

# Can't stop won't stop — how organ donation and transplant partners can maintain unprecedented momentum

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It's been quite a year in the field of organ donation and transplantation policy.

Even in the face of an unforeseen global pandemic, massive strides have been made, by both the Trump Administration and the organ donation and transplant community, to increase the number of organs available for transplantation.

Both have been laser focused on improving the system and maximizing the number of organs available for transplant.

Today, the number of Americans awaiting a solid organ transplant stands at just over 109,000.<sup>1</sup>

While few communities recognize the urgent need for improvements more than the organ donation and transplant community, it is also essential that lawmakers continue to spend the time and effort necessary to comprehensively understand the complex challenges facing the organ donation and transplant community so that meaningful policies can continue to be implemented.

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A balance of urgency and in-depth analysis are necessary to effectuate lasting and significant policies that honor those in need.

## THE YEAR IN REVIEW

In looking back over the past year, a number of important advancements in organ donation and transplant policy have been employed.

A little over a year ago, President Trump issued an Executive Order on "Advancing American Kidney Health,"<sup>2</sup> wherein the Administration announced a number of sweeping initiatives with the goals of addressing the high mortality rate of those awaiting kidney transplants and increasing the available number of organs for transplant.

Since then, the Department of Health and Human Services (HHS) has been working non-stop to implement these initiatives using an all-hands-on-deck approach, with assistance from a number of other federal agencies, including the Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), Centers for Disease Control (CDC), and the transplant community itself.

Impressively, many of these initiatives have been achieved even in the face of the COVID-19 pandemic upheaval.

In addition to the Executive Order, Congressional calls for systemic change have intensified the spotlight on the organ donation and transplant community.<sup>3</sup>

Hospitals, organ procurement organizations (OPOs) and transplant centers are the three distinct entities responsible for facilitation of organ donation and transplantation.

The process is generally governed by the United Network of Organ Sharing (UNOS), the private non-profit organization responsible for managing the nation's organ transplant system via a federal contract.

According to UNOS, in 2019, 41 out of 58 OPOs set their all-time organ donation record, and 48 out of 58 OPOs increased the total number of donors over the previous year.<sup>4</sup>

Notably, and in spite of these improvements, several of the Congressional inquiries and requests focus solely on OPO performance improvement and oversight as the best way to reduce the transplant waitlist.<sup>5</sup>

Although OPOs are improving, there are still areas for OPO growth. However, comprehensive systemic improvement depends on a complex review and analysis of the roles of each donation and transplant partner and the process as a whole.

## ORGAN DONATION AND TRANSPLANT PARTNERS

Together with OPOs, two other entities work to maximize successful organ donation and transplantation: hospitals and transplant centers.

The roles that each of the three partners in transplant play and how those roles intersect must be fully considered in order to most impactfully effectuate change.

Briefly, OPOs are non-profit entities governed by federal and state laws. OPOs generally assess the potential of organ donors and facilitate the donation and procurement process.

Each OPO is assigned a designated geographical service area (DSA) within which it is responsible for coordinating the surgical recovery of organs, working with donor families, ensuring the organs are allocated according to federal policy, educating hospital personnel, and educating the public on organ donation.

Importantly, OPOs are not “health care providers,” as they simply facilitate organ donation and do not provide health care in the traditional sense.

The role of the OPO is equally as important as the role of the donor hospital and transplant center. Virtually every hospital in the country is required by Centers for Medicare and Medicaid Services (CMS) to refer potential donors to the OPO in its DSA.

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Hospitals are required to timely notify their respective OPOs of individuals whose death is imminent or who have died in the hospital.

The role of the hospital is the critical first step in establishing a baseline number of potential donors; if the OPO does not receive timely notification, or notification at all, it cannot begin the donor assessment process.

The hospitals retain this obligation, even if the hospital clinicians believe the patient’s medical condition may rule them out as donors, and even during the COVID-19 emergency.

Hospitals are also required to provide OPOs timely and meaningful access to donor medical records, so that the OPO may begin the critical process of assessing donor suitability and confirming donor authorization.

Transplant centers play the third vital role in maximizing successful organ transplantation in that these centers evaluate the suitability of the organ for transplant and work with transplant candidates to make informed decisions about whether to accept or decline the proffered organ.

All three entities must comply with their respective CMS Conditions of Participation or Conditions of Coverage.

To that end, as part of the President’s Executive Order, one of the Government’s most challenging and complex efforts in the last year was, and remains, the introduction of a newly proposed rule proffering a revamped system of evaluating the performance of the nation’s 58 OPOs.<sup>6</sup>

### NEWLY PROPOSED OPO PERFORMANCE METRICS RULE

The “Organ Procurement Organization (OPO) Conditions for Coverage Proposed Rule: Revisions to Outcome Measures for OPOs,” (Proposed Rule) was generally well-received, as many inside and outside the organ donation and transplant community agreed that the existing rule did not accurately assess OPO performance because it partially relied on OPOs to self-report data.

