



*Saving and improving lives with transplantation.*

**American Society of Transplant Surgeons®**

February 20, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue S.W. Room 314G  
Washington, DC 20201

**Re: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization; file code CMS-3380-P; RIN: 0938-AU02.**

Dear Administrator Verma:

ASTS is pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposal to modify the outcomes requirements for Organ Procurement Organizations (OPOs), as set forth in the December 23, 2019 *Federal Register* (OPO Proposed Rule). ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS strongly supports CMS' efforts to increase the availability of kidney transplantation and believes that modification of the Conditions for Coverage (CfCs) for OPOs can have a significant impact on increasing the number of kidneys available for transplantation. We support the Administration's goal of doubling the number of clinically appropriate kidney transplants by 2030 and believe that increasing the availability of kidneys for transplantation is critical to achieve this important objective. We applaud CMS for its focus on this aspect of the current transplantation ecosystem and hope that these comments will assist the agency in effectively improving OPO performance while maintaining organizational stability in organ recovery efforts.

We think that a system-wide, disease-based approach to transplant system metrics is the best way to measure transplantation benefit. Unfortunately, the US ESRD healthcare ecosystem is regulated in silos: dialysis facilities, nephrologists, Transplant Centers (TCs), and OPOs each are regulated separately. It is likely that a change in one system will produce unintended consequences in another. We strongly agree that increasing the rate of kidney transplantation should benefit those with ESRD and that performance metrics change is essential to spur and assess process improvements. We also appreciate that CMS has time constraints for changes imposed by Executive Order 13879. However, system change to double the number of kidney transplants by

**President**

Lloyd E. Ratner, MD, MPH  
Columbia University

**President-Elect**

Marwan S. Abouljoud, MD, CPE, MMM  
Henry Ford Transplant Institute

**Secretary**

A. Osama Gaber, MD  
Houston Methodist Hospital

**Treasurer**

William C. Chapman, MD  
Washington University

**Immediate Past President**

Dixon B. Kaufman, MD, PhD  
University of Wisconsin

**Past President**

Jean C. Emond, MD  
Columbia University Medical Center

**Councilors-at-Large**

Talia B. Baker, MD  
Jonathan P. Fryer, MD  
Alan I. Reed, MD, MBA  
Michael J. Englesbe, MD  
Julie K. Heimbach, MD  
Debra L. Sudan, MD  
Matthew Cooper, MD  
Ryutaro Hirose, MD  
Kenneth Washburn, MD  
Georgeine Smith, MS, MHS, PA-C

**Executive Director**

Daniel D. Garrett, CAE  
daniel.garrett@asts.org

**National Office**

1401 S. Clark St.  
Suite 1120  
Arlington, VA 22202  
703-414-7870  
asts@asts.org  
ASTS.org

**American Transplant Congress**

May 30 – June 3, 2020  
Philadelphia, Pennsylvania

2030 will require performance metrics that recognize the interdependence of the various elements of ESRD/transplant care, including access to transplant care, the size and composition of the kidney waitlist, kidney availability/use and the maintenance of desired outcomes. Changes in composite transplant metrics will affect community providers and hospitals, dialysis units, TCs (plus others). Changing kidney availability and quality by modifying OPO metrics without anticipating the impact upon the other elements of the ESRD healthcare system can lead to unintended outcomes and underachievement of transplant goals. In short, we are concerned that unintended system consequences may follow from well-intended changes that address only one component of the complex transplant ecosystem.

For this reason, the ASTS/AST has established a Task Force on Transplant System Metrics to develop a comprehensive view of transplant metrics that incorporates the needs of people with ESRD, the provider, and regulatory communities that focus on the benefits of transplantation over other treatment options. While we agree that OPO metrics revision is necessary, the desired system change is unlikely without a more comprehensive approach: A broader system metrics change is necessary if transplant care is to be optimized.

We recognize, however, that system-wide metrics are difficult to design and implement and that it would not be prudent to delay modification of the OPO CfCs pending the development of a more comprehensive system. In that spirit and with the understanding that addressing this component of the system is necessary, but not sufficient, to maximize the benefit of transplantation, we are pleased to have the opportunity to share the following comments on the proposed OPO CfCs.

