

Addressing the Organ-Donation Crisis

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Summary

The organ-donation crisis is one of the most persistent, expensive, and yet solvable public-health challenges of our time. As of January 2020, nearly 115,000 Americans were waitlisted for an organ transplant.¹ The vast majority have kidney failure, which, as one of the rare conditions qualifying patients for Medicare, translates to billions of dollars of costs for taxpayers. Taxpayers spend an alarming \$114 billion on kidney disease—more than the entire budgets of the National Institutes of Health ([\\$39 billion](#)), the Department of Homeland Security ([\\$44 billion](#)), and the National Aeronautics and Space Administration (NASA, [\\$21.5 billion](#)) combined.²

The clear solution is to shorten the organ waiting list. For every Medicare patient who receives a kidney transplant, taxpayers save \$250,000 in avoided dialysis costs.³ Put another way, each 4% reduction in the number of people on the kidney waiting list saves 4,000 lives and \$1 billion in Medicare costs. In 2019, the current administration has made meaningful progress toward addressing these problems; in the next term, the administration should build on this momentum, including by:

- Holding organ procurement organizations accountable and reforming the deceased-donation system, enabling recovery of up to 28,000 more organs per year and saving \$12 billion in Medicare spending over five years.
- Removing financial barriers to living donation, enabling recovery of up to 1,600 more organs per year and saving \$1 billion in Medicare spending over five years.
- Spurring scientific and technological breakthroughs to change what is possible for patients with organ failure.
- Creating an Office of Organ Policy to fix the fractured government-oversight system that has left tens of thousands of patients to die while waiting for organs.

1. Challenge

1.1 *Accountability of organ-procurement organizations*

Though nearly 95% of Americans support organ donation, massive systemic inefficiencies prevent the United States' organ-donation system from recovering organs.⁴

¹ United Network for Organ Sharing, "Transplant trends", data as of January 15, 2020, <https://unos.org/data/transplant-trends/>.

² Department of Health and Human Services, "HHS Launches President Trump's 'Advancing American Kidney Health' Initiative", July 2019, <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>

³ Philip J. Held, Frank McCormick, Akinlolu Ojo, and John P. Roberts, "A Cost-Benefit Analysis of Government Compensation of Kidney Donors", *American Journal of Transplantation* 16 (2016): 877–885.

⁴ U.S. Government Resources on Organ Donation and Transplantation, "Organ Donation Statistics", Health Resources & Services Administration, U.S. Department of Health and Human Services, July 2019, <https://www.organdonor.gov/statistics-stories/statistics.html>.

Organs are only recovered from 30–40% of all potential donors.⁵ Put another way, up to 28,000 transplantable organs go unrecovered each year.

The critical task of coordinating organ recovery falls to a system of 58 federal contractors called organ procurement organizations (OPOs). OPOs operate as government-granted monopolies, managing all organ recovery in their designated geographic service areas. OPO responsibilities include maintaining relationships with donor hospitals, obtaining next-of-kin authorization for deceased donors, and managing the logistical transition of organs between donor hospitals and transplant centers. While most people have never heard of OPOs, their role is paramount. Research suggests that the biggest predictor of donation rates in any region is how positively a deceased donor's next-of-kin rates their interaction with the OPO (e.g., was the OPO compassionate or did it feel pushy?), rather than more visible-but-peripheral indicators, such as donor registration rates.⁶

Here is the key problem: OPO performance is wildly variable in ways that cannot be explained by demography.⁷ When an OPO does not perform well, organs are not recovered and people die while waiting for an organ transplant. Research shows that as of 2014, at least 16 of the 58 OPOs recover less than one third of their donation potential.⁸ The *Washington Post* found that “most [OPOs] collected fewer than half the organs available...[and] a dozen recovered fewer than a third,” and the *Associated Press* found that “some [OPOs] are securing deceased donors at half the rate of others.”^{9,10}

Despite extreme performance disparities, no OPO has been decertified by the federal agency responsible for oversight, the Centers for Medicare and Medicaid Services (CMS), in more than twenty years.¹¹ Key to the lack of accountability is a poorly written regulation that allows OPOs to self-report and self-interpret their own performance.¹² As a result,

⁵ *Reforming Organ Donation in America*, The Bridgespan Group (January 2017, data updated January 2019).

⁶ Heather M. Traino, Anthony J. Molisani, and Laura A. Siminoff, “Regional Differences in Communication Process and Outcomes of Requests for Solid Organ Donation”, *American Journal of Transplantation* 17, no. 6 (2017): 1620–1627.

