOs entering into a consolidation or assuming responsibility for a lower-performing OPO's DSA

High-performing OPO leaders assuming responsibility for a new service area can follow these high-level steps. While not exhaustive, this represents a comprehensive list of both management best practices for such expansions, in general, and organ-procurement-specific activities critical to increasing donation.

Asterisk indicates guidance is not relevant for situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, but does not enter into a consolidation; additional context is included in the footnotes	Before the merger	Day 1	Within first month	Within first 100 days
GENERAL (CROSS-CUTTING)				
Secure approval from each OPO board for merger, to take place on Day 1 ^{*1}				
Submit necessary forms to CMS to secure approval for merger*				
Outline critical post-merger components, including:*				
Internal regulations for merged entity (e.g., by-laws)				
Composition of governance and advisory boards (high-performing OPO may consider allocating one to two Board of Director seats to members from the low-performing OPO to ensure local voice)				
New financials for combined entity				
Projected organizational chart, including required positions/skills for the combined entity				
Transition plan to ensure no gaps in contract (likely to include plan for developing contract agreements with hospitals / transplant centers in DSA)				
Location of new corporate office or interim satellite office, as relevant				
File legal documentation and obtain state approval, as needed*				
Set explicit performance goals for merged / expanded OPO, including plan and interim milestones for ensuring OPO meets outcome measures and performance standards in its new service area within required timeline				
Conduct assessment of each OPO's critical functions to identify major differences and implications for integration*				
Determine the most critical processes and systems to put in place prior to Day 1 to ensure no lapse in service				
Develop metrics to track procurement performance on a regular basis (daily or weekly). Examples include: CALC data, authorization rate, MD huddle rate, conversion rate, organs transplanted per donor, organs transplanted				
Assign individuals to be accountable for each area of the integration / expansion and corresponding metrics, with clear reporting responsibilities				
Leadership team meets weekly to discuss and monitor progress of integration / expansion, correcting course as needed				
GENERAL (INTERNAL COMMUNICATIONS)				
Create and share detailed communications plan to keep staff informed of objectives of merger / expansion and key decisions. The plan would include key messages for each constituency (consistent across all of them), best mechanism to deliver each key message, and responsibilities				
Share regular updates with staff from both OPOs about implications of merger and key decisions, especially those related to staffing, soliciting input on an ongoing basis ^{*2}				
GENERAL (STAFFING)				
For each position in the new organizational chart, identify candidates from each organization with closest skill fit ³				
Create retention strategy for each top individual performer with single person accountability for managing the retention of each key employee				
Engage top talent in individual conversations				
Assess whether any staff will need to relocate (temporarily or permanently)				

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Asterisk indicates guidance is not relevant for situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, but does not enter into a consolidation; additional context is included in the footnotes	Before the merger	Day 1	Within first month	Within first 100 days
Determine overall compensation and benefits package for new staff				
Create senior HR committee to select best candidates for each position				
Set policies for offering severance for those not selected, or the opportunity to move into a different position in the integrated OPO*				
Transition staff from lower-performing OPO to higher-performing OPO payroll* ⁴				
Duplicative senior leadership at lower-performing OPO cease employment*				
CLINICAL				
Analyze CALC data on untapped donor potential to identify the greatest gaps in donor potential (ongoing)				
Use SRTR and OPTN data to model movement of donors, coordinators, and surgeons to determine transportation and local staffing needs				
Assess lower-performing OPO's clinical criteria in order to discern key differences and create expectations for incoming staff*				
Evaluate clinical staffing models in order to develop training plan for perceived gaps in staff skill set				
Locate frontline staff within a reasonable distance from local donor hospitals and transplant centers, to ensure reasonable response times to hospitals				
Set up transportation of donors to recovery facilities				
Train OPO employees on hospitals' Electronic Medical Records (EMRs) systems				
Evaluate lower-performing OPO's adherence to "First Things First" best practices developed by the US Organ Donation Breakthrough Collaborative:* ⁵				
Create OPO hospital presence or in-house coordinator				
Analyze and apply current hospital-specific data				
Identify a physician or clinician "champion" to provide the hospital-level dashboard and compliance data on referrals and donors (ensures that referrals happen, issues with patients or hospital processes are addressed, and the hospital understands if it is meeting its obligations to refer and convert potential organ donors)				
Conduct real-time death record reviews				
Establish clinical triggers				
Hold donation team huddles				
Identify and utilize effective requesters in every case				
Conduct after-action reviews				
Adopt initial screening protocols of high performer*				
Adopt on-site triage rules of high performer*				
Take placement out of the hands of the lower-performing OPO, and immediately switch to high performer's placement specialists*				
Increase quantity and effectiveness of frontline resources to address unmet needs				
Implement practices aimed at better supporting frontline coordinators				
Train all new clinical staff				
Implement strategies to improve frontline staff service to under-served groups, especially communities of color (e.g., implicit bias training and cultural competence training)				
Optimize frontline staff to address unmet needs, with priority toward hiring coordinators and leadership that represent the OPO community's demographics				
HOSPITAL DEVELOPMENT				
Alert donor hospitals and transplant centers of merger / expansion, share expected benefits, and any expected changes to communications and referral, procurement, or transplantation processes				
Ongoing in-person relationship building with local transplant center surgeons and hospital staff, including nursing leadership				

