

An Overview of and a Proposed Reform for the Organ Procurement System of the United States

By Spencer Ryan

About the Series

The *Studies in Applied Economics* series is under the general direction of Professor Steve H. Hanke, Founder and Co-Director of the Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise (hanke@jhu.edu).

About the Author

Spencer Ryan (sryan34@jhu.edu) is a sophomore at Johns Hopkins University in Baltimore, pursuing a double major in economics and biology. He wrote this paper as the chief undergraduate research assistant of the Supply-Side Economics team at the Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise. On campus, Spencer is a member of the varsity swim team and the Johns Hopkins Neuro-Oncology Surgical Outcomes Lab.

Abstract

Over 107,000 Americans are currently awaiting a lifesaving organ transplant. The vast shortage of organs for transplant in the United States is commonly known, but few are aware that the capacity exists for an additional 28,000 organs to be procured each year. These viable organs are not procured because of the limitations of the market and governance structure of the organizations primarily responsible for organ procurement across the United States, Organ Procurement Organizations (OPOs). In this paper, the author provides an overview of the current organ procurement system and its flaws, debates the newly revised organ procurement regulations to come into effect in 2022, and offers a sweeping, market-based reform proposal for the organ procurement system.

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Introduction

As of February 2020, over 107,000 Americans are on the U.S. organ transplant wait list.¹ Each day, 17 people die waiting for an organ transplant.² The need for organs far outstrips supply, yet, shockingly, as many as 28,000³ organs eligible for transplantation go unprocured each year.⁴ If these organs were procured properly and transplanted, not only would thousands of lives be saved, but also \$40 billion in taxpayer dollars could be saved within 10 years.⁵ Why are these organs not being procured and delivered to those in need? The answer: the vastly inefficient system of monopolistic government contractors known as Organ Procurement Organizations (OPOs) that handle much of the organ donation process.

To sum up the work of OPOs in one sentence, the Department of Health and Human Services (HHS) succinctly states, “there are currently 58 OPOs that are responsible for identifying eligible donors and recovering organs from deceased donors in the United States (U.S.).”⁶ As of January 1st, 2021, two organ procurement organizations, LifeChoice Donor Services and New England Donor Bank, have merged, bringing the total number of OPOs to 57.⁷

Overview of Organ Procurement Organizations and the procurement process

In order to be an OPO, an organization must comply with both the Social Security Act and the Public Health Service Act. Regarding the Social Security Act, an OPO must meet certain qualifications and requirements in order for organ procurement costs to be paid by Medicare or Medicaid. These qualifications and requirements are created by the Centers for Medicare and Medicaid Services (CMS), a part of the Department for Health and Human Services. Pursuant to the Public Health Service Act, the Secretary of the Department of Health and Human Services is required to establish outcome and process performance measures that OPOs will be required to meet in order to continue operating. If the OPO is unable to meet CMS’s performance requirements, it cannot be reimbursed for its procurement costs through Medicaid or Medicare and would be decertified as an Organ Procurement Organization. CMS’s performance requirements are explained in detail in the below section, lack of government oversight.⁸

¹ Organ Procurement and Transplantation Network: Data.” *OPTN*, 16 Feb. 2021.

² “Organ Donation Statistics.” *Organ Donor*, 28 Sept. 2020.

³ Goldberg, D., et al. “Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States.” *American Journal of Transplantation*.

⁴ “Reforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

⁵ Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

⁶ Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

⁷ “Organ Procurement Organization (OPO) Reports.” *OPO-Specific Reports*.

⁸ Final Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.” *Federal Register*.

Additionally, the Social Security Act requires an OPO to participate in the Organ Procurement and Transplantation Network (OPTN). The OPTN links all members of the transplantation system. Currently, the United Network for Organ Sharing (UNOS) serves as the OPTN contractor. OPOs are required to report their procurement data to UNOS, including the data used to calculate the outcome measures for OPOs by CMS.⁹

In total, 57 Organ Procurement Organizations operate in the U.S., each a monopoly service provider for the procurement of organs within outlined geographic territories, known as Designated Service Areas (DSAs). While some OPO boundaries are drawn along state lines, many cross state lines, and some OPOs even control islands of territory within other OPO's DSAs.¹⁰ The geographic divisions of OPOs are a fossil of how the system developed in its early years after the first OPO, the New England Organ Bank, based in Boston, was initially created in 1968. Over time, many OPOs were created, fell out of existence, were taken over by other OPOs, or merged with neighboring OPOs to form the system of 57 organizations that we see today.¹¹

The organ procurement process begins with an eligible patient in a hospital. Patients eligible for organ donation are most commonly those who have the potential to be declared brain dead, known as Donation after Brain Death (DBD). But, along with recent advances in medicine, Donation after Cardiac Death (DCD) has become a growing source of procured organs. Hospital care providers have agreements with their local OPO that describe “triggers” to refer a patient for potential organ donation. Should a patient meet these triggers (which are variable, discretionary, and not readily available for study, scrutiny, or comparison between OPOs), then the patient is referred to the hospital's organ procurement organization, as required by law. The OPO performs an initial screening after the hospital referral to determine if the patient would be an eligible donor. It is also worth noting that OPO criteria for “eligibility” for donation is variable, discretionary, and not readily available for study, scrutiny, or comparison by any stakeholder within the transplant system, including oversight bodies.

