

September 29, 2023

Secretary Xavier Becerra
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

The undersigned transplant leadership of all 14 Transplant Centers in Region 1 of the OPTN write to express our collective concern on a matter of great importance to the transplant patients we serve.

Baystate Medical Center	Lahey Hospital and Medical Center
Beth Israel Deaconess Medical Center	Maine Medical Center
Boston Children's Hospital	Massachusetts General Hospital
Boston Medical Center	Rhode Island Hospital
Brigham and Women's Hospital	Tufts Medical Center
Dartmouth Medical Center	UMass Memorial Health Center
Hartford Hospital	Yale New Haven Hospital

Federal regulatory action planned for organ procurement organizations (OPOs) under the current CMS performance metrics, as they currently stand, is on course to cause disorder within the nation's transplant system through the anticipated forced closure of many of the nation's OPOs using a metric that is significantly flawed.

The CMS performance metric methodology for OPOs is faulty in several key ways including:

- A comparative performance tier system that uses the median as a cut-off which statistically will likely result in a large number of OPOs assigned to the bottom tier regardless of significant increases in donation and transplant.
- A methodology for calculating the performance tiers that is statistically biased against OPOs serving large populations.
- A lack of risk adjustment for any of the most commonly adjusted risk factors in health care metrics.
- A calculation of donor potential based on death certificates which do not include ventilator status (ventilation being a clinical requirement for potential organ donation) or comprehensive co-morbidities rather than available patient-level medical record information.
- Holding OPOs responsible for the non-utilization of organs that OPOs obtained authorization for, recovered and offered for transplant but are rejected by transplant centers for their patients.
- The inclusion of "pancreas for research" into the metrics which skews both the donation rate and the transplant rate despite having no impact on patients actually being transplanted.

We specifically warned of these faults in our Region 1 joint public comments on the performance regulations submitted to CMS on February 19, 2020¹ and March 3, 2021².

Of greatest concern is that the regulations use a comparative performance threshold set unreasonably high at the top 25th percentile with automatic decertification if an OPO performs under the median *for either*

¹ <https://www.regulations.gov/comment/CMS-2019-0187-0324>

² <https://www.regulations.gov/comment/CMS-2019-0187-0963>

measure. This results in arbitrarily defining nearly half of the OPOs as “failing” regardless of significant year-over-year growth in donation rates. In fact, the OPO Performance Report released by CMS on April 27, 2023 (using data from 2021) demonstrates the illogic of this performance standard as evidenced by the report’s conclusion that 42% of the nation’s OPOs were designated as “failing” and would be subject to automatic decertification if those 12 months were the assessment year.³ CMS reports this high “failure” rate (which is then echoed in the media to the detriment of public trust) despite the fact that the United States ranked number one in the world in donation rate that same data year (2021)⁴, a year in which 45 of 57 OPOs set all-time records for deceased donors, marking the 11th consecutive year of record deceased organ donors in the U.S.⁵

Most importantly, the OPO median donation rate under CMS’ own calculation has increased every year for the past 4 years – see chart below. This data clearly demonstrates that although OPOs are collectively raising the bar on organ donation performance, CMS is not only ignoring this progress but instead is set to punish - rather than encourage - this performance improvement with a regulatory scheme that does not take such improvement into account.

Nationwide – all OPOs		
Data Year	CMS Donation Rate	
	Top 25% Cutoff (Tier 1)	Median Cutoff (Tier 2)
2018	11.37	9.72
2019	11.78	10.12
2020	12.96	11.10
2021	13.06	11.24

We reiterate our concern - first raised over three years ago⁶ - that a performance metric which mathematically is likely to result in automatic decertification of a large number of OPOs by the federal government despite world-leading and record setting performance is contrary to the best interests of patients and antithetical to strengthening our current system of donation and transplant. Our concern remains the same now as then, CMS has set thresholds for possible decertification (automatic or through forced competition) for any OPO not in the top 25th% of performance for both donation and transplantation (a rate, we note, that OPOs do not have substantial control over). Further, CMS has not provided an explanation as to why, given the performance of our nation’s system, even OPOs performing above the median are subject to possible decertification through forced competition. In short, the goal posts are moved each year to ensure that nearly 50% of OPOs will likely be targeted for automatic decertification, a decertification scheme found nowhere else in the nation’s health care regulatory system. CMS should focus on OPOs that are performing in the lowest quartile of both rates. To use the median of one single rate as the line for decertification will result in continual risk of OPO upheaval. There will always be a median in any population; only statistical outliers warrant intervention.