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Asterisk indicates guidance is not relevant for situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, but does not enter into a consolidation; additional context is included in the footnotes	Before the merger	Day 1	Within first month	Within first 100 days
Create and execute agreements to provide OPO staff access to Electronic Medical Records (EMRs) on referred donors	█			
Ensure all coordinators are credentialed				
Ensure OPO has ability to review and revise order sets for donor management in hospitals	█			
Update donor sets for hospital management		█		
Administrators on call (AOCs) of higher-performing OPO ensure no donor referrals are prematurely or mistakenly ruled out, because of lower-performing OPO's criteria*		█		
Standardize hospital death-record reporting to that of the new OPO*			█	
Update death-records review process to that of the higher-performing OPO across hospitals*			█	
Hire additional death-record review staff to look deeply at potential missed referrals and non-heartbeating referrals ventilated during terminal admission; identify hospitals that are chronically under-referring				█
PUBLIC ENGAGEMENT				
Develop communications plan on the merger / expansion for external stakeholders, including local transplant centers, donor hospitals, transportation partners, funeral homes, crematoriums	█			
Formulate an outreach plan that better serves communities of color				█
Develop outreach materials that are culturally appropriate				█
Conduct community PR campaigns that highlight health systems and hospitals that save lives through support of organ donation				█
Expand DMV donor registration activities and other donor-outreach functions				█
INFRASTRUCTURE				
Develop plan to take over lower-performing OPO's facilities and infrastructure, as needed*	█			
Ensure OPO meets hospitals' data security requirements	█			
Integrate OPOs' EMR systems into one operational model	█			
Ensure OPO employees have login access to hospitals' EMR systems	█			
Train new staff on higher-performing OPO's systems and processes			█	
Merge OPO call centers*			█	

Source: Based on Bridgespan Group analysis.

- 1 In situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA but does not enter into a consolidation, the OPO's board would not approve a merger; the OPO taking over would instead need to expand its operations into the open DSA based on Bridgespan Group analysis.
- 2 In situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, the OPO should share regular updates with staff about implications of expansion and key decisions.
- 3 In situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, procurement staff will not transfer directly to the OPO taking over the territory, so the higher-performing OPO should proactively reach out to the staff, solicit applications for open positions, conduct interviews, and make offers to the strongest candidates.
- 4 In situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, new hires would need to be added to the higher-performing OPO's payroll.
- 5 Evaluating adherence to these standards can occur before consolidation. In situations in which a higher-performing OPO assumes responsibility for a lower-performing OPO's DSA, the OPO should ensure it adheres to the "First Things First" best practices and continues to do so in the expansion.

Higher-Performing OPOs Assuming Responsibility for Designated Service Areas of Lower-Performing OPOs

If the leadership of a decertified OPO chooses not to collaboratively enter into a merger, it would not preclude CMS from moving forward in the best interest of patients.¹²¹ In such a case, the higher-performing OPO taking over procurement activity in the low performers' DSA would need to expand operations during a planning period such that on Day 1 of its new contract it could assume procurement duties.

Much of the guidance included in [Exhibit 4](#) is still relevant for OPO leaders in this scenario where a decertified OPO does not enter into a merger with its successor. However, the OPO taking over the open DSA might need to address additional issues, detailed below.

Clinical staffing. While procurement staff will not transfer directly to the OPO taking over the DSA, those looking to continue in their line of work are likely to seek employment with the new OPO. The new OPO should reach out to the staff, solicit applications for open positions, conduct interviews, and make offers to the strongest candidates. Presumably, the highest-performing staff of the decertified OPO would be eager to exchange employers for the higher-performing OPO, which is likely to offer better supports to frontline staff. As the December 2019 NPRM notes: "In most cases of potential decertification, we [CMS] would reasonably expect another OPO to take over that service area, retaining the original staff, but changing the leadership and many of the organ procurement practices."¹²² Higher-performing OPOs might pay special attention to retaining staff with important community relationships (e.g., with hospitals, local communities of color, and other key groups).