Following this initial screening, the organ procurement organization may decide to rule out this patient for organ donation eligibility or may continue to follow and assess the patient. High performing OPOs send a representative immediately to thoroughly evaluate whether or not the patient is an eligible donor.¹² If the patient is then determined to be an eligible donor, the OPO should approach the family of the patient for authorization to move forward with the organ procurement process. Upon family authorization, the OPO takes over clinical management of the donor from hospital staff. Once the OPO takes over, it provides staffing for the case, including nurses, surgical techs, and support staff to begin organ procurement. OPOs should have protocols

⁹ Ibid.

¹⁰ “Organ Procurement Organization (OPO) Reports.” *OPO-Specific Reports*.

¹¹ “Timeline of Historical Events and Significant Milestones.” *Organ Donor*.

¹² Center, LifeGift Organ Donation. “US Organ Donation Breakthrough Collaborative Increases... : Critical Care Nursing Quarterly.” *LWW*, 2008.

in place in order to maximize organ yield through this process. Concurrently, the OPO “allocates” the organs, using the UNOS system to attempt to find matches for the organs, once recovered.¹³

The contents of this paper will discuss the problems and a possible solution to inefficiencies at the OPO level that inhibit an OPO’s ability to successfully and efficiently procure organs. This paper will not discuss the match or allocation services, or waitlist policies created and enforced by UNOS.

Although the system is of maximal importance to the United States population, the organ procurement system is flawed and inefficient, with as many as 28,000 eligible organs going unprocured or otherwise untransplanted each year.¹⁴ Little is reported or understood about the efficiency and effectiveness of the OPO system, as OPOs report essentially no process-related data to any oversight body or UNOS. Notably, “critical process breakdowns...such as untimely referrals, suboptimal requests for donation, or early extubating, are therefore not visible to the national transplant community.”¹⁵ Due to poor oversight, many of the worst issues within the procurement system are kept secret. Several activist and policy reform advocate organizations, one of the most vocal being the patient advocacy group Organize, have been outspoken with their displeasure with the organ procurement system: “Performance varies across the OPO network, with many persistent underperformers failing to improve over the last decade.”¹⁶

Currently available objective data indicates wide variance among OPO performance; with many OPOs performing significantly worse than others. The term “performance” obscures the human meaning of this inefficiency, since low, ineffective, or inefficient performance means eligible organs go unprocured and Americans continue to hold a spot on a deadly transplant waitlist. Because of the significant OPO performance variance, many hospitals are stuck working with underperforming OPOs. Over time, “when OPOs are inefficient or ineffective, donor hospitals are reluctant to refer potential donors, and transplant centers have fewer organ offers for patients on the waiting list. The end result is a bottleneck within the system that leads to avoidable deaths and increased national health care spending.”¹⁷ In many instances involving the worst performing OPOs, upon a hospital’s referral, the OPO may respond late or not respond at all. In organ procurement, ischemic time (the time that organs are viable for transplantation) is severely limited,¹⁸ and extended case times or suboptimal OPO practice that adds ischemic time can result in far fewer successful transplantations. Moreover, data suggest that as hospitals become more

¹³ “The Deceased Donation Process.” *Organ Donor*.

¹⁴ Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

¹⁵ Doby, Brianna L., et al. “Improving OPO Performance through National Data Availability.” *American Journal of Transplantation*, vol. 19, no. 10, 2019, pp. 2675–2677.

¹⁶ “Reforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

¹⁷ Organize. *Organ Donation Report*. 2019.

¹⁸ “Acceptable Ischemic Times.” *Nebraska Organ Recovery - Organ Donation in Nebraska*.

frustrated with OPO performance, death referral rates from the hospital to the OPO tend to drop correspondingly. In some cases, hospitals have so grown so frustrated with OPOs and their lack of responsiveness, that they refer very few potential donors to their OPO.¹⁹

Another complaint regarding organ procurement argues that the metrics by which OPOs are judged, which are created by CMS and should incentivize maximal organ procurement, have actually steered organ procurement organizations in the opposite direction. A comprehensive report in 2019 compiled by the Bridgespan group noted that “existing regulations need dramatic improvement to remove perverse incentives to organ procurement (for example, OPOs are evaluated on the number of organs procured per donor, which leads to older single-organ donors being overlooked) and increase continuous performance accountability.”²⁰

Why do all of these problems occur within the organ procurement system? Organ Procurement Organizations have few incentives to succeed beside the good consciences of their executives. OPOs face no market pressures to succeed and have never faced significant retaliation from their regulatory body, CMS. This combination of a lack of market and government incentives has resulted in a massive 470% discrepancy in transplantation rates as a percentage of inpatient deaths between the best and worst OPOs.²¹

Potential of reform

If the discrepancies between OPOs were diminished and all OPOs were held to a high standard by CMS, benefits abound. A study by researchers at the University of Pennsylvania, and subsequent analysis by the Bridgespan Group found that each year, if the organ procurement system operated perfectly efficiently, an additional 28,000 organs could be procured and transplanted. And, because some patients receive more than one organ, this could result in an additional 25,000 lives saved each year.²²

In addition, the benefits to the American taxpayer are significant. The most common organ needed for transplant are kidneys. For those in need of a kidney transplant, many require dialysis treatments until they are able to receive a kidney transplant. Dialysis treatments cost Medicare about \$90,000 per person per year. When compared to the average cost of surgery and immunosuppressive drugs in the years thereafter, a kidney transplant would save Medicare \$250,000 per transplant over the first five years after the transplant.²³ When combining these cost

¹⁹ Doby, Brianna L., et al. “Results of a Data-Driven Performance Improvement Initiative in Organ Donation.” *Wiley Online Library*, John Wiley & Sons, Ltd, 2 Jan. 2021.