The April 2023 report also demonstrates that the flawed metric is mathematically biased against larger volume OPOs. This mathematical flaw was first raised prior to the adoption of the performance regulations by the Scientific Registry of Transplant Recipients (SRTR) in January of 2020⁷ when they stated that the

³ <https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf>

⁴ <https://www.irodat.org/img/database/pdf/Irodat%20year%202021%20-%20Final.pdf>

⁵ <https://unos.org/news/2021-all-time-records-organ-transplants-deceased-donor-donation/>

⁶ <https://www.regulations.gov/comment/CMS-2019-0187-0324>

⁷ <https://www.srtr.org/media/1449/snyder-cms-proposed-opo-metrics-ajt-2020.pdf>

proposed tiered system of measuring performance “will be biased against OPOs with more potential donors (large OPOs), and, conversely, biased in favor of OPOs with fewer potential donors (small OPOs) ... because the variance of the donation rate (and transplant rate) statistic is inversely proportional to the sample size, that is the number of potential donors.” Indeed, as expected the April report showed a disproportionately high number of the nation’s small OPOs in the top tier and a disproportionately high number of the nation’s largest OPOs in the bottom tier; Tier 1 OPOs collectively serve only 18% of the US population even though they represent the top 25th in performance under the metric whereas Tier 2 and 3 OPOs collectively serve 82% of the population.

As transplant leadership in the service area of New England Donor Services, one of the top five largest OPOs in the country that has demonstrated the power of substantial performance improvement through consolidation of two OPOs and a 50% increase in organ donors since 2020, we strongly believe that the faulty metrics which mathematically underrepresent the high performance of our community’s OPO must be urgently reconsidered and revised before it is relied upon as a performance measurement and causes unwarranted and unproductive destruction of the system. New England Donor Services was originally founded by area transplant professionals in 1968 including Nobel Prize winner Dr. Joseph Murray, to serve the transplant programs of the region. It has become a critical and dependable collaborative partner for transplant centers and our patients and reflects the expertise that comes with 55 years of institutional experience in supporting donor families and maximizing opportunities to give the gift of life.

We recognize no regulation is “perfect,” and that accountability for OPOs is important to serving the system. However, this regulatory approach of combining mathematically flawed metrics with draconian consequences for the majority of non-profit organizations in the world’s top performing donation and transplant system seems particularly ill-advised.

In November of 2020, an op-ed by a transplant surgeon in our region predicted, “The new regulations will bring chaos. More than half of the nation’s organ procurement organizations will be kept in a constant state of uncertainty, tracking a goal post that moves continually based on the performance of others, rather than being fixed to an objective standard. This will only serve to destabilize the system and harm the very people it is supposed to serve.”⁸ Now, nearly three years later, the transplant professionals of the New England region continue to seek specific assurance as to how HHS will guarantee the uninterrupted continuation of our nation’s high performing donation system in light of the highly concerning limitations of the current regulatory structure. More specifically, we ask that you direct CMS to reconsider and revise these OPO performance metrics as soon as possible.

[signature page to follow]

cc:

Carole Johnson, HRSA Administrator
Frank Holloman Director, Division of Transplant, HRSA
Chiquita Brooks-LaSure, CMS Administrator
Dora Hughes, MD, CMS Chief Medical Officer and Director of the Center for Clinical Standards and Quality
Lisa Parker, Director, Clinical Standards Group
Adam Richards, Director, Clinical Standards Group

⁸ <https://www.statnews.com/2020/11/23/organ-donation-transplantation-new-rules-will-bring-chaos/>


Sincerely,

DocuSigned by:



62BBE4427BB743C...
Kenneth McPartland, MD
Chief of Transplant Surgery
Baystate Hospital

DocuSigned by:



F6C561AA609348F...
Jeffrey Cooper, MD
Chief of Transplant Surgery
Boston Medical Center

DocuSigned by:



C99256CE32B2470...
Heung Bae Kim, MD
Director, Pediatric Transplant Center
Boston Children's Hospital

DocuSigned by:



1733F2B8DFB842F...
Glyn Morgan, MD
Chief, Surgical Transplantation
Hartford Hospital

DocuSigned by:



8943D7D04570412...
John Vella, MD
Chief of Nephrology & Transplantation
Maine Medical Center

DocuSigned by:



541DB0F81BF74FA...
Paul Morrissey, MD
Director of Transplant
Rhode Island Hospital

DocuSigned by:



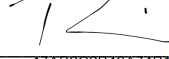
D562F137B0A740E...
Babek Movahedi, MD, PhD
Chief, Division of Organ Transplantation
UMass Memorial Medical Center

DocuSigned by:



172A5E3EF7BA42B...
Devin Eckhoff, MD
Chief of Transplant Surgery
Beth Israel Deaconess Medical Center

DocuSigned by:



47AB2C2B49A74B1...
Stefan Tullius, MD, PhD
Chief of Transplant Surgery
Brigham and Women's Hospital

DocuSigned by:



218090DF73C24B5...
Michael Daily, MD, MS
Chief, Solid Organ Transplant
Dartmouth Hitchcock Hospital

DocuSigned by:



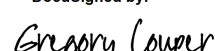
564B5C57ADA04AB...
Mohamed Akoad, MD
Chair of Transplantation
Lahey Medical Center

DocuSigned by:



B740C80E530427...
Joren Madsen, MD, DPhil
Director, MGH Transplant Center
Massachusetts General Hospital

DocuSigned by:



CB73BF22007A44F...
Gregory Couper, MD
Surgical Director
Tufts Medical Center

DocuSigned by:



AE5FA0B7EDBA49E...
Sanjay Kulkarni, MD, MHCM
Interim Division Chief, Transplantation
Yale New Haven Hospital