⁷ David S. Goldberg, Benjamin French, Peter L. Abt, and Richard K. Gilroy, “Increasing the Number of Organ Transplants in the United States by Optimizing Donor Authorization Rates”, *American Journal of Transplantation* 15, no. 8 (2015): 2117–2125.

⁸ *Reforming Organ Donation in America*, The Bridgespan Group. Note: for 9 OPOs data was not available to determine performance.

⁹ Kimberly Kindy, Lenny Bernstein, and Dan Keating, “Lives Lost, Organs Wasted”, *The Washington Post*, December 20, 2018, <https://www.washingtonpost.com/graphics/2018/national/organ-transplant-shortages/>.

¹⁰ Lauran Neergaard and Nicky Forster, “Where you die can affect your chance of being an organ donor”, *Associated Press*, October 19, 2019, <https://apnews.com/dbc0d75e5470407ca02f77b320acbb67>.

¹¹ Lenny Bernstein and Kimberly Kindy, “New York organ collection agency, nation's second-largest, threatened with closure”, *The Washington Post*, July 11, 2018, https://www.washingtonpost.com/health-science/new-york-organ-collection-agency-nations-second-largest-threatened-with-closure/2018/07/11/09c52824-847b-11e8-8f6c-46cb43e3f306_story.html.

¹² 42 CFR §486.318.

not only can it be difficult for CMS (or Congress or the public, for that matter) to hold OPOs accountable, it is functionally impossible for CMS to decertify underperformers.¹³

This reality has long been obscured by bad data and inflated performance reporting. In an op-ed published by the *New York Times* in June 2019, an OPO whistleblower stated it plainly: “I used to work at an OPO and we reported false numbers to make it appear we were doing better than we were. The research shows a lack of oversight, inefficiency, and a culture of dishonesty.”¹⁴

The lack of oversight or accountability for OPO performance is compounded by a problematic financial structure. OPOs are 100% reimbursed for all expenses, including expenses directly and indirectly related to organ-recovery activities. This means that in addition to lacking accountability for performance outputs, OPOs feel little financial pressure to improve efficiency or recover more organs. And indeed, investigative reporting has found a culture of rampant fraud, waste, and abuse.¹⁵ IRS 990 forms show that compensation for CEOs of OPOs can be as high as \$2.5 million annually. In 2012, two executives from the Alabama OPO were sent to Federal prison for running a multi-million dollar kickback scheme with a local funeral home to defraud taxpayers.¹⁶ These and other scandals have recently prompted Congressional inquiries. Senators Chuck Grassley (R-IA), Chairman of the Senate Finance Committee, and Todd Young (R-IN) wrote to the Office of the Inspector General in December 2019 on the topics of OPO performance, finances, and conflicts of interest.¹⁷

1.2 Financial barriers to living donation

Together, patients who need kidney and liver transplants constitute more than 95% of the organ waiting list. The U.S. deceased-donation system, even if performing optimally,

¹³ CMS tried to decertify the Arkansas OPO in 1999. A federal judge ruled that it did not have the legal ability to do so, in large part because its decision to decertify the OPO was based on flawed data. See *Arkansas Regional Organ Recovery Agency, Inc., v. Donna E. Shalala*, 104 F. Supp. 2d 1084 (E.D. Ark. 2000). Moreover, the New York Organ Donor Network wrote to the White House Office of Management and Budget in 2013 that “the data that OPOs submit to CMS...is self-reported and unaudited...Clearly, this type of ‘evidence’ fails to meet any reasonable definition of ‘empirical.’” See Helen M. Irving to Howard Shelanski, “Re: Unaddressed Implications of the Proposed Changes to the Conditions for Coverage for Organ Procurement Organizations (HHS/CMS Rule 0938-AR54)”, Letter, October 28, 2013, https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.

¹⁴ Tonya Ingram, Angelo Reid, Melissa Bein, and Maddi Bertrand, “11,000 Americans Will Die Waiting for Transplants This Year”, *The New York Times*, June 11, 2019, <https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html>.

¹⁵ Andrew Conte and Luis Fábregas, “Taxpayers help pay for organ donor groups’ parties, Rose Parade expenses”, TribLIVE, October 19, 2013, <https://webcache.googleusercontent.com/search?q=cache:YGgkMon4sHUJ:https://archive.triblive.com/local/pittsburgh-allegheeny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/+&cd=1&hl=en&ct=clnk&gl=us>.

