



February 11, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-2019-0187, Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization Proposed Rule

Filed electronically at <https://www.regulations.gov>

Dear Administrator Verma:

On behalf of the Cystic Fibrosis Foundation (CFF), we write in response to the CMS proposed rule titled *Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization*. We thank CMS for this opportunity to provide feedback on potential changes to measures used for Organ Procurement Organization (OPO) Conditions for Coverage.

Background on Cystic Fibrosis and the Foundation

Cystic fibrosis (CF) is a rare genetic disease that affects over 30,000 people in the United States. In people with CF, a defective gene causes a thick buildup of mucus in the lungs, pancreas and other organs. In the lungs, the mucus obstructs the airways and traps bacteria leading to infections, extensive lung damage and eventually, respiratory failure. Over 250 people with CF received transplants in 2017, the majority of which were lung transplants. However, some people with CF also may require liver or kidney transplants due to the disease.

In order to address the needs of people with CF living with advanced lung disease, as well as those considering transplant, the CF Foundation launched the Lung Transplant Initiative in 2016. Through this initiative, the Foundation is working to improve and standardize the care received by people with CF for whom transplant is an option and to find solutions to barriers that may adversely impact a person with CF's chance of receiving a donor organ.

Considerations on Efforts to Improve Donor Organ Availability

We applaud CMS for its efforts to improve the collection and use of available organs through revisions to OPO performance measures. The existing measures have long been criticized as being highly subjective due to reliance on self-reporting as well as the self-defined nature of terminology used in these measures. More objective methods for determining OPO performance are greatly needed to allow for more accurate comparisons across OPOs and to ultimately spur increased numbers of organs available for transplant and improvements in the transplant system.

We believe that this rule, which supports more objective measures and creates more opportunities for intervention for OPOs that are underperforming, moves the national transplant system in the right direction. As CMS proceeds with revisions to how OPO performance is measured, we ask that you keep in mind what matters most: the people on the waitlist. Patients awaiting transplants deserve a national transplant system that aspires to reduce waitlist mortality to zero, transplants the most medically urgent, minimizes the risk of post-transplant complications, and does so in a resource efficient manner.

Harmonizing OPO and Transplant Center Outcomes

We want to draw attention to the misalignment of outcome measures between OPOs and transplant centers. There is inherently some tension between how OPOs and transplant centers are evaluated. Existing outcome measures for OPOs tend to incentivize the use of as many organs as possible. In contrast, outcome measures for transplant centers drive centers to use organs that ensure survival outcomes are as good as possible. Transplant centers are therefore incentivized to transplant less-risky patients, to avoid less desirable organs, and to be more selective with donor organ offers for their patients. These practices may result in higher donor organ discard rates, and ultimately fewer transplants. We ask CMS to be cognizant of how these revised OPO measures may work with or against existing expectations for transplant centers, and that CMS consider how best to harmonize requirements between both entities.

Comparing Performance Between OPOs and Incentivizing Improvement

We support the proposal to compare OPOs to the top 25% of performers for each new metric. We believe the new standard must be bold to drive much needed improvements at lower performing OPOs. Establishing meaningful comparative performance standards like those included in CMS's proposal will allow for better identification of chronic underperformers and create opportunities to address issues tied to low performance.

While it is crucial that these metrics be used to identify and address issues impacting the lowest performers, efforts should also be taken to create opportunities to encourage mid and top-tier performers to reach excellence and continuously improve. Better performance at all levels is needed to ensure all transplant patients benefit from these changes. CMS should consider ways to encourage all OPOs, and not just low-performing organizations, to further invest in continuing improvement efforts and ensure adequate resources are made available to make these efforts successful.

Revised metrics are only a starting place for addressing challenges impacting performance at any given OPO. Quality improvement efforts will be key in making sustainable changes at OPOs a reality. It is therefore critical that quality improvement programs be adequately resourced to help OPOs identify and address challenges that impact overall performance. Existing quality improvement programs at OPOs may not be equipped to get the right expertise and capacity to OPOs to foster the needed changes.

The CF Foundation has firsthand experience in what it takes to make a quality improvement program successful. We support a number of quality improvement initiatives, including efforts to improve the CF care center model and care transition between CF care centers and lung transplant centers for those requiring transplant. We have seen great improvement in the care patients with CF have received over time as a result of our Learning and Leadership Collaboratives using the Microsystems approach.

We find that QI programs are most successful when programs are exposed to external expertise and are equipped with the right resources to implement the requisite reforms. CMS should consider further whether existing transplant quality assurance and performance improvement (QAPI) programs are set up to get the right expertise, knowledge, and resources to OPOs in need of improvement under this proposal.

Making Decertification More Feasible

Under the current system, the consequences of decertification are too severe to make it a meaningful solution for poor OPO performance. Consistent underperformers are able to continue operations without creating meaningful improvements in their programs because of this. We encourage HHS to make decertification a more feasible process to spur much-needed changes at OPOs where underperformance is an issue, and to replace consistent underperformers when necessary. For example, CMS could require a poorly performing OPO to administratively align with a higher performing OPO to create oversight and encourage uptake of best practices.

Incentivizing Transplant Research

We are concerned by the proposed change to exclude organs collected for research purposes from the count of procured organs in these new measures. Research is a critical method for improving outcomes, and we should aim for a system that encourages organs procured for research in balance with organs procured for transplant. If the number of organs collected for research is not measured, we expect that OPOs will fail to collect organs for such uses. We ask CMS to consider ways to encourage OPOs to collect organs for research, such as a third performance metric.

Concerns on Disincentivizing Imperfect Organ Collection

OPOs are currently incentivized to identify as many donors as possible, including donors who may be able to provide less-than-perfect organs for transplant. However, the revised metrics proposed in this rule discourage discards of any collected organs. Given that imperfect organs might be more likely to be discarded, these revised measures may inadvertently disincentivize

collection of imperfect organs for transplant. In addressing the national donor organ shortage, it is critical that we incentivize OPOs to collect all organs that have the potential to be transplanted. CMS should consider whether these metrics appropriately balance the need to collect all potentially transplantable organs, including imperfect organs, with the need to decrease inappropriately discarded organs.

Once again, we thank CMS for this opportunity to provide feedback on OPO outcome measures. We are happy to serve as a resource and look forward to working alongside CMS in the future on this issue.

Sincerely,

Albert Faro, M.D.



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