Hospital relationships. According to the regulations, unless CMS has granted a hospital a waiver, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.¹²³ While decertified OPOs could still maintain relationships with hospitals for non-organ-related work (e.g., tissue, eye procurement), conversations with OPO leaders indicate that most hospitals are likely to prefer working with a single, high-performing OPO for these services and transfer their existing contract to the new OPO. CMS could also conduct outreach to the transplant centers and donor hospitals within the DSA to alert them of the decertification and the expectation that, unless they are granted a waiver, they will enter into a new agreement on organ procurement and transplantation with the new OPO. The higher-performing OPO should also begin building relationships with hospital executives and surgeons soon after the selection process is finalized.

121 CMS could begin to require conflicts of interest disclosures from OPO executives and board members regarding financial arrangements with partner organizations of the OPO, which would help CMS ensure that personal interests are not placed above the public good. If a decertified OPO sought to maintain its legal nonprofit status, to the extent that organ recovery is written into its mission as filed with regulators, the decertified OPO would likely be required to notify the organization's state of incorporation and the Internal Revenue Service and amend its filings to focus on other activities than organ recovery. Venable LLP, "Informing Regulators When You Alter Your Mission," Guidestar Blog, February 20, 2014.

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

123 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Designation of one OPO for each service area](#). 71 Fed. Reg. 486.308 (May 31, 2006, as amended at 79 FR 27156, May 12, 2014).

Local office space and equipment. If the decertified OPO retains ownership of local office space and equipment, the OPO taking over the DSA should develop a plan for establishing a local presence in the new DSA and setting up the infrastructure to support local frontline staff as needed. While there will likely be costs associated with either a consolidation or expansion, there may also be savings; an analysis of OPO tax filings indicates there is a path for funding these activities through existing resources. CMS could take measures to ensure that any costs associated with the merger are not passed on to transplant centers.

Reallocating Resources to Lifesaving Activities

During consolidation, OPOs might be able to reallocate duplicative resources from several areas to increase the number of organ donations (e.g., expanding and investing in frontline procurement staff). As CMS noted in the December 2019 NPRM, “There are economies of scale as OPOs and hospitals expand their donor-related and transplant services.”¹²⁵ Key areas where redundant costs might be found and reallocated in a merger include: executive salaries (post-consolidation, an OPO would require only one CEO, one CFO, etc.); other staff costs (e.g., functional staff in finance, communications, community services, and call centers); and functional expenses (e.g., annual accounting fees). An illustrative analysis of publicly available financial data

124 These practices are distilled from Bain’s decades of M&A advisory work and adapted by Bridgespan in this report. For a recent example of Bain’s point of view on this topic, see *Global Private Equity Report 2019*, Bain & Company, (2019) 54–58.

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

Combining Entities in the OPO Context

Combining entities—whether through formal mergers, acquisitions, or affiliations—occurs regularly in the private and nonprofit sectors, including in healthcare. Bain & Company, a leading global management consulting firm, suggests that successful mergers follow a set of common practices.¹²⁴ In the OPO context, whether in a voluntary merger or in the case where a decertified, underperforming OPO enters into a collaborative consolidation with a higher-performing successor OPO, those principles could be applied as follows.

- Determine how to approach the integration. Set up a dedicated team to manage the merger and determine which areas of the organization should be integrated and to what extent, as well as the pace of integration, balancing value, risk, and timing. It’s important to do this as early as possible, allowing for sufficient time to transition and integrate the most critical systems.
- Focus the merger on the few critical issues that drive impact. Identify opportunities to maximize impact from the start and set explicit goals and priorities. For OPOs, an obvious focus is on opportunities to increase the volume of successful transplants by identifying more viable organs and successfully getting them to patients who need them. It will also be vital to develop explicit performance goals and interim milestones to ensure the OPO meets performance standards in its new service area within the required timeline.
- Address people and power issues quickly. Design the appropriate organization structure for the merged entity; align leadership early in the process, ensuring OPO management has clarity on roles and responsibilities throughout the transition; prioritize proactive, transparent communication with staff to garner buy-in and minimize uncertainty; and identify and address cultural differences between the organizations. Make staffing decisions according to the organizational structure required, with a focus on retaining the best management and staff at both entities and restructuring roles as needed. Share regular updates with staff from both OPOs about implications of the merger and key decisions.
- Integrate critical systems and processes. Ensure systems are in place to maintain continuity of the most critical operations, and pace the remaining changes appropriately. Focus on integrating procurement systems and establishing contracts and relationships with donor hospitals and transplant centers.
- Implement sound practices to manage the integration. Use project management best practices to regularly monitor and track the progress of the merger, make key decisions, and address risks. Best practices for OPOs include developing clear milestones and metrics to track integration progress on a regular basis, clear accountability and reporting responsibilities for individuals overseeing each area of the integration, and regular touchpoints with the integration team to monitor progress and course-correct as needed.