¹⁶ Birmingham Division, “Former Alabama Organ Center Executive Sentenced for Fraud”, Federal Bureau of Investigation, U.S. Department of Justice, May 16, 2012, <https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud>.

¹⁷ Charles E. Grassley and Todd Young to Joanne M. Chiedi, Letter, December 18, 2019, [https://www.finance.senate.gov/imo/media/doc/CEG.Young%20to%20HHSOIG%20\(OPO%20Oversight\)%20Dec.18.2019.pdf](https://www.finance.senate.gov/imo/media/doc/CEG.Young%20to%20HHSOIG%20(OPO%20Oversight)%20Dec.18.2019.pdf).

may not fully service this need. Fortunately, kidneys and livers can come from living donors. A healthy person has two kidneys and can remain healthy with one. The liver has the capacity to regenerate, meaning that someone can donate a portion of their liver and it will grow back to full size. Even so, living-donor kidney and liver transplants represent a minority of total kidney and liver transplants performed.¹⁸

Cost is one barrier to living donation. According to the American Society of Transplantation, “living donors may spend an average of \$5,000 related to their donation.”¹⁹ Some estimates raise this figure to as much as \$37,000 when accounting for additional long-term costs.²⁰ There is a strong ethical argument that a living donor’s altruism should not be punished with a financial burden. But even setting ethics aside, there is a strong economic argument to be made for eliminating financial barriers to living donation. An HHS review indicated “that reimbursement measures have increased organ donations anywhere from 14 percent to 65 percent, depending on the particular circumstances of the study” and that “donor income also appears to play a role in living organ donor transplant rates.”²¹ The taxpayer burden of covering costs for a living donor is far less than the burden of covering the costs of dialysis for a Medicare patient who spends years on the kidney waiting list (*i.e.*, the above-cited \$250,000 per patient) when organ supply is insufficient.

1.3 Fractured government oversight

Organ donation policy has long had bipartisan support. The National Organ Transplantation Act of 1984 was co-sponsored by Democratic Congressman Al Gore and Republican Senator Orrin Hatch. Tommy Thompson, Secretary of the U.S. Department of Health and Human Services under President Bush, advocated for better organ policy in the early 2000s. More recently, President Obama drew national attention via the 2016 White House Organ Summit²², while President Trump enacted sweeping reforms to the U.S. organ-donation system when he signed Executive Order 13879 in July 2019.²³

¹⁸ In the United States in 2019, 18,006 kidney transplants and 9,674 liver transplants were performed. Out of these, 6,856 (38%) kidney transplants and 523 liver transplants (5.4%) were from living donors. Source: Organ Procurement and Transplantation Network, “National Data: Donors Recovered in the U.S. by Donor Type”, U.S. Department of Health and Human Services, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.

¹⁹ Rebecca Hays and Lara Tushla, “Live Donation: Financial Toolkit”, American Society of Transplantation (n.d.).

²⁰ Frank McCormick, *et al.*, “Removing Disincentives to Kidney Donation, A Quantitative Analysis”, *Journal of the American Society of Nephrology* 30 (2019).

²¹ *Id.*, Section IV.A.

²² Alefiah Mesiwala, Jennifer Erickson, and Robbie Barbero, “Saving Lives and Giving Hope by Reducing the Organ Waiting List”, The White House, June 13, 2016, <https://obamawhitehouse.archives.gov/blog/2016/06/13/saving-lives-and-giving-hope-reducing-organ-waiting-list>.

²³ “Executive Order 13879 of July 10, 2019, Advancing American Kidney Health”, *Code of Federal Regulations*, title 3 (2019): 33817–33819.

Why, then, has there not been more progress to date? A central challenge has been a splintering of responsibilities for organ donation across different Federal agencies and Federal contractors. For example, CMS pays for dialysis (\$35 billion per year) and costs associated with kidney transplants for Medicare patients. But support for living donors, which can enable those transplants, is the responsibility of the small Division of Transplant, housed within the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services (HHS). Similarly, HRSA administers the federal contract for the Organ Procurement Transplantation Network (OPTN) that manages deceased donation. Yet it is CMS whose current responsibilities most overlap with—or at least abut—those of the OPTN.

When many entities are responsible for a small piece of an issue, it can result in no entity feeling real ownership or agency over that issue as a whole. The overlong organ waiting list is in part a legacy of fractured and unclear responsibilities for organ policy at the federal level. As the Editorial Board of the *New York Times* recently highlighted, there is “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.”²⁴ This is an unacceptable consequence when underperformance translates to thousands of patients dying unnecessarily each year.