#### I. The Proposed OPO Outcomes Metrics

We agree that it is time to replace the current OPO metrics with metrics based on a potential donor “denominator” that is calculated based on a verifiable, objective methodology. Without this, it is impossible to evaluate efforts to improve OPO performance or to compare performance over time or across OPOs. Because the current metrics are subjective and self-reported, we agree that change is needed.

CMS is proposing to revise the outcome measures for re-certification at §486.318 to replace the existing outcome measures with two new outcome measures that would be used to assess an OPO’s performance: “donation rate” and “organ transplantation rate” effective for CY 2022. Each of these is discussed separately below.

##### A. “Donation Rate”

Under the OPO Proposed Rule, the “donation rate” would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. This new metric differs in a number of key respects from the donation rate metric that it would replace. First, the numerator of the proposed metric is defined as the number of actual deceased donors in the DSA who had at least one organ transplanted based on data reported to the OPTN: CMS is proposing to change the current donation metric to require that, in order for the donor to “count,” at least one donor organ must be transplanted, not just recovered. Second, the denominator of this metric (and for the organ transplantation rate metric described below) is calculated based on data obtained from the Center for Disease Controls’ (CDC), National Center for Health Statistics’ (NCHS’s) Detailed Multiple Cause of Death (MCOB).

Generally, ASTS supports these changes in both the numerator and denominator of the “donation rate” metric. We believe that counting only those donors who had at least one organ transplanted in the numerator of the measure (rather than counting all organs acquired) will dissuade OPOs for pursuing

potential donors whose organs are unlikely to be suitable for transplantation. This may reduce organ wastage and the unnecessary organ procurement expenses that drive up the standard acquisition costs (SACs) for organs.

We also agree with CMS's efforts to redefine the denominator of this measure to reflect a more objective and verifiable definition of potential donors. In conjunction with a prior CMS Request for Information (RFI) on the issue of OPO metrics, ASTS, in conjunction with the American Society of Transplantation (AST), submitted comments on the use of the MCODE to calculate potential donors. In that response, we noted that while we support the use of an objective and verifiable methodology to determine the universe of potential donors, the MCODE files have a number of shortcomings that should be addressed before they are used for assessing OPO performance. For example, it is our understanding that the MCODE uses state data on inpatient hospital deaths and that each state has different rules for the collection of this data. If state databases are not collecting data using uniform reporting rules, they may be unsuitable for use to compare OPO performance in different states. We recommended that CMS establish a working group that includes OPOs, the transplant community, CDC and others to refine the MCODE data files before they are used for the assessment of OPO performance and to consider whether there are other inpatient hospital death data sources available that might be more suitable for this purpose.

***Recommendation:*** *We support the use of objective and verifiable inpatient mortality data files to determine potential donors. We urge CMS to form a Potential Donor Working Group that includes the CDC and representatives of the transplant and OPO communities to identify and address any shortcomings arising from the use of the MCODE data files to identify potential donors (including, but not limited to, variations in state mortality reporting practices) and to determine whether there is an alternative data source available.*

We also note that the OPO Proposed Rule would exclude from the definition of "potential donor" those with a cause of death that is an "absolute contraindication to organ donation." The OPO Proposed Rule requests comment on the ICD-10 diagnosis codes that should be used to exclude deaths from being counted as potential donor deaths. We agree that this list requires refinement: For example, bacterial sepsis is listed as an exclusion from donation, but at least some transplant surgeons may utilize these organs under certain circumstances. The list mentions skin cancers twice – once it specifies melanoma, while the second time it does not. Overall, the list is considerably narrower than that used in the transplant community to rule out potential donors, and using so narrow a list of exclusions has the potential to significantly overstate the number of potential donors, thereby distorting OPO performance measurement.