²⁰ “Reforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

²¹ “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

²² Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

²³ Kessler, Judd B., and Alvin E. Roth. “Getting More Organs for Transplantation.” *American Economic Association*.

saving figures with the 28,000 potential for procured organs, the Bridgespan group estimates roughly 40 billion could be saved in Medicare costs over ten years by capitalizing on the organ donation capabilities of the United States.²⁴

Flaws of the current procurement system:

Many key problems of the current system source from poor government regulations and are described in detail below. All of which result in wasted eligible organs and taxpayer dollars. In short, as phrased by Steve H. Hanke, “the shortage of kidneys and other organs is substantially, and probably fully, the fault of inhumane government regulations.”²⁵

Designated Service Areas (DSAs):

Each of the 57 OPOs have been given exclusive rights to the procurement of organs within specified geographic areas known as Designated Service Areas (DSAs). These areas do not follow lines that would imply efficiency, or perfectly follow states lines, but are rather a remaining, arcane factor leftover from when the system was originally set up in the 1960s, and how it grew in the years following. The adverse consequences of this setup are numerous.

First, while an OPO may have facilities, staff, and infrastructure near an OPO territory border, these resources are limited and bound. The OPO cannot procure an organ on the other side of its geographic boundaries, except in special cases, even if it may be the organization best fitted to perform the procurement. For example, although an OPO based in Maryland may be more efficient and timelier than its counterpart in Virginia, hospitals and patients in Virginia, even those near the Maryland border, are stuck working with their inefficient and slow OPO. This inefficient system means that although the infrastructure may be available for a successful and timely procurement to occur, many organs go unprocured or are procured too late.²⁶

A second factor regarding designated service areas is that OPOs do not have to compete with each other to secure hospital contracts or procure organs. Each OPO has complete reign over the procurement of all organs within its DSA. No other OPO, except in special cases where hospitals are granted a waiver to work with different OPOs, is able to procure organs within other DSAs. So, in their contentment, each OPO does not have incentives to beat out other OPOs, especially its neighbors, even if the OPO itself is underperforming. Each OPO does not have an incentive to better its relationship with hospitals, or improve its referral response time, because there is no other OPO that could work with the hospital and procure organs within its boundaries. In fact, OPOs disregard their service areas to the extreme extent that “just over half (56.4%) of the HCPs

²⁴ Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

²⁵ Hanke, Steve. “President Trump Delivers Lifesaving Deregulation.” *Forbes*, Forbes Magazine.

²⁶ Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

[health-care providers] interviewed found OPO staff to be helpful or supportive, and only 8% considered them part of the hospital team. While legal and regulatory statutes mandate the involvement of OPO staff during consent for donation and subsequent maintenance of donor-eligible patients, nearly two-thirds of respondents considered OPO staff “outsiders” while some characterized them as ‘bullies’ or ‘vultures’.”²⁷ It is clear that many OPOs, without incentives to succeed, have allowed their performance, and their patients, to suffer.

Hospitals do, in fact, have the ability to petition the Department of Health and Human Services to work with a different OPO.²⁸ Yet, the petition system is rarely used for a number of reasons. First, organ donation is a small part of any hospitals’ work, and at any given hospital, there is little incentive to expend effort or time to investigate or interrogate their local OPO’s effectiveness or efficiency. Compounding the problem is the lack of objective data on OPO performance, meaning hospitals may not even be aware that their OPO is underperforming because the hospital has only ever worked with its current OPO. And, the hospital receives potentially biased reports about its OPO’s performance as OPOs are not incentivized to tell the hospitals it serves that another OPO could provide superior service. Finally, the hospital may be securely within the center of an OPO’s geographic area and would actually experience diminished service by working with a distant OPO rather than their current OPO due to prolonged response times and a lack of OPO infrastructure nearby. So, the hospital, in reality, has few incentives to investigate alternatives and even fewer practical options to pursue them.

Lack of government oversight:

Another possible motivation for OPOs to perform well and efficiently would source from possible regulatory punishment for poor performance. All OPOs should be held accountable by their governing agency, the Center for Medicare and Medicaid Services (CMS), yet no OPO has had its certification for service revoked. CMS is responsible for reviewing all OPO performance every four years and should, in theory, be able to revoke contracts of those underperforming OPOs that do not meet performance requirements. Since their establishment in 2006, and until the new regulations take effect in January 2022, the “Conditions for Coverage” (CfCs) that OPOs are expected to meet are listed below. In order to retain certification as an OPO, organizations must meet at least two of the three criteria.

1. “The OPO’s donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO’s donation rate ratio are adjusted

²⁷ Traino, H M, et al. “Interim Results of a National Test of the Rapid Assessment of Hospital Procurement Barriers in Donation (RAPiD).” *American Journal of Transplantation*, U.S. National Library of Medicine.

²⁸ “New to State Operations Manual (SOM) Appendix Y- Organ Procurement Organization (OPO) Interpretive Guidance.” *Center for Medicare and Medicaid Services*.

by adding a 1 for each donation after cardiac death donor and each donor over the age of 70.

2. The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by SRTR.
3. The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.”²⁹

Yet, since the above CfCs were finalized in 2006, several problems have presented themselves to CMS and system stakeholders.