2. Proposed action

2.1 Hold contractors accountable to objective, high standards

Improving OPO performance starts with objective data and accountability. Recent progress has been made on this front. President Trump’s July 2019 Executive Order, “Advancing American Kidney Health”, directed the HHS Secretary to implement “more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.” In December 2019, HHS proposed a new rule that evaluates OPOs on the dual metrics of “donation rate” and “organ transplantation rate”. The former is the “number of actual deceased donors” as a percentage of total inpatient deaths in the DSA [donation service area] among patients who are eligible donors (*i.e.*, excluding those over the age of 75 or with health complications that preclude organ donation). The latter is the “number of organs procured within the DSA and transplanted” as a percentage of the same.²⁵ These metrics will be operationalized using data already collected by the Centers for Disease Control (CDC). Notably, this proposed rule also significantly raises the bar for the level of performance HHS deems necessary for an OPO

²⁴ The Editorial Board, “She Beat Cancer. Now, She’s in Another Fight for Her Life”, *The New York Times*, August 20, 2019, <https://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html>.

²⁵ “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization”, *Federal Register: The Daily Journal of the United States*, 84 Fed. Reg. 246 (December 23, 2019).

to maintain its contract. Under the proposal, 37 of the 58 OPOs are out of compliance on one or both of the new metrics.²⁶

The proposed rule also notes (emphasis added):

“There is no need to wait until the end of the four-year period to take action regarding any OPOs that are underperforming. With continuous assessment and public disclosure of the information, OPOs who cannot achieve the outcome measures may decide to voluntarily de-certify and allow a high performing OPO to take over the DSA, even before the end of the re-certification cycle or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA.”

In other words, transparency about OPO underperformance, coupled with corresponding public pressure, can – and should – drive immediate OPO board-level action in patients’ interest, even before the next formal re-certification cycle. As HHS Secretary Alex Azar said when the new rule was proposed, “We’re going to stop looking the other way while lives are lost and hold OPOs accountable.”²⁷

The push for OPO accountability also has bipartisan support. In July 2019, Senators Todd Young (R-IN) and Michael Bennet (D-CO) co-sponsored OPO-reform legislation,²⁸ and 74 members of Congress wrote a bipartisan letter to Secretary Azar and CMS Administrator Seema Verma urging that “OPOs should be held accountable with the new performance metric being proposed in the Hospital Outpatient Prospective Payment System for Calendar Year 2020.” Andy Slavitt, former Acting Administrator of the CMS under President Obama, and Adam Brandon, President of the conservative advocacy group Freedom Works, jointly published an op-ed in December 2019 calling on HHS to “take strong action to decertify OPOs not serving patients or taxpayer interests.”²⁹

²⁶ Ibid

²⁷ U.S. Department of Health and Human Services, “Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply”, December 17, 2019, <https://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html>.

²⁸ “Young Introduces Legislation to Bring Greater Accountability to Organ Donation”, July 9, 2019, <https://www.young.senate.gov/newsroom/press-releases/young-introduces-legislation-to-bring-greater-accountability-to-organ-donation-system>.

²⁹ Andy Slavitt and Adam Brandon, “Here’s how organ donation reform could save thousands of lives, billions in tax dollars”, USA Today, December 11, 2019, <https://www.usatoday.com/story/opinion/2019/12/11/organ-donation-reform-could-save-thousands-lives-billions-taxes-column/4377383002/>.

Medical trade associations and patient groups, including the American Society of Nephrology and the Global Liver Institute, have also supported OPO-reform efforts.³⁰ Reforms for meaningful OPO accountability are likely to face resistance only from some OPOs themselves, which are currently subject to no effective oversight.

2.2 Increase financial support for living donors

A federally funded program—the National Living Donation Assistance Center (NLDAC), a contract awarded by the HRSA and run by a private entity—already exists to provide financial support for living donors. But regulations currently constrain how much and to whom this NLDAC assistance can be provided.³¹ To increase living-donation rates, these constraints should be eliminated. All costs associated with living donation—e.g., costs of childcare and lost wages during pre-operation appointments and during the post-operation recovery period; costs of transportation to and from appointments—should be covered by the federal government, regardless the donor or recipient’s income level.