from OPO tax filings suggests that an average consolidation could free up an estimated \$4 million in annual costs. Some of these opportunities could be realizable in the first year of consolidation, offsetting additional expenses incurred by expansion. In the second and subsequent years, these resources could be reallocated toward activities that drive outcomes.¹²⁶

The following table summarizes this analysis.

Cost Category	Assumptions	Conservative estimate of cost savings
CEO compensation	Average CEO total compensation for OPOs listed as failing both CMS proposed measures: ~\$509,000 (including base salary, bonuses, and other compensation listed in 990 tax filings); 20% benefits rate	\$610,800 salary and benefits
Other executive salaries: Chief Financial Officer, Chief Operating Officer, Chief Administrative Officer, and Chief Clinical Officer	\$200,000 salary (a conservative estimate for these positions based on conversations with OPO leaders and available data in 990 tax filings); 20% benefits rate	\$960,000 (4 positions X \$240,000 salary and benefits)
Other duplicative staff costs: Assuming streamlined headcount in finance, communications, community services, facilities, admin, and call center staff	While salary data is not readily available for these positions, in conversations with OPOs we believe 5 percent of total annual expenses is a conservative estimate for this figure Note that typical OPO labor costs are 30–40% of total budget, so this assumption represents a small portion of total labor costs being reallocated Average OPO annual expenses \$42.5 million	\$2,125,000 in salary and benefits (5% of \$42.5 million)
Duplicative functional expenses: Accounting, legal, insurance, investment management, IT	Average OPO annual functional expenses \$2.3 million; while not all of these costs will be duplicative, we have used a conservative 15% estimate (validated in conversations with OPO leaders)	\$345,000 in functional expenses (15% of \$2.3 million)
Conservative estimate of total annual cost savings		\$4,040,800

126 The OPOs in compliance with CMS's proposed performance standards should further be able to fund the costs of expansion out of financial reserves. For the subset of OPOs passing the proposed standards for which there is available 990 financial data, these OPOs have an average of \$35 million in unrestricted net assets, including \$15 million in investment securities, and \$8.5 million in cash and cash equivalents on hand.

These significant resources could be reallocated to hire more than 50 organ recovery coordinators (focused on procurement and logistics), or more than 59 family services coordinators (focused on support and guidance of donor families); increase pay of existing coordinators; or some combination of these options based on the needs of the OPO.¹²⁴ While individual finances and staffing circumstances vary, this illustrative analysis shows significant opportunities to redeploy resources when a high-performing OPO takes over a low-performing OPO's service area, with funds then free to be reallocated to the costs of expansion or to the frontline staff who drive procurement and transplantation outcomes.

In addition, there might be one-time savings that could support costs associated with a merger or expansion, most notably in real estate. The average OPO has over \$9.3 million in fixed assets (land, buildings, and equipment), including real estate. Following consolidation, the OPO operating in the new territory would require some local office space to continue operations, but would not require two extensive headquarters buildings or multiple call centers. Depending on the geography, a post-consolidation OPO could also potentially streamline independent organ recovery centers (if this approach is used in the DSA to begin with).¹²⁸

These estimates illustrate significant opportunities for reallocating redundant costs toward the activities that drive organ donation. If 10 OPOs were to be decertified, this could represent over \$40 million in such resources. If all 32 OPOs deemed out of compliance by HHS's proposed rule were decertified, that would project to roughly \$128 million that could be reallocated toward activities like better supporting frontline staff, better serving underserved hospitals and donor groups, and, ultimately, increasing organ recovery rates.

Conclusion

There is an opportunity to implement the proposed new CMS rules for OPOs in a way that could increase the number of organ donations in many parts of the country, reduce the number of people who die while waiting for transplants, and save a tremendous amount of taxpayer dollars in avoided dialysis costs. The demonstrable variations in the performance of OPOs, even between those located in adjacent geographies, gives real hope that performance can be substantially improved. Based on an analysis of past experience, there is evidence that new leadership (including but not limited to higher-performing OPOs assuming responsibilities for areas previously assigned to lower-performing OPOs) can play an important role in realizing these opportunities for system improvement—and in saving many lives each year. Indeed, the evidence suggests that the OPO system is unlikely to improve without such changes.