First, OPOs are self-reporting their data with little oversight. The same data that should be used to judge OPOs and could result in their decertification, was being interpreted and reported by the OPOs themselves. So, it is no surprise that no OPO has ever been successfully decertified for not meeting the above CfCs.³⁰ OPOs are often able to interpret definitions of certain terms, and because they are reporting their own data without oversight, reported procurement data is unreliable. According to recent CMS documents outlining a proposed, and now finalized, rule change explained below, “most comments have centered on the self-defined and self-reported nature of the data on ‘eligible deaths’ that are used for the evaluation of the outcome measures. Stakeholders increasingly have brought to our attention that the interpretation of ‘eligible deaths’ appears to be inconsistent across donation service areas (DSAs), and that ‘all OPO data is unaudited and self-reported’ and therefore, ‘the accuracy and consistency of that data cannot be assured.’”³¹

Another common complaint of the CfCs focuses on the third condition. The OPTN donor yield measure judges OPO performance based on how many organs are procured per donor (donor yield). Yet, the problem associated with this rule is that high-yield donors (those that are younger and can donate several organs) are prioritized significantly over low-yield donors (those who are often older and may only be able to donate a single organ). Actually, pursuing too many low-yield donors would pull down an OPO’s donor yield measure. “According to stakeholders, there are ‘pressures from donor yield reporting’ that ‘drives OPOs to walk away from cases in which the donor only has one organ viable for transplant (such as for older patients, where it is common that only the liver is medically viable), even in cases where next of kin consents to donation.’ As a result, some commenters have suggested that ‘the regulations may be causing OPOs to ‘game’

²⁹ Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

³⁰ “Rosenberg, Paul, et al. “Transforming Organ Donation in America.” *Bridgespan.org*, The Bridgespan Group.

³¹ Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

the process of meeting [this] standard by only targeting ‘high-yield’ organ candidates.’³² Years after the third CfC was written into law, it continues to disincentivize OPOs from pursuing every possible donor, resulting in fewer organs available for transplant.

Costliness:

OPOs are not for profit businesses, and their costs are covered fully by the patient who receives an organ transplantation. Upon transplantation, the ultimate payor of the fees is that who receives the transplant(s). So, thereby, the ultimate and primary payor then becomes Medicare, Medicaid, or private insurance. Each payor is required to pay transplantation costs as calculated and reported by the OPOs, known as a standard acquisition cost (SAC). Not surprisingly, these costs vary widely across OPOs.³³ So, someone who receives a transplant could pay significantly more for transplantation services than someone within the same hospital who receives a similar transplant soon after only because of which OPO procured the organ.

For kidney transplants in particular, all costs are covered by Medicare. Medicare pays each OPO based on an established rate between CMS and the OPO.

Because OPOs are monopolistic contractors who simply pass through costs to insurers, they have no incentives to lower their costs. Because the patient is also not the direct, primary payor, the cost does not factor into his or her decision on whether to receive the organ or not. And, because receiving the organ is an absolute necessity, insurance companies or Medicare/Medicaid are stuck paying high prices for organ procurement services. Organ procurement organizations have no incentives to lower their costs because of these factors and so, each year, because of Medicare and Medicaid’s obligations to patients, millions of taxpayer dollars are spent on procurement services that could be done much more cheaply by the not-for-profit OPOs.

A new regulatory structure finalized in November 2020:

Although the organ procurement system had been under fire from stakeholders and activists groups for some time, President Trump took action with an executive order in July 2019. President Trump’s executive order, number 13879, covered many topics regarding kidney health in the United States and began with the lines: “[m]y Administration is dedicated to advancing American kidney health. The status of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the

³² Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

³³ Held, Philip J., et al. “The Cost of Procuring Deceased Donor Kidneys: Evidence from OPO Cost Reports 2013 2017.” *Wiley Online Library*.

current demand for transplants.”³⁴ Although the executive order was oriented towards improving kidney health in its entirety, the order also contained verbiage in section 7a that specifically regarded the topic of organ procurement organizations. In Section 7a, the Secretary of the Department of Health and Human Services was directed to “propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”³⁵ And so, as a result of the executive order and intense calls for reform from stakeholders, CMS finalized a new system under which organ procurement systems would be evaluated in November 2020.

Under this new regulatory structure, OPOs will be exposed to greater competition from other OPOs and will face heightened scrutiny from CMS, ideally resulting in incentives for OPOs to improve. The HHS described their reasoning for the new rule as, “in a continued effort to respond to these concerns and as required by Executive Order 13879 and controlling statutes, we are proposing to revise the outcome measures for re-certification.”³⁶ Indeed, the HHS significantly revised the performance measures by which OPOs will be judged. The change in performance measure was “based on public feedback and our own internal analysis of organ donation and transplantation rates, we agree that the current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates.”³⁷

The finalized rule aimed to “replace the existing outcome measures with two new outcome measures that would be used to assess an OPO’s performance: ‘donation rate’ and ‘organ transplantation rate’ effective for CY 2022.”³⁸ These performance measures address the problems associated with the previous ‘donor yield’ measure by removing the performance benchmark in its entirety. Also, the donation rate and organ transplantation rate calculations have been explicitly stated, and there is little room for interpretation by OPOs. The two new performance rules are detailed below:

1. “The “donation rate” would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation;

³⁴ “Advancing American Kidney Health.” *Federal Register*.

³⁵ *Ibid*.

³⁶ Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

³⁷ Final Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.” *Federal Register*.

³⁸ *Ibid*.

