



Comments of the Regulatory Action Center

Re: Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization

Docket ID: CMS-2019-0187-0001

February 21, 2020

The Regulatory Action Center at FreedomWorks Foundation is dedicated to educating Americans about the impact of government regulations on economic prosperity and individual liberty. FreedomWorks Foundation is committed to lowering the barrier between millions of FreedomWorks citizen activists and the rule-making process of government bureaus to which they are entitled to contribute.

On behalf of over 5.7 million activists nationwide, FreedomWorks Foundation appreciates the opportunity to offer these comments regarding the notice and request for comments on the Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization (CMS-2019-0187-0001). This notice seeks comment on the proposed changes to Organ Procurement Organization (OPO) outcome measures in an effort to increase transparency, transition to objective measures, and incentivize OPOs to adopt best practices to optimize organ donation and transplantation.

As we noted in our comment on the previous proposal¹ promulgated by the Centers for Medicare and Medicaid Services (CMS), every day, in America, 33 people die waiting for a transplant. As many as 8,000 people every year die while sitting on a waitlist. As of January 2019, 113,000 hard working American citizens have their names on the national transplant waiting list - 2,000 of those names are children's. Every ten minutes, a new name is added to that list.²

Yet, while so many Americans sit on waitlists, hoping that one day they might receive a life saving transplant, many OPOs have seemed unconcerned with their abysmal donation rates. While CMS requires OPOs to recover approximately 70 percent of available organs to be

¹ Medicare Program: Proposed Revisions of Organ Procurement Organizations Conditions of Coverage, 84 Fed. Reg. 39398 (August 9, 2019) (to be codified in 42 CFR Parts 405, 410, 412, 416, 419, and 486). <https://www.regulations.gov/document?D=CMS-2019-0109-0002>

² "U.S. Government Information on Organ Donation and Transplantation: Organ Donation Statistics." *Health Resources & Services Administration*. Accessed on September 18, 2019. <https://www.organdonor.gov/statistics-stories/statistics.html>



recertified, research has shown that the bottom tier of OPOs only recovers around 30 to 40 percent of available organs.³ In spite of blatant dereliction of duty, no OPO has ever been decertified. The primary reason for this inexcusable fact is that the current regulatory structure surrounding organ procurement has been rife with abuse and mismanagement. For this reason, FreedomWorks Foundation supports the Trump administration's continued emphasis on reforming this regulatory framework to increase oversight and efficiency.

The best way to think about OPOs economically is as the bottleneck in the supply chain for organs in America. If the OPO is being mismanaged, then the entire system of organ transplantation grinds to a halt. OPOs maintain geographic monopolies on organ procurement within their respective "donation service area" (DSA), meaning no competition exists to force OPOs to function efficiently. As such, many have fallen well below the standards set by CMS, but remain certified due to a myriad of unfounded fears and red tape.

CMS is not wholly to blame for the current condition of underperforming OPOs. One of the biggest impediments to improving performance has been the reliance on self-reported metrics coupled with a major lack of independent oversight. This fundamental issue has been recognized for decades. As highlighted by the 1999 Institute of Medicine Committee on Organ Procurement Policy; "A major impediment to greater accountability and improved performance on the part of OPOs is the current lack of a reliable and valid method for assessing donor potential and OPO performance."⁴

Allowing school children to determine their own grades is no way to determine their actual performance. Government agencies are no different. So, by replacing the existing outcome measures, and eliminating the self-reported "eligible deaths" performance measure, the proposed rule would bring much needed transparency and objectivity to the OPO performance metric.

Similarly, in choosing to reform the recertification process to focus on comparative analysis rather than gross numbers indicates the potential for significant progress towards approving OPOs. Currently, CMS has been stuck between a rock and a hard place after abrogating most of their oversight responsibility for OPOs. Because OPO performance metrics

³ "Reforming Organ Donation in America: Saving 25,000 Lives per Year and \$13 Billion in Taxpayer Funds over Five Years." *The Bridgespan Group*. Accessed on September 16, 2019. <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf>

⁴ Institute of Medicine Committee on Organ Procurement Policy. "Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule." *National Academies Press*. 1999. <https://www.ncbi.nlm.nih.gov/books/NBK224655/#ddd00059>



are primarily self-reported, and because CMS has been so far unwilling to decertify even the worst performing OPOs, it has become almost impossible for CMS to credibly convince underperforming OPOs to shape up. Under the new rule, CMS would regain some of its teeth, making CMS better able to punish underperforming OPOs.

There remains one tool that CMS has to deal with underperforming OPOs that is all but unmentioned in the proposed rule. Historically, the reason that so many OPOs are failing is due to bad management. Taking a page from the private sector playbook, several OPOs have found that changing executives is one of the least disruptive ways to fundamentally change the culture of an OPO from underperforming to excelling. This should be the first option that CMS takes in addressing OPO performance.

FreedomWorks Foundation applauds the Trump Administration's efforts to enhance the organ donation process and, in doing so, improve healthcare outcomes for thousands of Americans currently sitting on waitlists. This administration has made effective inroads at combating fraud, waste, and abuse by independent federal agencies, and FreedomWorks Foundation looks forward to working with CMS in the future to continue cutting red tape and rolling back those regulations that are most damaging to the healthcare of the American people.

Respectfully submitted,

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