



September 27, 2019

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

RE: CMS-1717-P, CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System 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 *CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule*. We thank CMS for this opportunity to provide feedback on potential changes to measures used for Organ Procurement Organization (OPO) Conditions for Coverage and transplant center Conditions of Participation.

**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 for OPO and Transplant Outcome Measures**

We are supportive of CMS's efforts to explore improved standards for the US organ transplant system. As CMS proceeds with revisions to existing transplant outcome measures, 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.

Developing Objective Outcome Measures for OPOs

We are pleased that CMS is considering revised outcome measures that aim to standardize reporting across OPOs and transplant centers. Reporting measures for OPOs that leave room for interpretation by individual organizations can make it challenging to obtain an honest assessment of OPO performance. It is critical that any new measures used to assess OPO performance are objective and standardized across organizations so that peer comparisons on performance are possible. Metrics that improve accountability and create opportunities for intervention are necessary for improving the performance of the US transplant system as a whole.

Harmonizing OPO and Transplant Center Outcomes

We want to draw attention to the misalignment of outcome measures between OPOs and transplant centers. Currently, 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 one-year 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. CMS should consider how OPOs and transplant centers can be better aligned on the respective outcome measures to improve both organ use and transplant outcomes that are meaningful to patients.

Revising the One-Year Survival Benefit Measure

CMS should also consider whether transplant center outcomes could benefit from revised measures that reflect the frequency of successful transplants in balance with existing one-year outcome measures. One-year survival rate alone does not accurately reflect how beneficial a transplant is for any given recipient. To better reflect transplant outcomes, we suggest pursuing additional measures, including three- or five-year outcomes, to improve evaluations for transplant success and benefit. Additionally, CMS should consider how data sources like Patient Reported Outcomes (PROs) or hospitalizations can be used to develop a more robust understanding of meaningful measures of patient benefit.

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Once again, we thank CMS for this opportunity to provide feedback on OPO and transplant center 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.



Senior Director, Clinical Affairs  
Cystic Fibrosis Foundation

Mary Dwight



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Cystic Fibrosis Foundation