2. The “organ transplantation rate” would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation.”^{39 40}

HHS has simplified and removed speculation from the outcome performance measures for organ procurement organizations. New from the previous system, an organ donor is now defined as a deceased individual from which a vascularized organ was procured and transplanted, not simply just procured as in the previous definition.⁴¹ This ensures that OPOs are motivated to increase the chances that an organ they procure will be transplanted, which encourages them to act in the best interest of the patient receiving the transplant when procuring an organ.

The first performance measure, the ‘donation rate’, change was designed so that all OPOs are incentivized “to pursue all potential donors, even if they may only be able to provide a single organ.”⁴² If this measure was to be met and exceeded by each and every OPO, the Center for Medicare and Medicaid Services (CMS) estimates that the United States could have approximately 7,200 more organs per year to transplant.⁴³

By introducing the second performance measure, the ‘transplantation rate,’ CMS estimates that if all OPOs meet or exceed the measure, the number of annual transplants could increase “from approximately 33,000 to 41,000 by 2026.”⁴⁴

Because the OPO outcome measures have now been corrected for many of their previous flaws, the accountability system for organ procurement organizations will be able to work more effectively. The finalized rule also addressed this area with reforms. Notably, since the release of the new regulations for OPOs in 2018, many OPOs have already significantly improved their procurement performance.⁴⁵

³⁹ Proposed Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization.” *Federal Register*.

⁴⁰ Note: definition was slightly revised in the final rule to include organs transplanted as part of research in the organ transplantation rate.

⁴¹ “Fact Sheet Organ Procurement Organization (OPO) Conditions for Coverage Proposed Rule: Revisions to Outcome Measures for OPOs.” *CMS*.

⁴² *Ibid*.

⁴³ Final Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.” *Federal Register*.

⁴⁴ “Fact Sheet Organ Procurement Organization (OPO) Conditions for Coverage Proposed Rule: Revisions to Outcome Measures for OPOs.” *CMS*.

⁴⁵ Doby, Brianna L, et al. “Public Discourse and Policy Change: Absence of Harm from Increased Oversight and Transparency in OPO Performance.” *American Journal of Transplantation*, U.S. National Library of Medicine.

Solely based on the two metrics above will OPOs be judged. Unchanged from the previous accountability system, all OPOs will be scrutinized every four years to conclude whether or not the OPOs are consistent with the two new conditions for coverage.

New to the finalized rule, at the end of each 4 year re-certification cycle, all OPOs will be grouped into one of three tiers. Tier 1 includes the highest performing OPOs, those in the top 25% of all OPOs according to the two performance metrics. Tier 2 will include the next best OPOs, those ranking above the median in both of the ranking measures, but below the top 25% of OPOs. Tier 3 will include the worst OPOs. Tier 3 OPOs will be those whose rankings in one or both measures fall below the median of all OPOs. Automatically, “Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.”⁴⁶

The key change to the procurement system in the finalized rule yields itself in how the OPOs will be incentivized to compete. To increase competition, at the end of each re-certification cycle, tier 2 and tier 3 OPO’s DSAs will be opened up for competition. Because these lagging OPOs have shown that they are unable to increase their procurement effectiveness, they will automatically lose their DSA. However, tier 2 OPOs will be able to compete to win their DSA back through competition with tier 1 OPOs. Tier 3 OPOs, since they have such poor performance, will automatically lose their DSA and will have no opportunity to win it back. The opened DSAs will be opened for competition to eligible OPOs. Tier 1 OPOs with an interest in a given DSA will compete with each other and make arguments to CMS as to why they should be the OPO to take over the newly open DSA. HHS reserves the right to either offer the entire DSA to a successful OPO or partition the area among several OPOs.⁴⁷

Opportunities for further reform of the new regulatory structure:

While the new system, to go into effect in 2022, may solve part of the competition problem among OPOs, several glaring issues still exist.

First and foremost, the first recertification cycle under the new provisions will occur in 2026. A glaring example of sluggish government policies at work: revisions introduced in November 2020 will not be judged upon for years. Meanwhile, patients continue to be added to the waitlist and many are losing their lives. Dialysis will continue for many suffering with kidney disease, and taxpayer dollars will continue to flow to costly OPOs. Organ reform must happen faster. While Organ Procurement Organizations must be afforded the ability to change their practices and improve, six years is much too long a period to allow OPOs to continue to be inefficient without decertification. As stated by Organize, “It is troubling, however, that the rule states that

⁴⁶ Ibid.

⁴⁷ Final Rule: “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.” *Federal Register*.

failing OPOs will not be decertified until 2026. HHS has shown, with objective data, that many of its contractors are failing, and that holding them to higher standards will save as many as 5,600 more lives every year; to wait six years to do so, by extension, is to consign more than 30,000 Americans to death.”⁴⁸ 4 years between decertification processes remains much too long of a time period as well. OPOs ought to be held accountable on much stricter time frames to ensure OPO compliance and improved performance. If an OPO remains an underperformer, quicker accountability and decertifications will allow those DSAs to be run sooner by efficient OPOs, resulting in more organs procured.

Yet another problem with the new rule is that the new judgement criteria, donation and transplantation rates, are not a comprehensive measure of OPO performance. Relationships with hospital administration and staff, referral response times, effectiveness of obtaining donation authorization from family members, and many other factors make an OPO successful. These factors cannot simply be measured by objective factors such as donation and transplantation rates. These sub-regulatory performance indicators could become very important in the DSA redistribution process, as OPOs with similar objective measurements, but different sub-regulatory indicators, vie for the same newly opened DSA. Without such sub-regulatory data available, the true differences in OPO performance may be unaccounted for in the redistribution process. However, the inclusion of these factors in CMS’s official decision making process could overburden CMS and allow loopholes for OPOs. In the proposed system below, these subregulatory factors would play an influential role without creating drag on the organ procurement system.

