

April 17, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Administrator Verma:

We welcome Secretary Alex Azar's recent remarks at the National Kidney Foundation's Kidney Patient Summit on how the Administration is "going to look at how we can deliver more organs for transplants." We agree with Secretary Azar that kidney disease is a huge burden to both patients and the Medicare program.

This is why we are writing to you about an opportunity to help the more than 100,000 Americans waiting for kidney transplants as well as the nearly 20,000 Americans waiting for other life-saving organs. By providing clear metrics and accountability for organ procurement organizations (OPOs), we can deliver more life-saving organs to patients.

There are 58 OPOs in the United States, each responsible for coordinating the donation process between donor hospitals and organ recipients in its own designated service area. Positioned between donor hospitals and transplant centers, an OPO's underperformance can be a limiting factor for all other stakeholders involved in the organ transplant process.

OPOs are evaluated by the Centers for Medicare and Medicaid Services (CMS) every four years and, despite serious issues of underperformance, no OPO has been decertified in the last twenty years.¹ The recent decision by CMS to recertify the New York City Organ Procurement Organization, LiveOnNY, despite persistent underperformance for nearly a decade, underscores the problem.

According to a recent *Washington Post* report, "the Centers for Medicare and Medicaid Services, which is responsible for oversight of the nation's OPOs, said it decided to keep LiveOnNY open to "lower risk" of disruptions to "patients waiting for organs" while it works with the organization to improve performance."² This decision comes after CMS had announced in June 2018 that they would not recertify the OPO for continued poor performance.

The New York City OPO, then-known as the New York Organ Donor Network, was first faced with decertification by CMS in 2014 for failing to meet performance requirements. Its organization's leadership acknowledged in a letter to the Office of Management and

¹ Bernstein, Lenny, and Kimberly Kindy. "New York Organ Collection Agency, Nation's Second-Largest, Threatened with Closure." *The Washington Post*, 11 July 2018, www.washingtonpost.com/national/health-science/new-york-organ-collection-agency-nations-second-largest-threatened-with-closure/2018/07/11/09c52824-847b-11e8-8f6c-46cb43e3f306_story.html?utm_term=.4a0799e67a9d.

² Kindy, Kimberly, and Lenny Bernstein. "Despite Low Performance, Organ Collection Group Gets New Federal Contract." *The Washington Post*, 4 Feb. 2019, 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=.467363d1aede.

Budget (OMB) that “the data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited,” noting that “clearly, this type of ‘evidence’ fails to meet any reasonable definition of ‘empirical.’”³ Furthermore, the OPO trade association, the Association of Organ Procurement Organizations, in defense of the New York Organ Donor Network, wrote to OMB that the “accuracy and consistency of [OPO] data cannot be assured.”⁴

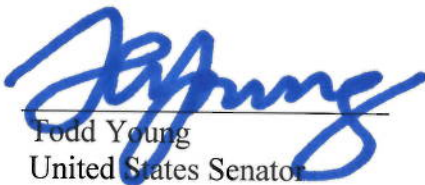
The New York Organ Donor Network was subsequently recertified by CMS under a performance improvement plan and renamed as LiveOnNY. However, in the years since, their performance hasn’t changed. According to the *New York Times*, the share of families approached by LiveOnNY who consented to become donors fell between 2014 to 2017, from 50 percent to 41 percent.⁵

We believe CMS is currently well positioned to push forward needed changes to how OPO’s are regulated and evaluated – something that will help deliver on the Secretary’s call to help “deliver more organs for transplant.” Such an effort would also contribute to the CMS Meaningful Measures Initiative, launched under your leadership, to focus on high-impact measure areas that safeguard public health and movement towards outcomes-based standards.

Consistent with these goals, we urge CMS to replace the metrics by which OPOs are evaluated to meet the criteria of being objective and verifiable, so that there can be meaningful transparency, evaluation, and accountability for OPOs across the country.

Thank you for your attention to this matter, and we look forward to working with you on this important issue.

Sincerely,



Todd Young
United States Senator

³New York Organ Donor Network. *Unaddressed Implications of the Proposed Changes to the Conditions for Coverage for Organ Procurement Organizations (HHS/CMS Rule 0938-AR54)*.

https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.

⁴ Ibid.

⁵ Alcorn, Ted. “New York Has World-Class Hospitals. Why Is It So Bad for People in Need of Transplants?” *The New York Times*, 11 July 2018, www.nytimes.com/2018/07/11/nyregion/organ-donation-is-desperate-in-new-york.html.