With the broad uniform goal of reducing the transplant waitlist, CMS proffered new OPO performance measurements.

Based on the comments to the Proposed Rule, many changes to the performance metrics were well-received. However, a number of elements were subject to criticism.

For example, the Proposed Rule calculates the donation rate by counting all donors from whom an organ has been actually “transplanted,” as opposed to simply “recovered.”

Many OPOs argued that this measurement unfairly reflects the transplant acceptance rate, not the effort of the OPO in procuring and offering the maximum number of organs, and effectively places the donation rate in the hands of the transplant centers, which have the ultimate voice in whether or not an organ is “transplanted.”

Some also expressed concern that this metric could have the unintended effect of deterring aggressive organ procurement, by incentivizing procurement of only the highest quality organs.

If OPO performance is to be measured, some argued, the discretion of another transplant partner should not be considered.

In addition, many in the organ donation and transplant community were concerned that CMS’s proposed use of death certificate data to establish the initial number of eligible donors would create an inaccurate and overly broad picture of donor potential.

Death certificate data is notoriously inaccurate, and many have argued that utilization of death record data that is known to be unreliable does not advance the goal of providing a uniform calculation of available donors.

Importantly, many commenters to the Proposed Rule noted the lack of acknowledgement of the roles both donor

hospitals and transplant centers play in ensuring successful organ donation and transplantation.

Because the metrics used will be important in future analysis of areas of improvement, it is imperative that CMS implement accurate and reliable methods of measurement.

To date, whether and to what extent CMS will ultimately adopt the Proposed Rule remains to be seen, and the organ donation and transplant community continues to analyze its provisions.

### NEW SOLID ORGAN TRANSPLANT GUIDANCE

In addition to the Proposed Rule regarding OPO Performance Measurements, in June of this year, the U.S. Public Health Service (PHS), in conjunction with the CDC, introduced new solid organ transplant guidelines specifically meant to advance organ utilization and availability even further.

Data and input from both OPOs and transplant centers were pivotal in targeting a historically underutilized category of donors — those considered at an “increased risk” due to the opioid epidemic.

Of the 111 transplant centers surveyed, 80.2% of deceased-donor kidney transplant programs reported operating with at least some restrictions, and 71.8% reported complete suspension of live donor kidney transplants and these transplants.

The new guidelines encourage the safe transplantation of organs, particularly from donors who may have been at risk for HIV, hepatitis B virus (HBV) or hepatitis C virus (HCV).

Advances in testing for these infections, specifically the development of effective HIV and HBV suppression therapies and a cure for HCV, have made results highly accurate, and accordingly, have drastically reduced the risk of transmission during transplant.

These considerations, in addition to significant input from OPOs and transplant partners, drove the changes.

Previous PHS guidelines required that certain donors be classified as “increased risk donors” (IRDs). As part of the OPOs’ role in assessing donor suitability, under the old guidelines, OPOs analyzed donor risks relating to certain medical and social behavioral risks of the donor.

If donor information was unavailable for any of those categories, or if the donor’s blood sample for HIV, HBV or HCV was unusable, the donor was given the designation “IRD.”

The previous guidelines then required additional HIV testing for the donor and specific informed consent from the potential transplant recipient regarding risk of potential disease transmission.

In practice, obtaining this comprehensive level of donor information quickly, and often with limited medical record availability, is already challenging, and as the opioid epidemic has grown, so has the number of donors labeled IRD.

Not surprisingly, IRD organs were underused.

With the goal of maximizing the pool of potential donors, OPOs and transplant partners expressed concerns that the IRD designation terminology was, in some cases, unnecessarily deterring organ acceptance, and as such, organs that were suitable for transplant were going unused.

Despite data showing that IRDs were often higher quality organs from typically younger candidates, the rate of IRD acceptance was low.

Importantly, this rate remained low, even though the data showed that candidates on the organ transplant waitlist who decline IRD organs have higher rates of death than patients who accept IRD organs.

As far back as 2018 and 2019, OPOs, transplant partners and several federal agencies, including the CDC and HRSA, conferred on possible improvements to the PHS guidance.

PHS used this comprehensive input in combination with its consideration of public comments to develop the new recommendations for solid organ procurement and transplant practices, including elimination of the “IRD” label and removal of the specific informed consent requirement.

While a detailed review of these policies may seem laborious, it further underscores the importance of the dedication required to fully comprehend and offer meaningful suggestions for improvements to the system.

### COVID-19 IMPLICATIONS AND CONGRESSIONAL RESPONSE

In spite of these and other major efforts undertaken by HHS and the organ donation and transplant community to expeditiously effectuate advancements, some Congressional representatives are pressuring HHS and CMS to implement the proposed rule regarding OPO performance in its current form and are discouraging federal funding for OPOs, even in the face of a global pandemic.

