



Comments of the Regulatory Action Center

Re: Medicare Program Revisions

Docket ID: CMS-2019-0109-0002

September 27, 2019

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 Proposed Revisions of Organ Procurement Organizations Conditions of Coverage as part of the proposed changes to the Medicare program (CMS-2019-0109-0002). This notice seeks to revise the current definition of “expected donation rate” to better reflect the proper expected donation rate for each donation service area (DSA). This notice also solicits public comment regarding potential future changes to organ procurement organization (OPO) and transplantation center regulations.

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.¹

In a hyper-partisan era, organ donation is one place in which it seems nearly everyone is in agreement. Yet, action in this area has come slowly, if at all. For this reason, FreedomWorks Foundation applauds the efforts by the Trump administration and the Department of Health and Human Services to reform our inefficient organ procurement system. Furthermore, we feel that the administration’s emphasis on reforming the OPO regulatory framework is properly directed, as the current structure has been rife with abuse and mismanagement; operating with a lack of oversight or any visage of constraint.

¹ “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>



If we choose to think of organ donation purely through an economic lens, it becomes clear that OPOs represent the middlemen, and thus the bottleneck, in the supply chain for organs in America. In accordance with federal law, OPOs are the only organizations that are licensed to evaluate and procure deceased-donor organs within their DSA. There are currently 58 OPOs in the United States, each with a monopoly over organ procurement in their designated geographic zone. Each of these organizations must be periodically recertified by the Centers for Medicare and Medicaid Services (CMS) in order to retain their certification.

In order for an OPO to be recertified, the organization has historically had demonstrate to CMS that they recover approximately 70 percent of available organs. Research conducted by The Bridgespan Group, in conjunction with researchers from the University of Pennsylvania, has shown that some OPOs are actually recovering around 30 to 40 percent of available organs.² Yet, since the program's inception, not a single OPO has ever lost a government contract. Even though some OPOs are chronically underperforming, CMS continually renews their contracts, clearly abdicating their supposed supervisory role.

Yet, CMS is not wholly to blame for this. The biggest issue with the current organ procurement framework is that OPOs are self-reporting organizations with minimal - if any - independent oversight. This glaring problem with our organ procurement system has been known for decades. As far back as 1999, the Institute of Medicine was advising that "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."³

Fortunately, that same study by The Bridgespan Group found that properly reforming the transplant procurement system has the potential to retrieve an extra 28,000 organs every year. As such, it is crucial that the Department follow through on the Trump administration's promise to revise "Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics," by passing the proposed rule.⁴ Reforming the metrics used to determine expected donation rates will serve as a basis from

² "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>

³ 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>

⁴ Exec. Order No. 13879, 84 F.R. 33817 (2019)



which to improve consistency and quality of analysis by relying more heavily on independent data rather than letting OPOs write their own report card.

The proposed rule represents a great step forward for bringing OPOs back into compliance by increasing federal oversight. Yet, the proposed rule presents us with only a single remedy to an issue that spreads across many organizations and systems. Although the proposed rule will surely provide greater incentive to increase the efficiency of organ procurement, much still needs to be addressed before organ donation advocates can rest easy.

Historically, CMS has demonstrated themselves to be unwilling to strictly enforce the standards they set, refusing to decertify underperforming OPOs. The abrogation of their corrective role has left CMS between a rock and a hard place where effective oversight is difficult. Since OPOs are aware of the Catch-22, it can be even more difficult to secure compliance since the OPOs know that threats of decertification are all but empty. Fortunately, CMS has another tool at its disposal to intervene when OPOs underperform; they simply need to wield it properly.

Empirically, the single best action that can be taken to induce underperforming OPOs to improve their record has been to replace the CEO. Ultimately, the reason that so many of these organizations are underperforming is because they are being mismanaged. Taking advice from the private sector, several OPOs have recently found that changing executives is one of the least disruptive ways to reorganize and improve. When an OPO is habitually underperforming, replacing management should be a top priority and CMS should consider reforming existing practices to streamline the ability of the Department to monitor and control the management of these organizations.

FreedomWorks Foundation is proud to join like-minded individuals and groups in supporting the administration's efforts to reform our inefficient organ procurement system. Although we would like to see future changes to the existing regulatory framework surrounding OPOs, the Trump administration's move to revise the current definition of "expected donation rate" is laudable but overdue. FreedomWorks Foundation looks forward to working with the Department in the future to continue cutting red tape and rolling back those regulations that are most damaging to the American people.

Respectfully submitted,



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