127 Complete salary data for OPO frontline staff is not publicly available. Using data from Glassdoor.com, we identified a high-end assumption for salaries for organ recovery coordinators (\$81,000 per year) and family services coordinators (\$68,000 per year). We further validated these figures as representative estimates in interviews with current OPO staff and applied an assumed 20 percent benefits rate to arrive at the above figures for potential cost redeployment.

128 In analysis of the most recently available 990 tax filings, the average OPO has \$9.3 million in fixed assets (land, buildings, and equipment), which includes real estate. Note that some of these potential savings might not be realized until the second year given time required to divest of assets.

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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/ PASSES 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

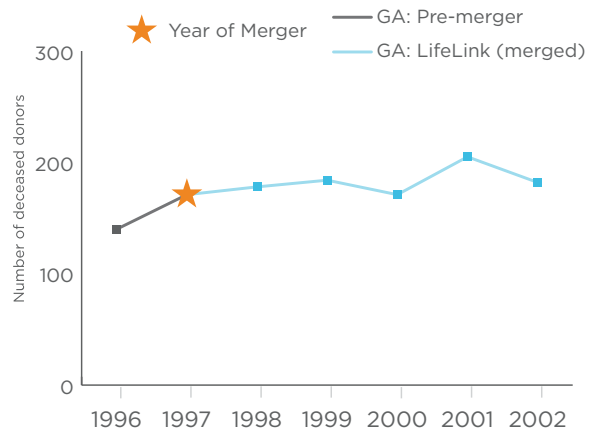
Appendix B: Data on Historical OPO Mergers

Data on five recent mergers shows consolidation can occur while maintaining continuity of service.

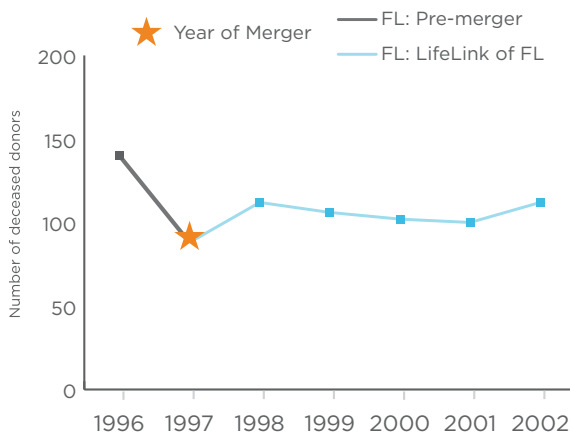
OPO	Year of consolidation	5-year growth in donations (national growth rate)
LifeLink (GA)	1997	1.3% (2.5%)
LifeLink of Florida (FL)	1997	4.9% (2.5%)
LifeCenter Northwest (WA)	1997	7.1% (2.5%)
OneLegacy (CA)	2000	5.4% (4.9%)
LifeNet Health (VA)	2001	6.6% (5.7%)

Source: Data on donations retrieved from OPTN

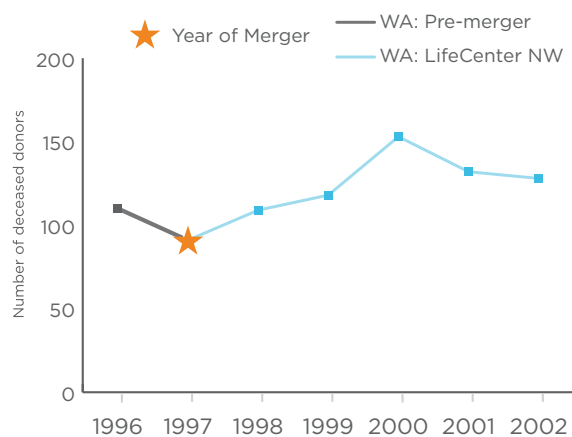
LifeLink (GA - 1997)



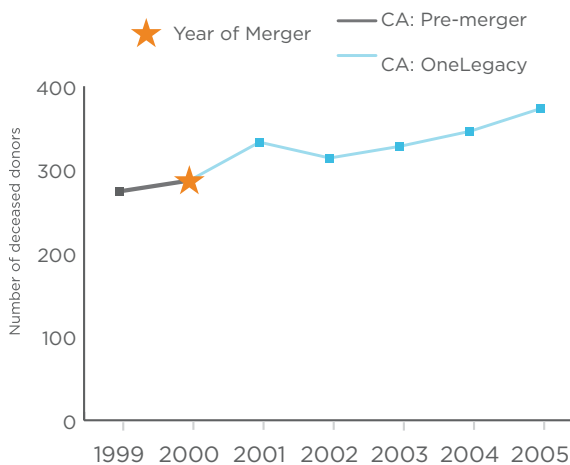
LifeLink of Florida (FL - 1997)