President Trump’s July 2019 Executive Order directed HHS to propose a new regulation “to remove financial barriers to living organ donation.” In December 2019, HHS proposed a new rule that would expand the definition of reimbursable expenses for living donation to include lost wages, child care, and elder care.³² HHS has also indicated it intends to propose a separate new rule to raise the income limit on NLDAC reimbursement from the current limit of 300% of the federal poverty level.³³

HHS conservatively estimates that the regulation would increase living donations by 20%, representing 500 new kidney transplants annually. This would result in an estimated \$68 million in federal budgetary savings (via avoided Medicare costs) over 10 years.³⁴ An outside estimate from patient advocacy group Waitlist Zero is even more positive. Waitlist Zero suggests that covering the costs specified in the Executive Order alone could lead to 1,600 more kidney transplants annually.³⁵ Yet more can be done. Studies suggest that compensating donors for additional disincentives, above and beyond those specified in the Executive Order, could lead to 11,500 more kidney transplants annually. As such, the administration should build on the recent progress by the White House and HHS to ensure that living donation is financially neutral. This includes identifying and

³⁰ Global Liver Institute to Seema Verma, Letter, March 12, 2019,

https://static1.squarespace.com/static/53bafd3ce4b0ae714af7153f/t/5c87f053f9619a5321461051/1552412755862/Request_OPO_Metric_Fix_on_behalf_of_Transplant_Patients.pdf.

³¹ Authorized by 42 U.S.C. §274f.

³² U.S. Department of Health and Human Services, “Trump Administration Proposes New Rules”.

³³ “Removing Financial Disincentives to Living Organ Donation”, *Federal Register: The Daily Journal of the United States*, 84 Fed. Reg. 245 (December 20, 2019): Section II.B.

³⁴ *Ibid.*

³⁵ Dylan Matthews, “The Trump administration is quietly helping people get kidneys”, *Vox*, June 26, 2019,

<https://www.vox.com/future-perfect/2019/6/26/18744536/kidney-transplant-requirements-rules-trump-white-house>.

reimbursing any additional costs to living donors, such as any potential decrease in their long-term quality of life—both at the time of donation and over the course of a donors’ lifespan—that are not currently covered by federal funding.³⁶

2.3 *Spur scientific and technological breakthroughs to change what is possible for patients with organ failure*

While reforming the current organ-donation system is imperative in the short term, scientific and technological advances could eliminate the need for organ donation in the future. Policymakers should strongly support development of bioengineered, artificial organs that can replace organs from human donors.

An important step towards this goal is reducing regulatory uncertainty surrounding artificial organs. Such uncertainty currently hinders private-sector investment in organ bioengineering, as venture capitalists wonder whether the FDA will approve artificial organs if developed, and whether CMS will pay for them. Successive administrations have begun work in this arena; the Obama Administration launched the [Advanced Regenerative Manufacturing Institute](#) in 2016, and the Trump Administration launched [KidneyX](#) with the American Society of Nephrology (ASN) in 2018, as well as the aforementioned Executive Order that encourages development of an artificial kidney.

Policymakers should build on these efforts, marshaling federal resources and agency attention to ensure that public-private partnerships continue supporting breakthroughs in organ bioengineering, to streamline testing and approval at the federal level, and to ensure that patients have easy, low-cost access to approved technologies. Specifically, policymakers should:

- Direct FDA to periodically update a regulatory “roadmap” to facilitate development and deployment of artificial kidneys and other artificial organs.³⁷
- Use CMS payment policy to drive innovation in organ bioengineering.
- Coordinate efforts of the National Institutes of Health, CDC, and other relevant federal agencies to support organ bioengineering.

Moreover, the administration should request \$25 million per year in federal funding for KidneyX. Assuming KidneyX is able to replicate the success of Carb-X Accelerator (another HHS public-private partnership)³⁸, Federal investment in KidneyX could generate a significant return from the private and philanthropic sectors, and would build on the FY2020 \$5 million appropriation for KidneyX. Support for KidneyX includes both

³⁶ Frank McCormick, *et al.*, “Removing Disincentives to Kidney Donation”.

³⁷ Kidney Health Initiative, “Technology Roadmap.” <https://khi.asn-online.org/rtrroadmap>

³⁸ CARB-X. <https://carb-x.org>

the current Republican Administration; bipartisan support in the House and Senate; and key industry stakeholders, including ASN (which has pledged \$25 million to the effort), the National Kidney Foundation, and the American Association of Kidney Patients.

2.4 Create a national Office of Organ Policy

To address the federal patchwork of regulation and oversight for organ donation, the administration should create a dedicated Office of Organ Policy (OOP) within HHS. This office would serve as a clearinghouse for all federal efforts to help patients with organ failure, and would facilitate federal coordination with non-federal entities towards this end.