***Recommendation:*** *If CMS chooses to implement a methodology that excludes potential donors based on ICD-10 Diagnosis Code, we recommend that CMS charge the Potential Donor Working Group with the task of formulating the list, based on a consensus based approach that includes substantial transplant surgeon representation.*

Ideally, however, we recommend that CMS define "potential donors" based on the CALC method proposed by Goldberg et al, as described in the Regulatory Impact Statement discussion of "Alternatives Considered" by CMS. The primary difference between the CALC methodology and our proposed methodology is that the CALC method uses the ICD-10 codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas the OPO Proposed Rule would exclude ICD-10 codes that are an absolute contraindication to organ donation (that is, exclusion criteria). As CMS notes, while the two methods generally flag the same OPOs, when the two methods are applied to the 2017 data, the CALC results in a donor potential of 101,479 inpatient deaths, whereas CMS' proposed methodology results in 272,105 inpatient deaths—nearly three times as many.

We believe that modifying the definition of eligible donor as set forth in the Proposed Rule is likely to result in significant over-identification of potential donors: At least initially, the data set is likely to be relatively messy, and it is our understanding that errors in reporting the cause of death are not uncommon. We also understand that OPOs already experience relatively high call volume from donor hospitals notifying the OPOs of inpatient deaths of patients who are not suitable donors. Under these circumstances, we believe that it would be prudent to define eligible donors as narrowly as practicable, at least initially. This approach has the potential to focus donor hospital attention on ensuring accurate cause-of-death reporting for a manageable set of ICD-10 codes and to focus OPO attention on potential donors with diagnoses that meet specified criteria.

***Recommendation:*** *Because we believe that many of the patient deaths identified using CMS' proposed criteria are unlikely to be suitable donors, we believe that the CALC method is likely to result in a more accurate measurement of OPO performance and that it would be more appropriate to utilize the CALC method than that described in the OPO Proposed Rule to define the universe of potential donors.*

ASTS would also like to address the issue of risk adjustment in the definition of potential donors. ASTS is concerned about establishing risk-adjustments based on clinical characteristics, particularly as it pertains to racial disparities among potential organ donors. There are 58 OPOs in this country, with significant variation in population demographics between many of the OPOs. OPOs serve populations with varying racial/ethnic diversity. In the past, it has been suggested that minority populations have lower rates of donation compared to Caucasians, thus accounting for lower observed donation rates in areas that have more racially diverse populations. However, much of this data is not current, is incomplete, and is not representative of the current understanding of the interplay between health outcomes, healthcare delivery, and unconscious bias.

ASTS supports efforts to provide more research data relating to organ donation rates, OPO practice, and effectiveness of OPO practice. We believe this is an area that is underserved in both resources and research data; we have many questions as a community of providers that can be answered with OPO-specific process data that is already gathered by OPOs on a daily basis. More and better research will lead to structured, balanced, and culturally humble approach to donation amongst minority populations.

We believe that allowing for risk adjustments for race, demographic, and public health factors is a misguided proposition, doubly bad for the communities that such adjustments would attempt to 'correct' for and for the transplant system at large. In effect, adjustments based on historically poor results serve only to elevate stereotypes of poor minority donation to the level of doctrine while systematically excusing OPOs from fully engaging with these populations.

Not including such risk-adjustment models in performance goals will help stimulate the donation community to more optimally identify all potential donors and maximize donation. This belief is supported by arguments made to Congress in 2014 when there were proposed risk adjustments for race in Medicare's Value-Based Purchasing Programs, where it was stated that "...adjusting measures for social factors risks masking disparities in the quality of care provided...directly adjusting measures could excuse the delivery of worse care...adjusting the measures may have a negative impact on transparency." Consistent, thorough OPO-level data reporting at each step in the OPO process would allow researchers and TCs to be better partners to OPOs in identifying interventions that would support OPOs in their life-saving work. Resisting the inclusion of a race-based adjustment stimulates the transplant community to better collaborate with the OPO community, increase donation, and save more lives.