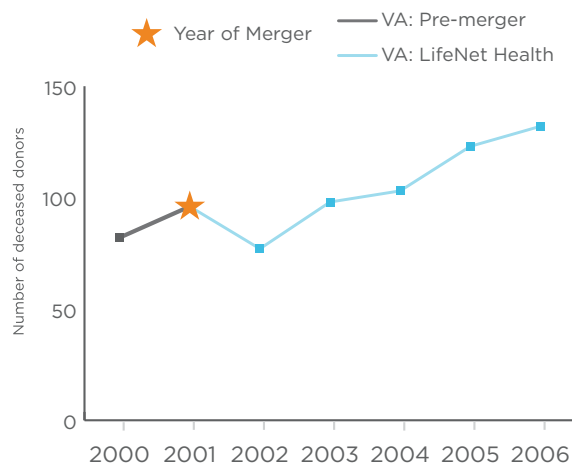
LifeCenter Northwest (WA - 1997)



OneLegacy (CA - 2000)



LifeNet Health (VA - 2001)



Source: Data on donations retrieved from OPTN

Note: Pre-merger segments were calculated by adding the number of deceased donors for each organization, before the merger

Appendix C: Data on Historical OPO Leadership Changes

Data on five recent leadership changes imply that changes in practices and management can lead to improvement in performance. Data below compare the growth in the number of organ donors compared to the national average during the same time period. An increase in deaths from opioid overdose has tragically boosted the number of donors, as well.¹⁶⁸ To understand how increases in OPO performance might be related to regional trends driven by the opioid crisis, we further compared growth in deaths (at the state level) during the same time period. In each case where data were available the increase in performance appears to be unrelated to increases in the number of deaths due to opioids.

OPO	Year of leadership transition	1-year growth in donors compared with national trend	5-year growth in donors compared with national trend	Growth in opioid overdose deaths, in respective states, over comparable time period ¹⁶⁹
LifeCenter Northwest (WA)	2010	14.8% (2.3%)	7.1% (2.7%)	0.9%
LifeShare Transplant Donor Services of Oklahoma (OK)	2012	-5.3% (1.5%)	14.3% (4.8%)	-6.4%
Nevada Donor Network (NV)	2012	38.7% (1.5%)	10.4% (4.8%)	-3.1%
Donor Network West (CA) ¹⁷⁰	2019	29.2% (10.7%)	N/A	N/A
Life Connection of Ohio (OH)	2020	34.4% (N/A)	N/A	N/A

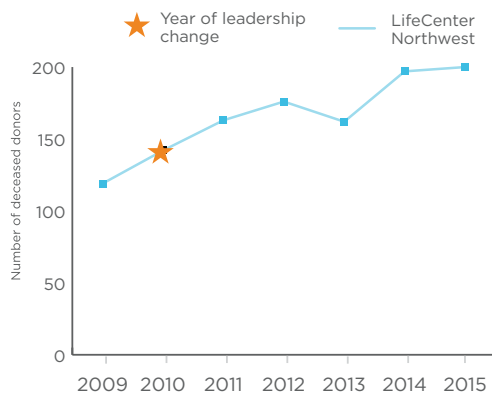
Source: Donation data retrieved from OPTN and/or validated with OPOs. Ohio figures are projections for the year as of September 2020. Opioid trends from Kaiser Family Foundation.

168 Goldberg and Lynch, “Improvements in organ donation: Riding the coattails of a national tragedy.”

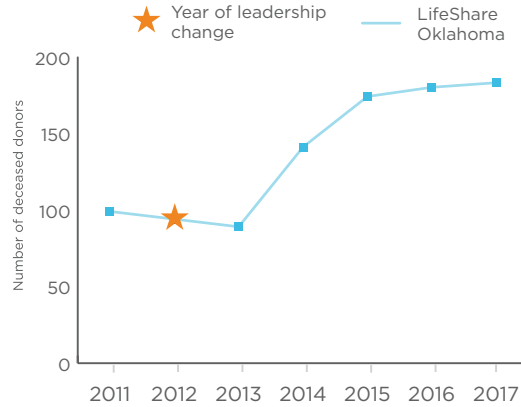
169 “Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted),” Kaiser Family Foundation.

170 “Donor Network West Breaks Historical Record Of Organ Donors,” Donor Network West, January 2020.