The OOP could reabsorb some key oversight responsibilities currently held by the OPTN, which has been run by the United Network for Organ Sharing (UNOS) as a Federal contractor for more than 30 years. The Editorial Board of the *New York Times* advocated for HHS to “revisit the UNOS monopoly [because a] lack of competition has thwarted innovation, allowed the organization to become mired in bureaucracy and made it resistant to change,”³⁹ and former UNOS board members have also highlighted opportunities to improve its performance.⁴⁰

HHS has already taken a first step towards increasing competition in the organ-donation system by issuing a Request for Information (RFI) for a piece of the OPTN contract. HHS should explore all options to ensure the most innovative solutions are available.⁴¹ According to a recent editorial from leading researchers at Johns Hopkins University, “restructuring the OPTN contract to separate the information technology requirements from the policy/regulatory responsibilities might allow more number and effective specialty contractors to offer their capabilities in service of the national transplant enterprise.”⁴² The administration should also look for opportunities to better manage conflicts of interest, potentially reabsorbing key oversight functions of the OPTN contract (such as OPO oversight), and clarifying and realigning key federal responsibilities in organ donation.

Consolidating federal involvement in organ donation at a single office would also improve federal capacity to support living donors and drive scientific and technological

³⁹ The Editorial Board, “She Beat Cancer”.

⁴⁰ Charles Ornstein and Tracy Weber, “Transplant monitor lax in oversight”, *Los Angeles Times*, October 22, 2006, <https://www.latimes.com/news/la-me-transplant22oct22-story.html>.

⁴¹ Health Resources and Services Administration, “Modern National Resource Allocation System”, U.S. Department of Health and Human Services, Notice ID HRSA20191114, November 14, 2019, <https://beta.sam.gov/opp/a064f4c2903c41629aacd9637532c6b7/view>.

⁴² Sommer Gentry and Dorry Segev. “Restructuring the Organ Procurement and transplantation Network contract to achieve coherence and infrastructure excellence”, *American Journal of Transplantation* 19, no. 6. (2018) 1622-1627.

breakthroughs. The recent Executive Order, and its widespread bipartisan support, is a useful precursor to and catalyst for establishment of such an office. As other opportunities for the federal government to help patients emerge (e.g., the recent insight that covering lifetime immunosuppression for transplant patients saves both lives and taxpayer dollars,⁴³) the OOP can push towards rapid and effective implementation.

3. Conclusion

The problems with our organ donation system are acute but eminently solvable. Our organ-donation system is broken not because it is difficult to fix, but because for too long government largely ignored the system since it was first established via legislation in 1984.

In the next term, the administration can build on recent actions from HHS and the White House to right the ship through a mix of commonsense reforms to help patients waiting now, as well as smart policies and targeted investments that will change what is possible for patients in the near future. Specific steps policymakers can take include:

- Most immediately, demanding more accountability and higher performance from OPOs.
- Removing all financial barriers for living donors.
- Aggressively promoting scientific progress in organ transplantation through KidneyX.
- Coordinating all organ donation and transplantation efforts through a new, dedicated Office of Organ Policy at the U.S. Department of Health and Human Services.

Nearly 115,000 Americans are sick and waiting for organs. Every month, 1,000 patients are removed from the waiting list—not because they’ve been helped, but because they have died or become too sick to transplant. Policymakers have a responsibility to the American people to help. Actions widely supported on both sides of the aisle will not only lay the groundwork for ongoing improvements in the coming years, but will also make a meaningful difference for patients today.

⁴³ Office of the Assistant Secretary for Planning and Evaluation, “Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs under Medicare”, U.S. Department of Health and Human Services (May 2019).

About the authors

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clinical interests include management of resistant hypertension, hypertension in pregnancy, and progressive chronic kidney disease.

Greg Segal is the co-founder and CEO of Organize, a patient advocacy group focused on systemic reforms to increase patient access to organ transplants. Greg served as the Innovator in Residence in the Office of the Secretary of the U.S. Department of Health and Human Services from 2015–2016. During this time, he led research in partnership with the University of Pennsylvania and the Bridgespan Group, which was cited by President Trump during the signing of the July 2019 Executive Order on Advancing American Kidney Health. Greg won the 2015 Stanford MedX Health Care Design Award and a 2016 Tribeca Disruptive Innovator Award. Prior to co-founding Organize, Greg worked in venture capital at Rethink Education. He received a B.A. from Duke University and is currently a Columbia Business School Innovation Fellow.

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