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The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave S.W.
Washington, DC 2021

Dear Secretary Azar and Administrator Verma,

I greatly appreciate your focus and leadership on organ donation and recovery reform and was very happy to see the President's Executive Order on Advancing American Kidney Health¹, especially its emphasis on Organ Procurement Organization (OPO) reform. For too long, HHS has been a key part of the problem in organ recovery, so your commitment to lead the solution is a welcome change!

Your leadership presents an opportunity to more fully realize the potential of the bipartisan National Organ Transplant Act (NOTA) legislation signed into law by President Reagan. As the primary staff person who drafted the legislation for Representative Al Gore and the cosponsors, including former Senator Hatch, I wanted to assist your reform efforts by bringing to your attention the oversight strategies the authors saw as central to ensuring all OPOs deliver high-quality services to the benefit of the vulnerable patients they serve.

¹ <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>

NOTA established OPOs, the government-granted monopoly contractors which lead organ recovery, as well as the Organ Procurement and Transplantation Network (OPTN), which is tasked with providing oversight of the system. At the time, our goal in writing the legislation was to create a system that would ethically pursue every transplantable organ each time one might be available, leading to as many viable organ recoveries as possible, significantly and equitably increasing the number of successful organs transplanted to improve and save lives.

Unfortunately, the infrastructure we put in place has not yet achieved its intended goal and, historically, HHS, the Center for Medicare and Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA) have been largely responsible for this shortcoming. The system has enabled systemic OPO underperformance through an over-reliance on government contractors operating with limited oversight. While there are many reputable OPOs, allowing OPOs to operate without adequate controls has created a culture of complacency, inefficiency, and underperformance. Given this history, your Administration's recent and forceful focus on the issue is welcome and gives me hope that these previously intractable problems may finally be addressed.

When Congress passed NOTA, we believed that by establishing OPOs as cost-reimbursed we would ensure that financial considerations would not cause a disincentive for organ recovery. But in return for cost-reimbursement we expected careful oversight. Specifically, we called for OPOs to operate as nonprofit entities with "accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization".²

Vigorous HHS oversight is essential to a successful organ recovery system. Cost-reimbursement ensures the recovery network attempts to recover more organs, saving more lives, improving the quality of lives, and lowering dialysis-related costs. But it is subject to abuse, and as authors of NOTA we knew it could lead to undesirable practices, such as high salaries and excessive expenses, which have been documented

² <https://history.nih.gov/research/downloads/pl98-507.pdf>

at some OPOs.³ However, after weighing the benefits and risks, we kept cost-reimbursement but mandated active HHS oversight because it seemed like the right policy for patients and their families.

Cost-reimbursement, however, has not been enough to ensure OPO effectiveness. Research supported by Arnold Ventures indicates that variability in OPO performance leads to as many as 28,000 organs for transplant not being recovered every year.⁴ In a June 11 *New York Times* op-ed, an OPO whistleblower admitted to the OPO practice of “reporting false numbers to make it appear we were doing better than we were” to mislead CMS, and characterized the OPO industry as being plagued by a “lack of oversight and a culture of dishonesty”.⁵ Clearly, this is not the system as NOTA’s authors intended or the nation needs.

Additionally, the OPTN — the contract which has only ever been held by the United Network for Organ Sharing (UNOS) — has too often failed to provide the necessary oversight over OPOs. UNOS has been characterized by the *Los Angeles Times* as a “reluctant enforcer”.⁶ We established the OPTN as a membership organization, run mostly by transplant professionals, stakeholders, and affected families as a sacred trust for those most involved and impacted to join together to set the required policies for an effective system. We understood the risks of that model but counted on the thoughtful public leadership from HHS and CMS to ensure the public interest was served.

Until your recent leadership, HHS, CMS, and HRSA have not provided the expected oversight. The result has been ineffective organ donation oversight, with jurisdiction splintered across various bodies. Far from enabling more oversight, this dynamic has allowed federal oversight to slip through the cracks, as no one agency has truly felt both responsible for and empowered to clean up the clear abuses and chronic underperformance of the OPO industry.

³ <https://archive.triblive.com/local/pittsburgh-allegheeny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>

⁴ <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>

⁵ <https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html>

⁶ <https://www.latimes.com/archives/la-xpm-2006-oct-22-me-transplant22-story.html>

When we passed NOTA, we had hoped that organ donation responsibilities would be consolidated within the Office of the Secretary. We were disappointed by the decision to place the Division of Transplantation within HRSA which, given its many and varied mandates, has seemed unable to make transplantation a priority. It is perhaps unsurprising then that OPO underperformance has persisted unaddressed.

As the legislative authors, we knew at the time of NOTA's passing in the mid-80s that OPO performance was highly variable. With the establishment of the OPTN, which was given the explicit responsibility to "collect, analyze, and publish data concerning organ donation and transplants,"⁷ as well as the Scientific Registry of Transplant Recipients (SRTR), we hoped HHS and CMS would address this variability over time by informing evidence-based practices and measures of meaningful accountability.

Disappointingly, new research suggesting that OPO performance almost four decades later still varies by as much as 100 percent across OPOs⁸ is incredibly dispiriting. To realize that no OPO has ever lost a contract, even despite this widely-acknowledged and widely-reported underperformance⁹ — shows how critical your leadership is now in reforming the system in patients' interests.

While the authors of the legislation were operating in good faith and on the best information available to us at the time, there is no question now that the OPO industry, as it has evolved, must do much more to serve the public interest. As such, reforms to install meaningful oversight and accountability for OPOs are urgently needed, specifically by fulfilling the President's Executive Order of implementing new objective OPO metrics that are "transparent, reliable, and enforceable".

Additionally, structural reforms are important to ensure that future Administrations will not fall victim to the same problems that plagued those in the past. Specifically, there

⁷ <https://history.nih.gov/research/downloads/pl98-507.pdf>

⁸ <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>

⁹ https://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html?utm_term=.e502479a1253

would be tremendous benefit to both the patients and the taxpayers in streamlining organ donation oversight responsibilities within HHS, ideally in a new, dedicated office that can deliver the ambitious goals of the President's Executive Order.

As you move forward on these reforms, please let me know if I can be of service, as I would be glad to share my perspective of what was — and can be again — a bipartisan effort to help some of our most vulnerable citizens. Thank you for all you are doing to help these patients and their families.

Sincerely,



Jerold Mande
Professor of the Practice
Senior Fellow, Tisch College of Civic Life

cc: Senators Alexander, Grassley, Murray, and Wyden
Representatives Brady, Neal, Pallone, and Walden