The COVID-19 crisis has seriously impacted the organ donation and transplant community. While some data indicates that the initial sharp decline in transplantation may be on the rebound in certain areas,<sup>7</sup> a recent article surveying national transplant centers indicates otherwise.<sup>8</sup>

According to a national survey of solid organ transplant programs, transplant centers have decreased the number of transplants they perform due to COVID-19.

The survey results suggest that “COVID-19 is widely recognized in the United States as a major threat to the field of [solid organ transplantation].”

Of the 111 transplant centers surveyed, 80.2% of deceased-donor kidney transplant programs reported operating with at least some restrictions, and 71.8% reported complete suspension of live donor kidney transplants and these transplants.

These numbers are disheartening, despite CMS’s classification of organ transplantation as a tier 3b activity, meaning such procedures should not be delayed.

In short, although transplants are occurring, or are occurring at a significantly reduced rate, hospitals and OPOs are still tasked with identifying donors and procuring each and every potentially transplantable organ.

Moreover, due to COVID-19, both OPOs and transplant centers must conduct additional screening of donors and recipients, respectively.

Per the American Society of Transplantation guidelines,<sup>9</sup> OPOs are now screening potential donors for COVID-19 using epidemiologic and clinical screening, as well as laboratory testing.

Transplant centers are testing recipients similarly. While these policies prioritize patient safety, they also increase expenses for OPOs and transplant centers.

Other COVID-19-related factors have created significant challenges for donation and transplantation.

These and other related issues were raised by the Association of Organ Procurement Organizations (AOPO) in a June 6, 2020 letter to HHS requesting (1) a waiver of the performance metrics during the Public Health Emergency, (2) CARES Act funding, and (3) a delay implementation of the proposed rule regarding OPO performance metrics until after the public emergency.

The letter details the OPO staffs’ outstanding efforts to continue their lifesaving work, including risking their own lives to work inside hospitals during the pandemic. To date, HHS has not responded to AOPO’s letter.

In spite of the over \$2.5 trillion approved under the CARES Act, Congress still has not expressly allocated any funding to OPOs, while hospitals and transplant centers have benefitted, as they should.

Meanwhile, and as AOPO pointed out, many OPOs continue to face challenges related to significantly reduced transplant activity.

Even for those OPOs in areas less affected by COVID-19, the entire nationwide organ allocation system works together, such that a disruption in one area affects the system as a whole.

Several Congressional representatives have articulated opposing positions on this issue. Congresswoman Eleanor Holmes Norton recently wrote to HHS on behalf of the OPO in the DSA for the District of Columbia, encouraging the distribution of CARES Act funding.

The letter emphasizes the need for these funds to help address loss of income due to the reduction in donor referrals from hospital partners, the reduction in number of suitable organs for transplantation due to COVID-19, and the challenges faced by limited interactions with families of potential donors.

It also highlights the already overwhelming need of racial and ethnic minorities in particular for kidney transplants in the D.C. area and urges OPO funding from the CARES Act.

In contrast, other Congressional representatives responded in a letter to HHS and CMS on July 10, 2020.

Therein, the representatives acknowledge that OPOs have suffered in the wake of the pandemic, but assert that Congressional funds “are intended to support those health care providers who are on the frontlines of this crisis, and whose revenues have plummeted in the wake of safety measures, increased equipment costs, and the suspension of elective procedures.”

They also cite a USA Today article to support the statement that OPOs may actually see an increase in available organs due to “despair deaths” from suicide or substance use disorders and urge HHS to quickly adopt the proposed rule in its current iteration.

While the debate continues at the federal Congressional level, ultimately, it is absolutely critical to the 109,000 Americans awaiting transplants that lawmakers, the Administration, and the three organ donation and transplant partners continue to work together toward an understanding of the complex challenges facing the community.

To that end, and with the goal of increasing available organs, OPOs, hospitals and transplant centers should be given every tool necessary to overcome the COVID crisis in order to continue the momentum of the past year.

Although oversight and meaningful performance evaluations are unquestionably an essential part of this process, both should be designed and employed in a way that effects meaningful improvement, without being punitive or collaterally diminishing a patient’s access to organ transplantation. This way, the significant advances made over the past year can continue, and exponentially greater strides can be made in the years to come.

## Notes

- <sup>1</sup> <https://bit.ly/34FXiJd>
- <sup>2</sup> <https://bit.ly/3j9c7rr>
- <sup>3</sup> See, e.g., <https://bit.ly/2QnoCU5>
- <sup>4</sup> <https://bit.ly/2FPEPiJ>
- <sup>5</sup> See, e.g., <https://bit.ly/31l0SJw>; <https://bit.ly/2EyGmcd>
- <sup>6</sup> <https://bit.ly/2EkRgCQ>
- <sup>7</sup> See <https://bit.ly/3aRhFnD>
- <sup>8</sup> See <https://bit.ly/3gr4IHC>
- <sup>9</sup> <https://bit.ly/3JgRmvl>

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