***Recommendation:*** *ASTS does not endorse risk-adjustment models involving race, demographic, or public health factors.*

B. “Organ Transplantation Rate”

Under the OPO Proposed Rule, the “organ transplantation rate” would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. The OPO Proposed Rule also provides clarification as to how the organs are counted for purposes of determining the organ transplantation rate and excludes organs procured for research but not transplanted, except for pancreata that are procured for islet cell transplantation or research (transplanted or not transplanted).

We have serious reservations about using organ transplantation rate as a measure of OPO performance at this time, and we urge CMS to delay finalizing this measure pending further consideration. As noted in the OPO Proposed Rule, some OPOs have objected to measuring OPO performance based on transplant rate because OPOs do not control TC acceptance practices, and, in general, we agree. Fundamentally, we believe that while transplant rate is an appropriate systems metric, it is not appropriate to hold OPOs solely responsible for the transplant rate associated with the organs it procures. In fact, area TC(s), nephrologists, dialysis facilities, and others all play a role in determining the transplant rate for organs procured by an OPO. OPOs do not have control over the TC(s) to whom an organ is initially offered, or whether an organ is offered to a TC with liberal or conservative acceptance practices: OPOs are required to offer organs in accordance with OPTN allocation policy based on the waitlist maintained by the OPTN. And while OPOs may have a role in placing organs that are not otherwise placed, by the time an organ has been considered and rejected in accordance with OPTN allocation policy, it is often difficult or impossible to place. While it is true that, as stated in the preamble to the OPO Proposed Rule, transplant surgeon involvement in OPO operations and OPO involvement with TCs have the potential to impact TC organ acceptance practices, OPOs ultimately have no control over whether or not a TC accepts an organ.

Unfortunately, TCs continue to have a strong regulatory disincentive to transplant imperfect organs. Imperfect organs may result in poorer outcomes, and, while CMS has eliminated one year outcomes requirements as a condition of Medicare recertification for TCs, substantial change in TC organ acceptance practices is unlikely unless and until the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) similarly eliminate or substantially modify the use of one year outcomes measures in assessing TC performance.

More specifically, the OPTN currently utilizes one year outcomes measures—measures that are significantly stricter than those recently rescinded by CMS—in determining TCs’ continued eligibility for OPTN membership, and the SRTR utilizes one year outcomes measures in its “five star” TC ratings—ratings that are routinely used by private payers in determining which TCs may participate in their networks. Thus, unless and until the disincentive for TCs to accept imperfect organs is removed, TCs will continue to be reluctant to transplant imperfect organs. Therefore, OPTN and SRTR evaluation methodologies for TC evaluation create a substantial impediment to CMS efforts to increase the availability of transplantation and, unless and until these OPTN and SRTR methodologies are modified, any effort by CMS to hold OPOs responsible for Transplant Rates will inevitably place OPOs in conflict with TCs. The non-utilization of organs retrieved but not transplanted is a very multifactorial metric which includes both OPO retrieval of poor quality organs and TC “cherry picking.” The ultimate way to address this is to link OPO and TC performance metrics, but this cannot be done until regulatory disincentives to transplant imperfect organs have been eliminated.

***Recommendation:*** ASTS strongly urges CMS to work with HRSA to eliminate the current disincentives for TCs to transplant imperfect organs—disincentives that are created by current OPTN membership evaluation and SRTR star ratings methodologies—prior to instituting any metrics that measure OPO performance based on transplant rate. With respect to kidney transplantation, we also urge CMS and HRSA to work together on metrics that compare the outcomes of transplantation to the outcomes of dialysis as a more appropriate metric of transplant benefit for the individual with ESRD. The desired measure of system success is not defined by ranking TCs; rather, it should be defined by the amount of benefit the people with disease gain from transplantation relative to alternative treatments for their organ failure (e.g., for ESRD, dialysis).

While we have considerable reservations about making an OPO responsible for the transplant rate as described in the OPO Proposed Rule, we recognize that it may be imprudent to place substantial pressure on OPOs to increase organ donation rates without including some mechanism to ensure that the organs retrieved are transplantable. Otherwise, it is possible that at least some OPOs may retrieve organs that are clearly unsuitable for transplantation solely to meet the organ donation rate threshold (whether that threshold is relative and variable or static (see discussion below)). For this reason, if CMS decides to include a transplant rate metric in the OPO Final Rule, we urge CMS to modify the performance standard, such that the transplant rate metric focuses on improvement in an OPO's transplant rate, rather than comparing an OPO's transplant rate to that of other higher-performing OPOs. See discussion below.

