March 6, 2024

Xavier Becerra, Secretary
U.S. Department of Health and Human Services
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Re: Ensuring the Lives of Our Transplant Patients

Dear Secretary Becerra:

We, the undersigned, are physicians and surgeons from the nine transplant programs in Southern California, and we are writing to express our concerns with the 2020 Federal Regulation of Organ Procurement Organizations (OPOs).[1] This regulation threatens the integrity and viability of the country's organ procurement system by relying on metrics that lack scientific foundation putting our patients' lives at risk.

When the regulation was proposed in 2019, there were numerous public comments questioning the methodology by which OPOs were to be evaluated. One concern was that the measure of organ donor potential was flawed because it includes numerous cases that are absolute contraindications to organ donation and transplantation, and that these contraindications are unequal across OPO service areas. Another concern was that the rule automatically decertifies any OPO performing less than the prior year median and could decertify any below the top 25th percentile; a standard used nowhere else in healthcare. These concerns were dismissed, and the rule was implemented in the face of considerable scientific and professional opposition.

Three years' experience with the rule since publication have confirmed those concerns. First, several independent scientific publications have challenged the reliability of the rule's metrics. Most significantly the rates of contraindications have been proven to be different across OPO service areas; invalidating the use of the measure of organ donor potential in the rule.[2] Second, analysis by the HHS Scientific Registry of Transplant Recipients (SRTR) has identified statistical and demographic risk factors that should be factored into the measurement system to ensure accurate determination of OPO performance.[3] Third, two studies have determined that making certification decisions using single year data is highly unstable and an inaccurate measure of OPO performance over time.[4] These findings show conclusively that well-functioning OPOs will be decertified, an outcome that benefits no one and making it likely that any CMS attempt to decertify OPOs under the rule would not withstand appeal and legal challenge.

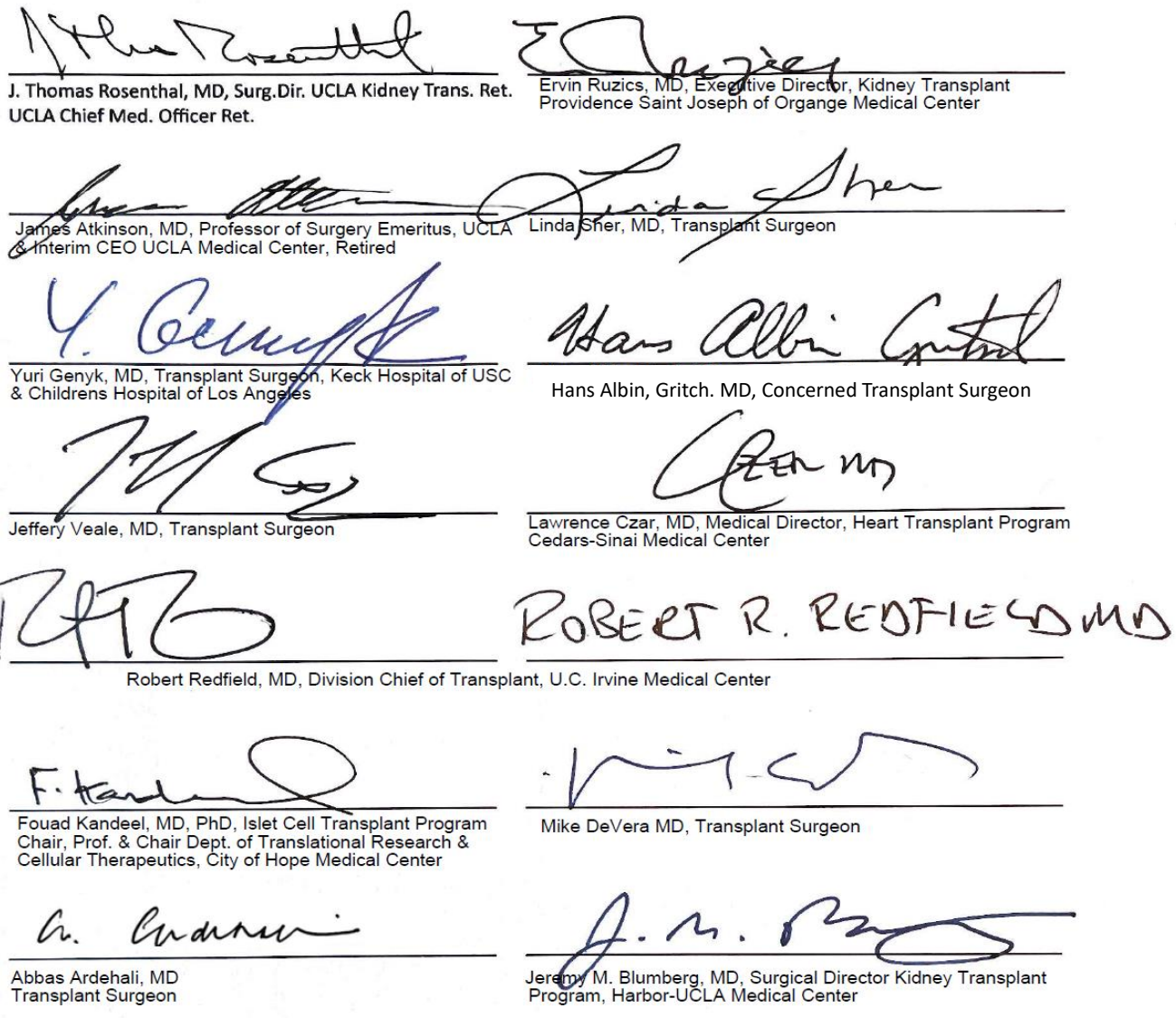
Now, despite the nearly 30% increase in donation across the country since the rule was published, based on CMS's 2023 published data of OPO rankings, as many as 74% of the country's OPOs will be subject to decertification, because of the rule's flawed design.[5] This would completely disrupt organ donation and transplantation in the United States, putting thousands of lives at risk…our patients' lives. The rule now threatens the donation and transplant system.