A third problem coincides with the redistribution of DSAs following a decertification of a tier 2 or tier 3 OPO. The new rule states that either the entire DSA would be awarded to a tier 1 OPO, re-awarded to the same tier 2 OPO, or partitioned among several OPOs. Yet, we run into the same problem: slow and ineffective government involvement. How will the governing body be sure that the hospitals in the DSA in question prefer one OPO to another? Nowhere in the new regulations are hospital’s perspectives included in decision making regarding DSA reallocation. How would CMS pick the absolute best OPO for the newly open DSA? If several tier 1 OPOs are all vying for the same open DSA, how will CMS be able to discern which OPO would be best suited to expanding its network and effectively beginning the procurement of organs in the new area rapidly, especially in the first round of decertifications when CMS has not been able to see how OPOs handle territory expansions. One possible solution to this problem would be for CMS to deploy new guidelines regarding how they will distribute newly-opened OPO territories. To the extent that CMS would be able to state that the opinions of hospitals within a given DSA to be redistributed would be weighted heavily in distribution decisions, the system would be much more stakeholder driven and result in the best possible redistribution outcome.

⁴⁸ “OPO Final Rule.” *ORGANIZE*.

Importantly, in the decertification process, by awarding all or some of a DSA to a new OPO, would CMS be able to avoid a gap in time between service coverages? In the proposed rule, CMS estimated that between 7 and 33 OPOs could be decertified in the first cycle.⁴⁹ This is a large proportion of the procurement system that would be completely overhauled in a short period of time. Those OPOs taking over new territories would have to work quickly to ensure quality of service did not diminish for the patients of those regions during the service transition. Because of this rapid change brought about by CMS, in the short-term, after decertifications, eligible organs could go unprocured as DSAs are dealt new OPOs. However, although this remains a possibility in the new system, there is no evidence to support that gaps in coverage have occurred historically. Of the 71 OPO mergers in history, never was there any discernable disruption in OPO performance.⁵⁰ Also serving as a counter-point, recent evidence has shown that OPOs have already significantly improved their own procurement performance since the announcement of the proposed rule change in December 2018. This suggests that, before the first decertification cycle of the new system, many OPOs may have already improved their performance so as to avoid decertification.⁵¹

Lastly, unchanged from the current conditions for coverage, OPOs are judged on their compliance with the new conditions for coverage according to their average performance across their entire DSA. It is absolutely possible for a tier one OPO, maintaining optimal objective procurement numbers in its DSA, to be severely underperforming within small pockets of its territory. In this scenario, although underperformance would exist in some localities, the OPO would not face retaliation or threat of decertification from CMS. While this issue in OPO performance is not newly introduced by the new outcome measures, it was also not addressed. With the new regulations, the enlargement of individual OPOs territories would make it easier for Tier 1 OPOs to mask procurement shortcomings in some small areas, especially rural ones. Because OPOs cannot easily access and assess patients in rural areas, these populations are most likely to be overlooked or ignored. This capability for OPOs to underserve rural populations without risk of retaliation could exacerbate rural health access issues.

Clearly, HHS's new provisions will serve to better the procurement of organs, but opportunities still exist to improve upon the procurement system and save thousands of lives each year.

Introduction to a proposed system: removing geographic boundaries and allowing hospitals to negotiate contracts with Organ Procurement Organizations

⁴⁹ Proposed Rule: "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization." *Federal Register*.

⁵⁰ Rosenberg, Paul, et al. "Transforming Organ Donation in America." *Bridgespan.org*, The Bridgespan Group.

⁵¹ Doby, Brianna L, et al. "Public Discourse and Policy Change: Absence of Harm from Increased Oversight and Transparency in OPO Performance." *American Journal of Transplantation*, U.S. National Library of Medicine.

While the proposed changes from HHS will improve the OPO system by facilitating competition and instituting more concrete, comparable metrics, the systematic problems brought about by the OPO's structure, their geographic monopolies and DSAs, and government involvement could hinder the effectiveness of OPOs and restrict the future supply of viable procured organs.

Although the new system does increase the threat of decertification, each OPO is only incentivized to be in the top 25% of OPOs, not the absolute best. Because each OPO is given a government backed monopoly over a certain geographic territory, OPOs do not have incentives to outperform their neighboring OPOs, as long as their figures are just good enough, since they have no risk of losing hospital partnerships to competitors. As before the new regulations, the only threat to OPOs is the federal government revoking their certification. And after the revocation of a certification, in the DSA redistribution process, taxpayer dollars will be unnecessarily and inefficiently allocated to CMS. Instead, this redistribution could occur at no charge to the American taxpayer by allowing the primary stakeholders of the procurement system, hospitals and organ procurement organizations, to independently negotiate. The solution to government waste, slow change, and lagging bureaucracies is to nearly completely remove the government's involvement in the hospital-OPO relationship.

The Department of Health and Human Services ought to allow hospital systems to independently negotiate contracts with OPOs for procurement services. The only involvement from the government in the procurement system would be:

1. to mandate that all hospital systems contract with an OPO;
2. to continue to mandate that hospitals must refer all potential donors to OPOs;
3. to ensure compliance of OPOs with the Social Security and PHS Acts;
4. to offer permits to operate as organ procurement organizations to those already in the system, and to any new organizations wishing to enter the market that can prove their worthiness.