#### C. Other Potential Measures

While we have serious reservations about the transplant rate metric, especially in light of the high transplant rate threshold described in the OPO Proposed Rule, we do not support a single metric system that would rely solely on the organ donor rate to assess OPO performance. We strongly agree that the current organ yield metric historically has dissuaded OPOs from pursuing single organ donors and we believe that it is appropriate to include a revised organ yield metric in the OPO Final Rule. Unlike the current yield measure however, the organ yield should not be assessed based on the number of organs recovered from each donor but the number of organs recovered from organ donors as a whole. Along these lines, the OPO Proposed Rule includes a clarification of how organs are to be counted for purposes of determining the organ yield. For example, table 1 in the OPO Proposed Rule indicates that pancreata procured for islet cell transplantation or research are to be counted as organs and that two organs are to be counted for recovery of both left and right organs; double/en block organs; and two organ segments.

***Recommendation:*** We recommend that CMS include in the Final Rule a revised organ yield outcomes requirement whose numerator is calculated based on the number of organs procured from actual deceased donors within the DSA. For the purposes of this measure, the term “actual deceased donors” would be defined to include only donors from whom at least one organ is transplanted.

Second, we recommend that CMS consider including an improvement focused metric in the OPO Final Rule, so that OPOs that do not meet the ambitious standards for established OPO performance with respect to donation and/or transplant rates but that nonetheless make substantial progress do not face decertification. The uncertainty and potential disruption resulting from the decertification of an OPO has the potential to significantly and adversely impact our patients and potential patients in the affected DSA. For this reason, we urge CMS to consider the including in the Final Rule a mechanism to extend the certification of an OPO that does not meet donation rate, transplant rate, or yield metrics if the OPO is making substantial progress in making more transplantable organs available. Also see discussion below regarding mitigating factors.

***Recommendation:*** We recommend that CMS consider including in the OPO Final Rule a provision that facilitates continued certification of an OPO that is making substantial improvement in meeting donation, transplant rate, or yield outcomes requirements, and to work with the TC and the OPO communities in establishing the parameters for what constitutes substantial improvement.

## II. Threshold Requirements

The OPO Proposed Rule would establish a threshold donation rate and organ transplantation rate based on the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated. For example, since the OPO Proposed Rule would go into effect for the 2022-2026 cycle and would consider only the fourth year of performance in determining whether an OPO would be eligible for recertification (calendar year ending December 2026), then the assessment would use data from January–December 2025 and would be based on the top 25 percent of donation rates and organ transplantation rates during the 12-month period from January to December 2024. By establishing a definition of success that is compared with the top performing OPOs, CMS hopes to increase the number of organs, particularly kidneys, to achieve the goal of doubling kidney transplantations by 2030.

We support the goal of doubling the number of transplants by 2030 and understand that establishing the definition of success based on top performers appears to be supported by the wide variation in OPO performance. At the same time, we believe that it is critical that the metrics used to evaluate performance be realistic and enforceable. Based on the data published in the OPO Proposed Rule, if the new metrics were applied based on 2017 data, assuming that the high performers remain at steady state, eight OPOs would be subject to de-certification in 2026 for failure to increase their donation and/or transplantation rates by more than 50 percent to meet the threshold rates, eighteen OPOs would be subject to de-certification for failure to increase their donation and/or transplantation rates by more than 25 percent to meet the threshold rates, and thirty-three OPOs may be subject to decertification for failure to increase their donation and/or transplantation rates by more than 10 percent to meet the threshold rates.

