



February 1, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities**

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

Dear Administrator Brooks-LaSure:

Leadership at the Cystic Fibrosis Foundation (CFF) and academic partners are writing in response to the Centers of Medicare and Medicaid Services (CMS) request for information *Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End Stage Renal Disease*. We thank CMS for this opportunity to provide feedback on potential changes and improvements used for Transplant Programs and Organ Procurement Organizations (OPO).

**Background on Cystic Fibrosis and the CF Foundation**

Cystic fibrosis (CF) is a rare genetic disease that affects approximately 35,000 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. Historically, over 300 individuals with CF have received an organ transplant each year with CF accounting for ~10-15% of the annual lung transplant volume. Although lung transplants have declined dramatically since 2019 due to an impactful new therapy, people with CF will continue to require transplantation each year. Some people with CF also develop liver or kidney failure requiring transplantation of those organs.

In order to address the needs of people with CF living with advanced lung disease, including those considering transplant, the CF Foundation launched the Lung Transplant Initiative in 2016. Through this initiative, the Foundation is working to improve and standardize care for people with CF for whom transplant is an option and address barriers to lung transplantation. Based on the mission of our organization and the needs of our community, we would like to offer commentary on the following components of the Request for Information.

## **Cross-Agency Coordination and Communication**

We would like to draw attention to the siloed oversight and misalignment of standards between the Organ Procurement and Transplantation Network (OPTN) and CMS. In July 2021,<sup>1</sup> the Health Resources and Services Administration (HRSA) published a Membership Evaluation Plan as guidance for members outlining the conduct of UNOS reviews, as well as the evaluation of member performance and compliance with OPTN standards. In this, HRSA used a statistically driven methodology that incorporated a holistic approach to evaluating programs beyond graft and survival outcomes. We believe that CMS should take a similar approach and consider other program metrics to capture quality of care delivered in its standards for OPOs and Transplant Programs.

As the Agency seeks to improve the transplant system, we ask CMS to take a step back and allow for a more holistic and innovative approach that integrates oversight to remove existing silos and establish mechanisms to ensure that CMS and OPTN policies and performance metrics are better aligned.

## **Outcome Measure Requirements and Metrics for OPOs and Transplant Programs**

There is inherently some tension between how OPOs and transplant programs are evaluated. Existing outcome measures for OPOs tend to incentivize the use of as many organs as possible. In contrast, outcome measures for transplant programs drive programs to use high quality organs in lower risk recipients to increase probability of excellent graft and patient survival. Transplant programs are therefore incentivized to transplant less-risky patients, avoid less-desirable organs, and 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 OPO measures may work with or against existing expectations for transplant programs, and that CMS consider how best to harmonize requirements between both entities.

We are not advocating an approach that might result in risk taking that produces poor outcomes for patients. Rather, we recommend an approach by which calculated risks, using a quality improvement approach that allows for learning and advancement, is adopted and promoted throughout the field of organ transplant. To implement meaningful change CMS will need to innovate with courage. For example, some patients with cystic fibrosis are chronically infected with organisms known to be associated with poorer outcomes after transplant. Rather than denying them the opportunity for a lifesaving transplant, perhaps a system could be developed by which a few, select centers with expertise in clinical care and quality improvement methodology would transplant these high-risk individuals. They would not be penalized for below average one-year outcomes and instead be given the opportunity to learn and improve the approach to these high-risk patients. Indeed, the OPTN has already piloted this type of approach with the COIIN project (<https://unos.org/news/improvement/what-we-learned-coiin/>) intended to leverage transplant center and OPO partnerships to increase the use of higher risk kidneys) As importantly, we recommend consideration of intermediate and long-term outcomes (3- and 5- year survival) rather than a focus on one year survival since some individuals with lower than average one year survival have comparable 3- and 5- year survival to average risk lung candidates.

Furthermore, current OPO metrics discourage discards of any procured organs. Given that suboptimal organs might be more likely to be discarded, these measures may inadvertently disincentivize procurement of suboptimal organs for transplant. In addressing the national donor organ shortage, it is

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<sup>1</sup> [https://optn.transplant.hrsa.gov/media/1202/evaluation\\_plan.pdf](https://optn.transplant.hrsa.gov/media/1202/evaluation_plan.pdf)

critical that we incentivize OPOs to procure all organs that have potential to be transplanted, particularly given the availability of organ rehabilitation devices such as *ex vivo* lung perfusion to improve allograft function. CMS should consider whether these metrics appropriately reflect the potential to rehabilitate and transplant some suboptimal organs through aggressive procurement practices coupled with organ rehabilitation devices. Perhaps metrics should incentivize procurement itself, rather than disincentivizing discards following procurement if we hope to increase organ utilization through all means possible.

Finally, it is important to recognize that current metrics and oversight strategies provide limited incentives for transplant centers and OPOs to form Quality Assessment and Performance Improvement (QAPI) driven partnerships to improve donor organ utilization and increase transplant rates while maintaining acceptable survival and quality of life.

### **Equity in Organ Transplantation and Organ Donation**

Cystic fibrosis affects people of all racial and ethnic backgrounds. However, for many years there has not been adequate representation of people of color shared in the stories and descriptions of the disease by medical and public health entities, including the CF Foundation. Improving the representation of people of color within the CF community and addressing health disparities that exist within these groups – including organ transplantation and organ donation – is critical to the Foundation’s mission of serving all people with CF.