A simple solution to the OPOs severe lack of incentives to compete would be to dissolve each OPO's geographic monopoly, and to replace the antiquated system with a freer market, hospital system contract structure.

The proposed system detailed:

In this passage, a new, proposed system for organ procurement will be outlined using a market and competition based ideology. By allowing and encouraging OPOs to compete with each other directly, greater successes and advances can be made in organ procurement, ensuring as many organs as possible are procured, taxpayer dollars are conserved, and, most importantly, lives are saved.

Removing DSAs

The proposed system would begin by dissolving OPO DSAs and allowing OPOs to compete in each other's territories. Each OPO would retain its facilities and network in its home region, but now OPOs could begin to expand (or shrink) their procurement networks into other regions that were previously unavailable to them. For instance, an OPO operating in Maryland is The Living Legacy Foundation. In Washington D.C., the Washington Regional Transplant Community is the local organ procurement organization. In the proposed system, this artificially constructed DSA line between the two OPOs would be erased and The Living Legacy Foundation could now begin to work with hospital systems in Washington D.C., and Washington Regional Transplant Community would be able to do the same in Maryland. This would remove constraints on OPO infrastructure and capabilities as surgeons, staff, and OPO facilities would now be able to expand their reach into other DSAs, and the OPO would be able to fully utilize its available resources to procure organs in an efficient and effective manner.

Benefits to hospitals

Hospital systems would also benefit greatly from the proposed system. Hospital systems would no longer be required to work with a specific OPO based on their location and would be able to entertain offers from multiple OPOs.

Each hospital system, not hospital (to be explained why below), would negotiate a contract of optional length that would devote exclusive organ procurement rights within the hospital system to a single OPO. Hospital systems, because OPOs would now begin to attempt to expand their service areas into previously unallowed areas, would be able to field multiple contract offers from different OPOs with conditions of service stated in the contract. Conditions of service would not be mandated by the federal government but would be negotiated between each hospital system and potential OPOs, based on which qualities the hospital system values and what services the OPOs are able to provide. These conditions of service may include referral response time requirements, operating room time constraints, and other factors that could be negotiated between the hospital and OPO. The hospital system would grant the exclusive contract to the OPO that is able to offer the best terms of service. The OPO that would be able to offer the best terms would also be the most efficient and effective OPO. Through this system of hospital system contracts, OPOs would be forced to either improve their processes or lose hospital contracts, and procurement area, to more efficient OPOs. By exposing OPOs to market forces of competition, OPOs would be forced to improve their operations or be gradually phased out of the procurement market over time.

Each hospital system is incentivized to sign with the best OPO available because when hospitals work with inefficient and slow OPOs, the hospital bears real financial costs of ensuring the

patient remains viable for transplantation. By rewarding its procurement contract to the best possible OPO, the hospital system reduces its costs and actively saves the lives of many on the transplant waiting list.

Contracts must be negotiated at the hospital system level in order to ensure those hospitals with few eligible donors, usually small rural hospitals, would not be ignored. Large hospital systems with small hospitals could include in their contracts that certain conditions of service must be met for all hospitals within the system. If an OPO was to disregard smaller hospitals within the hospital system, the relationship between the OPO and hospital system could become strained, encouraging the hospital system to not renew its contract with the OPO.

Contracts would not be mandated to be any length of time but could be independently negotiated between hospital systems and OPOs. Rather than decertification cycles every four years, this variable contract process ensures quicker accountability for OPOs who have provided unsatisfactory procurement services to the hospital system. First time contracts between hospital systems and OPOs could reasonably be expected to be on the order of one to three years, as hospital systems search for the best possible OPO.

Effects of the proposed system in the short and medium-term

In the beginning of this systems implementation, hospitals would likely continue to work with their previous OPOs, but some, likely on the borders of the previous DSAs, having been disappointed in their local OPO's procurement ability, would openly consider offers from neighboring OPOs that already have the infrastructure in place nearby to effectively procure organs in a timely manner. For instance, the OPO located in D.C. could gradually expand into Virginia and Maryland as it is able to offer generous terms to the hospital systems nearest its previous DSA borders. Over time, this process would continue across the country as the worst performing OPOs would be phased out as hospital systems opt to reward their contracts to more efficient OPOs. The most effective OPOs would expand their networks and inefficient OPO's service areas would shrink, increasing the percentage of eligible organs procured by the best OPOs. Over time, fewer OPOs would exist and only the most efficient OPOs would remain. And, as a beneficial side effect, duplicate overhead costs, which make up approximately 60% of total procurement costs, could be eliminated.⁵² Market conditions, rather than government interference, would push some OPOs out of the market, and expand the geographic range of others.

⁵² Held, Philip J., et. al, Cost Structures of US Organ Procurement Organizations, *Transplantation*.

Minimal government involvement

Upon initial setup of the new system, the duties of HHS and CMS would be to require and ensure that each hospital system signs an exclusive procurement contract with an OPO. At a minimum, CMS ought to provide OPOs and hospital systems notice of two years before the implementation of the new system. This grace period is necessary to ensure that no viable organs go unprocured while hospital systems and OPOs sort out their contractual obligations. CMS would also need to mandate, as it already does under the current system, that each hospital must refer all eligible donors to their OPO, in order to ensure proper compliance from hospitals in the procurement process.