Under these circumstances, we are concerned that the adoption of the metrics set forth in the OPO Proposed Rule has the potential to result in the “flagging” of so many OPOs that it may prove impracticable for CMS to take effective and timely enforcement action without substantially disrupting organ procurement in the United States. While we recognize that some provisions of the OPO Proposed Rule—for example, provisions requiring annual assessment and continuous quality improvement—are intended to ensure that OPOs reach the goals established through the metrics, we believe that, if the goals are considered unreachable, this may dissuade underperforming OPOs from putting forth their best efforts.

For this reason, we urge CMS to consider modifying the organ donation and transplant rate thresholds described in the OPO Proposed Rule. In the “Alternatives Considered” section of the Regulatory Impact Statement, CMS solicits comments on whether it would be preferable to use an absolute threshold as a viable alternative to use as a relative performance metric. Specifically, the OPO Proposed Rule models using the geometric mean or the median donation rate and/or transplant rate, rather than using a variable performance rate that would change every year based on the performance of the top 25%.

We believe that using an absolute threshold in assessing OPO donation rate performance has a number of significant advantages over the use of a relative performance metric. We believe that most OPOs would benefit from a clear objective standard that would remain unchanged during the certification cycle and that having a clear donation rate goal would provide some assurance to key OPO personnel that they are not chasing a “moving target.” Moreover, a variable performance metric is impracticable over the long term, since, at some point, OPOs may become “victims of their own success” by continuing to move the threshold

ever higher. While we acknowledge that establishing an absolute threshold has the potential to incentivize complacency once the threshold is reached, we note that establishing the threshold at either the geographic mean or at the median would leave substantial room for improvement for most OPOs. And establishing a fixed threshold of performance appears to be particularly well suited to minimize the current variation in OPO performance levels. Once OPOs are all functioning at an acceptable level, the threshold can be further increased, or a relative performance metric can be instituted at that time to further incentivize exemplary performance.

***Recommendation:*** We urge CMS to establish the organ donation rate threshold for OPOs based on a fixed median donation rate rather than on the basis of a variable performance rate.

Establishing an appropriate transplant rate threshold measure is a considerably more complex and problematic task. For the reasons set forth above, we have considerable reservations about subjecting OPOs to a transplant rate performance metric: The transplant rate for organs procured by an OPO is an appropriate systems measure, an OPO is not solely—or even principally—responsible for transplantation rates. Ultimately, the transplant rate in any geographic area is the result of a multitude of factors, including, but not limited to, referral patterns by area nephrologists and dialysis facilities, the number of TCs and their organ acceptance practices, and the quality of the organs procured by the OPO. These factors vary significantly from one region to another. We do not believe that it is appropriate, for example, to require an OPO with a relatively small designated service area (DSA) and a single TC that may have conservative organ acceptance practices to have a minimum transplant rate based on the performance of OPOs in a DSA with numerous TCs that may have more liberal organ acceptance practices.

***Recommendation:*** If the OPO Final Rule includes a Transplant Rate measure, we urge CMS to adopt a performance measure that focuses on the improvement in an OPO's transplant rate rather than on a comparison of the OPO's transplant rate with that of OPOs with different DSAs.

### III. “Flagging” and Its Consequences

In our view, while the OPO Proposed Rule includes a comprehensive analysis of the need for new OPO metrics and compelling rationale for the metrics that have been proposed, it does not set forth with sufficient specificity what will happen to the OPO—or to the patients or providers in the OPO's DSA—if an OPO is flagged for failure to meet the organ donation rate or the transplant rate thresholds. Specifically, it is unclear based on the proposed regulatory language and the statements in the preamble whether an OPO that fails to meet the organ donation and/or transplant rate thresholds will be decertified or whether it may be decertified. In light of the serious disruption in organ retrieval that necessarily will result from decertification and the uncertainty that OPO decertification would necessarily trigger for potential transplant recipients and providers in the area, we believe that it is critical for CMS to clearly delineate the consequences of an OPO's failure to meet one or both of the new metrics.

In so doing, we urge CMS to include in the final regulations intermediate sanctions that could be imposed short of decertification. For example, prior to the recent elimination of TC Medicare recertification outcomes requirements, TCs that failed to meet outcomes requirements could apply for a mitigating circumstances exception.

