



February 21, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-3380-P
P.O. Box 8010
Baltimore, MD 21244-8016

RE: CMS-3380-P: Medicare and Medicaid Programs; Organ Procurement Organizations
Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ
Procurement Organization

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. Part of RPA's mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA strongly supports the objectives of the Administration's Advancing American Kidney Health Initiative, including the aim of increasing the supply of available kidneys for transplantation. Within this objective, a critically important component is the effort to reform the organ procurement process through this proposal to revise the conditions for coverage for organ procurement organizations (OPOs). We commend the Administration for pursuing these long overdue reforms.

Further, RPA has an organizational commitment to quality measurement and accountability in health care delivery. RPA has been the lead nephrology organization responsible for developing and testing physician performance measures related to kidney care. RPA served as the lead kidney organization with the American Medical Association Physician Consortium for Performance Improvement (AMA PCPI) to develop chronic kidney disease (CKD), end-stage renal disease (ESRD), and palliative care measures and remains actively involved in the PCPI Foundation. RPA also collaborated with the American Society of Diagnostic and Interventional Nephrology (ASDIN) to develop physician-level measures related to interventional nephrology. RPA measures have been used in PQRS and MIPS. RPA is the only nephrology organization with a qualified clinical data registry (QCDR) -- the RPA Kidney Quality Improvement Registry -- which demonstrates our willingness to hold nephrologists accountable for the care they provide

and manage, and we believe that the nation's organ procurement organizations should be held to similar standards of accountability and transparency.

Using Comparative Metrics for Defining OPO Success

In the proposed rule, CMS outlines its plans to use comparative donation rates and organ transplantation rates relative to the highest-performing OPOs nationally (defined as the highest performing 25 percent of OPOs) to benchmark success for other OPOs. This construct will ideally encourage the performance of all OPOs to cluster around the highest performers. We believe this is a reasonable, straightforward and expedient method for raising the bar for OPO performance nationally, and RPA supports this process as proposed.

Assessment of Transplantation Rates by Organ Type

CMS solicits comment in the proposed rule as to whether OPO outcome measures should also include an assessment of organ transplantation rates by type of organ transplanted. RPA firmly believes that such an assessment should be differentiated by type of organ transplanted. Differences in waitlist criteria and approval protocols for transplantation by organ type are of sufficient variance that not breaking out the assessment by organ type is an opportunity lost in terms of gaining insight into OPO performance.

Further, the sheer differences in volume of patients waiting for a transplant by organ type call for categorization. According to the Organ Procurement and Transplantation Network (OPTN) as of mid-February 2020, approximately 60,000 patients were waiting for kidneys, while the next largest organ type on the waiting list, livers, has a waiting list of less than 10,000 patients. RPA believes that these distinctions argue for specificity in transplant rates by organ type, and we urge CMS to take this approach in developing OPO outcome measures.

Changes in the Recertification Process

RPA supports the proposal to use calculations of confidence intervals (CIs) compared to threshold rates to allow all OPOs the opportunity to re-certify as long as their performance is not statistically significantly different from the top 25 percent. Use of hard and fast thresholds to determine success or failure of OPOs is not necessarily constructive, and does not reward those OPOs who have made a good faith effort to reach the threshold but fall slightly short, often due to circumstances beyond their control. Such an approach accounts for the real-life situations that may lead to an OPO not completely achieving the threshold, and minimizes the risk of decertification of OPOs in a manner that is not reflective of patient need. RPA believes that de-certification of an OPO should be a last resort, and the Administration should ensure that patient access will not be impacted in cases where it is necessary.

Further, RPA supports the proposal that the outcome measures assessment performed as part of an OPO's Quality Assessment and Performance Improvement (QAPI) program occur at least annually and be based on the most recent 12 months of data. Use of a four-year cycle heightens the possibility of an OPO underperforming for an extended period of time in a way that is diametrically opposed to optimal patient care, and thus use of annual review minimizes the potential for that to occur by more swiftly identifying problems at underperforming OPOs.

Accounting for Heterogeneity in Risk Tolerance Among Transplant Centers

In the context of the proposed organ transplantation rate measure, the proposed rule includes a discussion of transplant centers' acceptance practices and the impact of these protocols on the OPO's ability to achieve success on the transplantation rate measure. RPA fully concurs with the Administration's commitment to ensuring that the opportunity to place "less than perfect," but still transplantable organs should be maximized to the greatest degree possible, and that encouraging OPOs to be engaged partners in this process is appropriate and reasonable.

Given that, we urge the Administration to recognize that transplant centers of different sizes will have different degrees of risk tolerance in their programs. Large transplant centers with greater numbers of patients and thus larger denominators in the quality measurement equation will likely have a higher degree of risk tolerance. Thereby the large transplant centers may be more willing to transplant "less than perfect" kidneys because the impact of a failed transplant will not significantly affect their quality scores. Conversely, smaller transplant centers with smaller patient denominators may be more circumspect in the transplantation of "less than perfect" kidneys due to the disproportionate impact an unsuccessful transplant will have on their quality scores. To be clear, RPA agrees with and supports the Administration's commitment to reducing the organ discard rate in the U.S., but we also believe that consideration should be given to why different sized transplant centers have varying degrees of risk tolerance in transplanting "less than perfect" kidneys; therefore, provisions should be put in place to avoid unduly punitive corrective actions for smaller centers with isolated adverse outcomes.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work to revise the organ procurement process in the U.S. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in black ink, reading "Jeffrey A. Perlmutter" followed by a stylized flourish.

Jeffrey A. Perlmutter, MD
President