Other responsibilities of CMS, in order to ensure the system operates properly and legally, would be to ensure compliance of OPOs with the Social Security and PHS Acts. Lastly, in order to ensure the system operated with a steady number of OPOs, CMS would offer permits to operate as a procurement organization to all OPOs already in operation and would be allowed to offer permits to new organizations that could prove worthiness regarding the successful and timely procurement of organs. As a part of this proposed system, because CMS may be currently statutorily precluded from certifying new OPOs, it may be necessary for new federal legislation, statutory guidance, or statutory provisions to be enacted in order to permit CMS to certify new OPOs.⁵³

As the least efficient OPOs are phased out of the market, the existence of fewer OPOs would also benefit taxpayers. By consolidating organ procurement organizations, not only would the system become much more efficient, but also redundant positions and processes could be eliminated.

The entire OPO industry is spending far too much on problematic costs. Notably, over 60% of organ procurement costs are directly due to overhead.⁵⁴ For instance, OPO CEOs are paid handsomely, with many earning over a half of a million dollars in 2019.⁵⁵ In fact, CEO salary is clearly not associated with OPO performance. Many CEOs of failing OPOs, according to the new regulations, were suspiciously paid over a million dollars per year recently.⁵⁶ These positions, other executive positions, and many overhead costs of inefficient OPOs would be removed as the number of OPOs are consolidated under the market system. As the most successful OPOs grow larger, duplicative processes could be eliminated and the OPOs could streamline their own procurement processes by maximizing capabilities of surgeons and support staff. And, because the costs of these positions and processes are included in the costs of organ transplantation that is passed onto private and public insurance, once they are eliminated, organ

⁵³ United States, Congress, *National Organ Transplant Act*. 1984. 42 USC 273.

⁵⁴ Held, Philip J., et. al, Cost Structures of US Organ Procurement Organizations, *Transplantation*.

⁵⁵ Review of IRS Form 990.

⁵⁶ “Letters to Organ Procurement Organizations (OPOs).” *House Committee on Oversight and Reform*.

procurement costs would decrease, saving the American taxpayer millions of dollars each year in Medicare and Medicaid services.

No longer would the federal government be responsible for handling hospital's petitions to work with different OPOs or would be responsible for revoking contracts from organ procurement organizations for poor performance. The market oriented system would perform these tasks quickly and without any additional cost to taxpayers. OPOs would be held accountable for their own actions and inefficient work by the hospital systems themselves, who are arguably much better judges of effectiveness than the distant and bureaucratic Centers for Medicare and Medicaid Services.

Enactment of the Proposed Reform

The system of Organ Procurement Organizations is governed by both laws and regulations. The relevant law is in Chapter 42 of the U.S. Code, section 273.⁵⁷ The section states, "a qualified organ procurement organization... has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area." Clearly, designated service areas for OPOs are required by law. So, for the above reform to take place, two options remain. Either Congress must pass new legislation that would permit the removal of designated service areas, or the law may be interpreted such that the Department of Health and Human Services could make the change independently as a regulatory matter. The law above does not state that the designated service areas cannot be overlapping and imposes no limit to their size. Perhaps, then, the Department of Health and Human Services could declare each OPO's designated service area as the entire United States. This would then open the door to allow OPOs to compete with each other without constraints of non-overlapping designated service areas.

A second legislative obstacle exists in allowing OPOs to independently negotiate procurement contracts with hospital systems across the entire United States. Section 273 also states that "an organ procurement organization shall... have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations." If service areas were to be expanded according to the proposal above, then this clause might not be capable of being met by any OPO. Because each OPO would have the entire United States as its DSA, OPOs would not be able to have effective agreements with a substantial majority of all U.S. hospitals. Most likely, this clause would have to be changed through Congressional action to pose no constraints on the number of

⁵⁷ United States, Congress, *National Organ Transplant Act*. 1984. 42 USC 273.

hospitals each OPO works with, and to mandate that OPOs must sign contracts with hospital systems, not individual hospitals.

Conclusion

The organ procurement system in the United States has been rife with perverse incentives and a lack of accountability since conditions for coverage were first announced in 2006. Never has an OPO truly faced consequences for poor operations from either the market or the federal government. But in 2019, President Trump and CMS took action to greatly reform the system. In a politically contentious United States, organ donation reform has received resounding bipartisan support in Congress. In December 2019, Dan Diamond of Politico wrote, “Trump's organ donation overhaul is arguably his most popular public health effort, with bipartisan support for cracking down on the organ procurement organizations that are responsible for recovering organs.”⁵⁸ The design of the procurement system is essential to the American people and successful design could result in thousands of lives saved each year.

While the changes made recently by CMS are necessary and certainly improvements to the previous procurement system, the system's architecture will always limit its effectiveness and prohibit the supply of transplantable organs. The limitations of Designated Service Areas and government oversight will continue to burden the procurement system. The procurement system could benefit from steep reform utilizing the mechanics of a stakeholder-based, freer-market system by allowing hospitals to independently negotiate with OPOs, thereby provoking competition between organ procurement organizations without any ethical issues. By allowing Organ Procurement Organizations to compete without the constraints of DSAs, and by handing the reigns of the system from CMS to hospital systems themselves, the system would guide itself to its most efficient and effective state, thereby procuring more organs, and saving American lives.

⁵⁸ Diamond, Dan. “Coming Today: New Organ Donation Rules.” *POLITICO*.

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