

# Congress of the United States

Washington, DC 20515

October 30, 2020

The Honorable Alex M. Azar  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: *CMS-3380-P, CMS, Organ Procurement Organizations Conditions for Coverage*

Dear Secretary Azar,

We write to present our recommendations to the Department in response to the proposed rule by the Centers for Medicare and Medicaid Services (CMS) concerning Organ Procurement Organizations (OPOs). Like you, we want to ensure the fairest, most effective, and most efficient organ donation and transplant system possible. However, CMS's proposed rule falls short in a number of ways and demands further refinement.

As you may know, on February 19, 2020, New England's 14 transplant centers as well as the regional OPO, New England Donor Services (NEDS), submitted a joint comment letter expressing their shared concerns about the CMS's proposed rule change. We share the view of these experts that the proposed rule would likely be detrimental to America's donation and transplant system, which has among the highest donation rates in the world. Indeed, in New England, organ donation increased 30 percent and transplants increased 47 percent between 2015 and 2019. For those in need of an organ, it would be disastrous if this progress was halted or reversed by a faulty rule.

With that in mind, we wish to underscore a number of the comments submitted earlier by NEDS and our region's transplant centers. Specifically, we ask the following of HHS:

1. ***Establish a performance-based threshold for the donation and transplantation rate metrics based upon a methodology that is statistically sound with a specified, ambitious but achievable reference point.*** The proposed rule's establishment of a standard based upon the top 25 percent of OPOs could lead to the unjustified decertification of many other high-performing OPOs, destabilizing the system and potentially putting patients' lives at risk. The proposed rule would be improved by establishing a performance threshold that would move lower performing OPOs up to a reference point – perhaps within a standard deviation of the mean – that would drive all OPO performance to greater achievement.
2. ***For donation rates metrics, use inpatient ventilated deaths as the data set.*** The proposed rule would rely upon death certificate databases as the population set for determining potential organ donors. However, experts have shown these databases to have error rates of between 30-60%. The regulation should be revised to support the use of highly-accurate, independently reported patient-level data to assure that the final OPO measure reflects actual performance and is not distorted by differences in how death certificates are recorded. This could be done by the transmission of such patient-level data from donor hospitals directly to CMS, HRSA or another responsible, legally authorized entity.

3. **For transplant rate metrics, retain the Observed to Expected Yield measure.** At the outset, it is important to acknowledge the fact that transplant programs, not OPOs, decide whether to transplant an available organ. Nevertheless, the proposed rule's organ transplantation rate "*would be measured as the number of organs procured within the [donation service area] and transplanted as a percentage of total inpatient deaths in the [donation service area].*" In essence, the proposed rule would assess an OPO's transplant success rate on the basis of decisions made by the medical experts. We do not dispute that these decisions *should* be made by the medical experts. However, it is far from clear that those decisions should be a factor in grading an OPO's performance. Rather, CMS recently adopted the scientifically-validated Observed to Expected Yield (O/E) measure, which takes into account factors that can affect the likely success or failure of organ transplantation. The O/E measure has earned wide support across the donation and transplant community as an appropriate and preferred method to accurately measure an OPO's performance with organ placement.

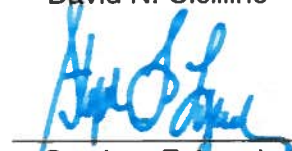
To be clear, we commend the Department for intending to drive continual improvement in organ donation and transplantation. Too many lives are dependent upon organ transplants for us to settle for anything less than the best possible system. However, in our view, the proposed rule needs serious revision. The final rule should be designed to preserve or strengthen practices that work well and reform those that do not. Therefore, we respectfully request that the Department direct CMS to rewrite the proposed rule, as described above, so that the final rule will aid rather than hinder progress.

Sincerely,

  
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