***Recommendation:*** We urge CMS to institute a mitigating circumstances process for OPOs that fail to meet the new OPO outcomes metrics, to ensure that an OPO's certification status is not terminated in the event that its failure to meet these requirements is attributable to factors beyond its control.



We note, too, that while chronic and substantial underperformance of an OPO can and should result in decertification, there may be closer cases that require CMS to carefully balance the increased organ availability that could result from re-bidding against the substantial disruption that would inevitably accompany decertification of the area's OPO. In such cases, CMS may wish to have the flexibility to impose intermediate sanctions and other requirements, rather than going through full decertification procedures.

***Recommendation:*** We urge CMS to include in the OPO Final Rule authorization for the imposition of intermediate sanctions on an OPO that fails to meet outcomes requirements if the OPO is in substantial compliance with process requirements and if the OPO's compliance with outcomes requirements has improved over time. Such intermediate sanctions may include a requirement that the OPO enter into a Systems Improvement Agreement with CMS, which may, for example, require an OPO to replace its executive management team; require it to enter into a management contract with a high performing OPO; require it to institute new information systems or to commit other resources or mandate the performance of other improvement activities not specifically required in the OPO CfCs.

Finally, we cannot overstate the potential disruption that decertification of an OPO could cause for TCs and patients in an OPO's DSA. While such disruption may be necessary in the case of an OPO that has a long history of chronic underperformance, it is critical that the transition be seamless and transparent.

***Recommendation:*** We urge CMS to include in the OPO Final Rule a new OPO CfC that requires any OPO that fails to meet the CfCs or whose certification is terminated for any reason to cooperate fully with CMS in the transfer of its responsibilities and to make all information regarding its certification status public through written notice(s) to TCs donor hospitals, potential recipients and other affected patients and providers.

#### IV. Other Issues

The OPO Proposed Rule also raises a number of other issues, discussed below.

First, under the OPO Proposed Rule, an OPO's performance with respect to the new outcome requirements would be evaluated based solely on its performance during the last year of its four year agreement with CMS. We believe that it is not prudent to shorten OPO evaluation period to one year, since the one year used for evaluation purposes may be turn out to be an outlier that is not reflective of the OPO's overall performance. In addition, we believe that shortening the evaluation period in this manner has the potential to impact an OPO's allocation of resources and limit its focus to the evaluation year.

***Recommendation:*** We recommend that CMS consider an OPO's performance during the entire period covered by its contract with CMS in determining whether or not the OPO meets outcomes requirements, rather than limiting the assessment to the last year of a four year certification period.

Second, we urge CMS to consider modifying those provisions of the current regulations that mandate a four year certification period for OPOs. We believe that there may be circumstances under which CMS wishes to extend the certification of an OPO for a period of less than four years. For example, an OPO that fails to meet the new outcomes requirements but makes substantial improvement in its donation or transplant rate (or any other additional outcomes measures included in the OPO Final Rule) may require evaluation to determine whether sufficient progress is being made to support continued certification. Likewise, in the event that CMS adopts a "mitigating circumstances" process comparable to that used when a TC failed to

meet recently repealed Medicare certification requirements, CMS may wish to extend certification of an OPO pending completion of the process and implementation of action plan.

Third, we urge CMS to maximize its own flexibility in assigning parts of a decertified OPO's DSA to different OPOs. The size and populations of the current 58 DSAs vary significantly, with some DSAs covering a large geographic area. In the event that an OPO fails to meet the new standards, CMS should retain the flexibility to break up the decertified DSA and award different parts of the DSA to different high performing OPOs.

***Recommendation:*** We urge CMS to remove the requirement that an OPO that submits an application to take over the responsibilities of a decertified OPO agree to take responsibility for the entire DSA served by the decertified OPO.

We look forward to working with you to achieve the goal of doubling the number of transplants by 2030, while simultaneously minimizing the disruption for our patients and for providers.

Sincerely yours,



Lloyd E. Ratner, MD, MPH, FACS  
President  
American Society of Transplant Surgeons