We share and support CMS’ efforts to address social determinants of health and recognize the critical impact of social factors on health outcomes, organ donation rates, and access to organ transplantation. There are several levers CMS can use to help address barriers to transplant evaluation and listing as well as prioritization on the transplant list.

Language barriers can significantly reduce the rates of underrepresented minorities enrolled in organ transplantation and organ donation programs. To encourage access for underrepresented minorities, providing information in a range of commonly spoken languages, in a culturally sensitive manner, may support diversity by ensuring availability of understandable information on transplant for all individuals. It could be beneficial to engage focus groups of underrepresented minorities to provide feedback on sample language, accurate translations and cultural considerations.

Moreover, the performance measures under the current OPO structure have been criticized as being highly subjective due to reliance on self-reporting as well as self-defined nature of terminology used in these measures. More objective methods for determining OPO performance are greatly needed to allow for more accurate comparison across OPOs and to ultimately spur increased organ availability and to remove barriers to accessing the transplant system. As CMS continues to evaluate more equitable distribution of organs and how that relates to OPO performance measures, we ask you to keep in mind what matters most: the people on the waitlist. Patients awaiting transplant deserve a cohesive transplant system aligned to reduce waitlist mortality, transplant the most medically urgent, optimize allograft function and availability, and maximize post-transplant outcomes in the most resource efficient manner possible.

Finally, with the exception of kidney transplantation where end stage renal failure is overseen by Medicare, one of the key gaps in achieving equity in organ transplantation is the lack of knowledge about patients who are never referred for transplant who face additional challenges to accessing

transplant care. To date, the OPTN and CMS transplant metrics focus on equity for patients who have been evaluated and listed. As CMS reimagines the transplant system, developing ways to monitor and improve equity in referral for transplant will be important as well. For instance, an analysis of data in the CF patient registry found that patients with greater socioeconomic barriers (which includes data on race/ethnicity, marital status, education level, employment, insurance type, zip code, and distance to transplant centers) accessed transplant about half as often as those with fewer barriers – irrespective of disease severity.<sup>2</sup> This underscores the need to take a broad approach when considering how to improve equity and outcomes in organ transplantation and include the experience of patients who may never be evaluated or referred for transplant.

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We thank CMS for this opportunity to provide feedback on this RFI regarding *Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End Stage Renal Disease*. 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.  
Vice President, Clinical Affairs  
Cystic Fibrosis Foundation



Mary Dwight  
Chief Policy and Advocacy Officer  
Cystic Fibrosis Foundation

### **CF Lung Transplant Consortium Members**

#### **Luke Benvenuto, MD**

Assistant Professor of Medicine  
Center for Advanced Lung Disease and Transplantation  
Columbia University Medical Center

#### **Jason Christie, MD, MS**

Chief, Pulmonary, Allergy and Critical Care Division  
Penn Medicine

#### **Courtney Frankel, PT, MS**

Research Program Leader  
Duke University Medical Center

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<sup>2</sup> Lehr, C.J., et al. (2020) Impact of Socioeconomic Position on Access to the U.S. Lung Transplant Waiting List in a Matched Cystic Fibrosis Cohort. *Annals of the American Thoracic Society*, 17(11), 1384–1392.

<https://www.atsjournals.org/doi/pdf/10.1513/AnnalsATS.202001-0300C>

**Ramsey Hachem, MD**

Professor of Medicine, Lung Transplant Program Medical Director  
Washington University School of Medicine

**Matthew Hartwig, MD, MHS**

Associate Professor of Surgery  
Duke University Health System

**Steven Hays, MD**

Medical Director, Lung Transplant Program  
University of California San Francisco

**Marshall Hertz, MD**

Professor of Medicine, Division of Pulmonary, Allergy, Critical Care and Sleep Medicine  
University of Minnesota

**Christian Merlo, MD, MPH**

Associate Professor of Medicine and Epidemiology, Division of Pulmonary and Critical Care  
Johns Hopkins University School of Medicine

**Jagadish Patil, MD**

Assistant Professor of Medicine, Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine  
University of Minnesota

**Joe Pilewski, MD**

Associate Chief, Division of Pulmonary, Allergy & Critical Care Medicine  
University of Pittsburgh Medical Center

**Kathleen Ramos, MD, MSc**

Assistant Professor of Pulmonary, Critical Care, and Sleep Medicine  
University of Washington, Seattle

**Laurie Snyder, MD, MHS**

Associate Professor of Medicine, Pulmonary Allergy & Critical Care Medicine  
Duke University School of Medicine

**Stuart Sweet, MD, PhD**

Professor of Pediatrics, Division of Allergy, Immunology and Pulmonary Medicine  
Medical Director, Pediatric Lung Transplant Program  
Washington University School of Medicine in St. Louis

**Fanny Vlahos**

Cystic Fibrosis Lung Transplant Consortium Patient Representative

**Stephen Weight, MD**

Associate Professor of Medicine, Pulmonary and Critical Care  
University of California Los Angeles Medical Center