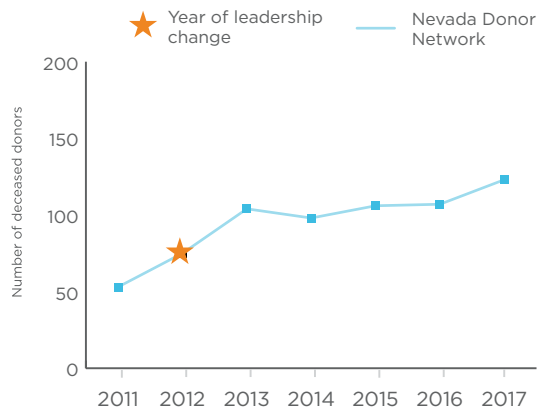
LifeCenter Northwest (WA - 2010)



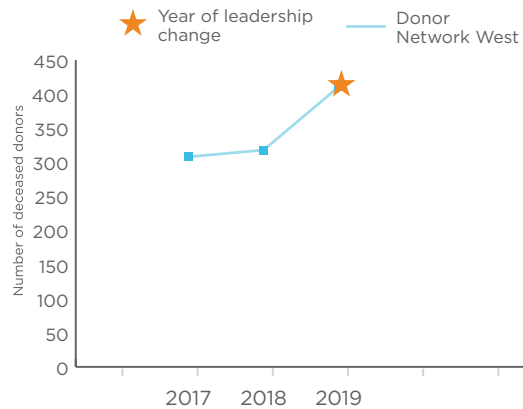
LifeShare Transplant Donor Services of Oklahoma (OK - 2012)



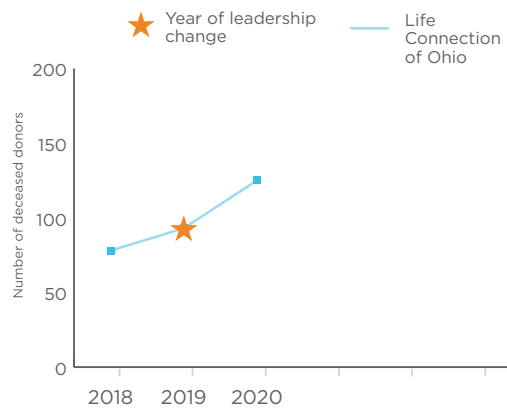
Nevada Donor Network (NV - 2012)



Donor Network West (CA - 2019)



Life Connection of Ohio (OH - 2020)



Source: Data on donations retrieved from OPTN.

Note: For Donor Network West and Life Connection of Ohio, new CEOs took over near the start of the calendar year (January, 2019 in CA and December, 2019 in OH), and charts reflect improvement in their first year of leadership.

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

The regulations indicate that OPOs must maintain data, such as donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations, in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO.¹⁷¹ At the same time, having access to additional data and information could be helpful to inform both the decision-making process around whether to compete for a service area, as well as post-selection planning for a higher-performing OPO to take responsibility for the territory of a lower-performing OPO. A suggested list of data and information, generated in conversations with OPO leaders and researchers, that CMS could explore making available to OPOs in order to incentivize competition in patients' interest and maintain continuity of service during the transition is included below.

Note: Some of the information listed below may not be relevant if a decertified OPO chooses not to enter into a collaborative merger with the successor OPO.

OPO data that CMS could explore making available to OPOs prior to competing for a service area in order to inform decision making about whether to apply:

Procurement operations

- All referral data and disposition data broken down by hospital and by month (in order to project productivity and develop a staffing structure, strategic plan, and financials)

Finances

- Key financial statements related to the OPO and any supporting organization they have established
- Detail on prior years' organ acquisition charges/standard acquisition charges (by organ)
- All liabilities, including how they've funded any building projects (as relevant)

Hospital relationships

- Agreements with donor hospitals and transplant centers
- Key contacts of all major hospitals
- An overview of which hospitals the OPO engages with on tissue procurement

Staff and governance

- Organizational chart
- Board makeup

171 [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Condition: Information Management](#). 71 Fed. Reg. 486.330 (May 31, 2006, as amended at 79 FR 27156, May 12, 2014).

OPO data / information that CMS could explore making available to an OPO after being selected to take over a service area

Procurement operations

- Standard operating procedures for critical procurement functions, including death-record review processes

Finances

- Investment policy/strategy

Hospital relationships

- Plan for how donor hospital and transplant center contracts will be transferred to the new OPO

Staff and governance

- Pay ranges and bonus structure associated with each type of position
- Personnel files

Transition plan

- Plan for whether entity will seek to enter into a consolidation with the higher-performing successor OPO and transfer assets

General

- Strategic plan (as relevant)

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

Note: To address considerations about how the differences among OPOs may impact their ability to take over a new DSA or enter into a consolidation, we have outlined the major structural differences (e.g., OPO size, governance, geography) and relevant considerations for civil servants, generated in conversations with OPO leaders and field experts.