The leadership of the transplant centers in New England have shared their concerns with you and identified additional problems with the rule, the reliability of the metrics in the rule, and the potential to harm patients.[6] In the interest of brevity, we will not restate these additional problems.

Correcting the issues identified requires reopening the rule to allow for the proposal and assessment of more accurate OPO metrics and performance evaluation. The 2022 Report of the National Academy of Science, Engineering, and Medicine on transplantation in the United States provided a roadmap forward.[7] It

recommended the consensus-based development of a reliable and accurate donation rate to assess OPOs' performance, and more importantly, for that rate to be one of many quality measures of performance, including process measures as CMS uses in its certification of hospitals, clinics, and transplant programs. Relying on a simple and statistically unreliable metric as the sole criteria for OPO performance measurement and certification has failed CMS each time it has attempted to decertify OPOs since 1994. Now is the time to develop an effective regulatory framework for OPOs.

Organ donation is critical to the well-being of the patients we are responsible for who are waiting for life-saving organs. It is essential that OPO performance is measured accurately, that improvement is incentivized, and proven persistently poorly performing organizations are replaced. The metric in the rule, however, does not reliably identify OPO performance, disregards variation in clinical and demographic factors, and imposes an unreasonable and unworkable cutoff for decertification. The rule threatens the very patients it was intended to help. We urge you in the strongest possible terms to direct CMS to reopen the rule.



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[1] CMS 42 CFR Part 486. Federal Register/VoI.85, No.232/Wednesday, December 2, 2020.

[2] Schold J, Lopez R, Zingmond D. "Significant Discrepancies to Evaluate Organ Procurement Organization performance based on Exclusion Criteria." Am. J. Transpl. (2023); 23(6, Supplement 1), S930. Abstract # C55.

[3] Snyder JJ, Musgrove D, Zaun D, et al., The Centers for Medicare and Medicaid Services' proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients. Am J Transplant. 2020; 00:1–15.

[4] Schold J, Lopez R, Mohan S. "OPO Measured Donation is Highly Volatile Year to Year and Not a Stable Quality Indicator." Am. J. Transpl. (2023); 23(6, Supplement 1), S615. Abstract # A3.

Israni A., Snyder J. Stability of New CMS Metrics for Organ Procurement Organizations: Comparison of 2 Consecutive Years AJT, Volume 23, Issue 6, Supplement 1.

[5] U.S. Centers for Medicare and Medicaid Services. "Organ Procurement Organizations: Annual Public Aggregated Performance Report." Accessed 9/25/23.

[6] Letter to Secretary Xavier Becerra from Region 1 Transplant Centers, September 29, 2023.

[7] National Research Council 2022. Realizing the Promise of Equity in the Organ Transplantation System. Washington, DC: The National Academies Press. https://doi.org/l O. 17226/26364. https://nap.nationalacademies.org/catalog/26364/realizing-the-promise-of-equity-in-the-organ-transplantation-system