OPO Size

In cases where an OPO overseeing a large DSA is decertified, CMS could choose to break up the DSA and distribute it to multiple OPOs.¹⁷² However, in cases where a single hospital system operates across the DSA, it may be beneficial to maintain one DSA for ease of contracting. High-performing small OPOs, with a thorough, well-conceived five-year growth plan, an organizational chart that reflects this plan based on volume, and sufficient planning time, could be strong candidates for taking over the entire DSA despite their size.

OPO Governance

Hospital-based OPOs are subject to the hospital's governing board, and—if decertified—the governing board would influence whether or not the OPO entered into a collaborative consolidation with the successor OPO. In cases where the hospital's governing board chooses not to enter into a collaborative consolidation with the successor OPO, the successor OPO would need to expand operations into the new DSA.

OPO Geography

Because most OPOs serve both cities and suburban or rural areas, high-performing OPOs with skilled leadership should be able to reach and effectively serve diverse populations within a DSA. Moreover, while serving a new DSA may require an OPO to adjust its current transportation and staffing systems or processes, such shifts should be well within the capabilities of higher-performing organizations. For example, OPOs are able to shift operations temporarily during natural disasters without disrupting service (e.g., sharing a neighboring OPO's call center during a hurricane). Since the onset of the COVID-19 crisis, many OPOs have successfully transitioned to remote or decentralized staffing models, which could provide further lessons to build upon in taking a data-driven approach to best staffing the DSA.

172 The regulations state that “if no OPO applies for the open service area, CMS may ... adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area.” [Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations: Condition: Information Management](#). 71 Fed. Reg. 486.316 (May 31, 2006, as amended at 79 FR 27156, May 12, 2014).

Contiguity

In cases where a high-performing contiguous OPO applies for the open DSA, it may make sense to prioritize the contiguous OPO over a non-contiguous OPO bidder, however, the logistical challenges (e.g., establishing local presence, understanding local labor laws) are not so high that a higher-performing non-contiguous OPO with skilled leadership could not overcome them. In fact, there are already two “holding companies” that operate multiple non-contiguous OPOs: LifeLink (which operates OPOs in Puerto Rico, Florida, and Georgia) and DCI Donor Services (which operates OPOs in Tennessee, New Mexico, Nevada, and California).

To the extent there are additional financial costs to an OPO in operating a non-contiguous OPO, CMS could request competing OPOs submit financial projections and operational plans as part of the application process to take over a service area, and CMS could determine then how much weight to give this consideration.

Appendix F: Waiting Lists by State and by Organ Type

	Waiting list for all organs as of November 2020
Alabama	1,263
Alaska	N/A - No transplant centers in state
Arizona	1,627
Arkansas	268
California	21,547
Colorado	1,575
Connecticut	1,164
Delaware	192
District of Columbia	1,621
Florida	5,165
Georgia	4,570
Hawaii	330
Illinois	3,880
Indiana	1,073
Iowa	574
Kansas	414
Kentucky	964
Louisiana	1,982
Maine	140
Maryland	2,953
Massachusetts	4,395
Michigan	2,591
Minnesota	2,560
Mississippi	933
Missouri	1,572
Nebraska	331
Nevada	209
New Hampshire	97
New Jersey	2,632
New Mexico	544
New York	8,985
North Carolina	3,226
North Dakota	146
Ohio	2,977
Oklahoma	587
Oregon	857
Pennsylvania	6,891
Puerto Rico	314
Rhode Island	264
South Carolina	1,258
South Dakota	344
Tennessee	3,098
Texas	10,135
Utah	785
Vermont	54
Virginia	2,423
Washington	1,817
West Virginia	110
Wisconsin	1,632
Total	108,645

	National waiting list by organ type as of November 2020
Kidney	91,872
Liver	12,131
Pancreas	890
Kidney / Pancreas	1,714
Heart	3,481
Lung	982
Heart / Lung	41
Intestine	225

Source: Data retrieved from OPTN.

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

Following the initial publication of this report, CMS issued a final rule in November 2020 revising the outcome measure requirements for organ procurement organizations. The final rule includes an updated donation rate measure and transplantation rate measure, as well as a tier ranking system for OPOs based on performance on these measures.

