American Society of Transplant Surgeons®

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March 1, 2021

The Honorable Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date; Docket No.: CMS-3380-F2

Dear Administrator Richter:

ASTS is pleased that the Centers for Medicare and Medicaid Services (CMS) has chosen to reopen the comment period on the revised Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) finalized in a Final Rule published in November, 2020 (the "OPO CfC Final Rule" or the "Final 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 appreciates CMS' recent focus on increasing access to transplantation, and we strongly support revision of the OPO CfCs to incentivize increased retrieval of organs suitable for transplantation.[1] With this overall objective in mind, when revisions to the OPO CfCs were initially proposed in November 2019, ASTS filed extensive comments suggesting modifications designed to maintain stability in organ procurement while incentivizing OPOs to increase retrieval of organs suitable for transplantation. Unfortunately, none of the changes we proposed were adopted in the OPO CfC Final Rule. We urge CMS to reconsider the full range of our policy and

[1] Kidney transplantation restores kidney function to a far greater extent than dialysis and is associated with improvements in health-related quality of life metrics and reduced risk of mortality compared to dialysis. The cost saving to the health care system that would result from increased access to transplantation is significant: Medicare spending for hemodialysis is $91,000; $76,000 for peritoneal dialysis, and $38,000 for transplantation. Furthermore, current overall adjusted mortality per 1000 patient-years rates is 166 for hemodialysis patients and 154 for peritoneal dialysis patients, compared to only 29 for transplant recipients. Since the shortage of organs suitable for transplantation is the single most significant facto limiting access to transplantation, we support CMS' efforts to incentivize improvements in OPO performance as a critical step necessary to increase organ availability. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. Am J Transplant. 2011; 11: 2093-2109. Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. Am J Transplant 2018;18: 1168–76.

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technical comments (see ASTS Comments on OPO Proposed Rule, February 20, 2020) as part of the current review of the Final Rule.

In order to facilitate the current re-evaluation, we highlight below those aspects of the OPO CfC Final Rule that we believe warrant special scrutiny.

I. An OPO's "Transplant Rate" should not be used to evaluate its performance so long as Transplant Centers (TCs) face substantial regulatory and financial incentive to maintain near perfect outcomes. However, if an OPO's Transplant Rate measure continues to be included in the Final Rule, it should focus on an OPO's Transplant Rate improvements and not compliance with a comparative threshold.

As indicated in our initial comments, we believe that it is highly problematic to use an OPO's Transplant Rate to measure OPO performance unless and until regulatory disincentives that discourage TCs from accepting organs and transplanting recipients who are viewed as "high risk" are eliminated. In particular, while CMS has recognized that patient and graft survival outcome metrics create disincentives for TCs to increase transplantation and has eliminated the use of such outcomes requirements under the Medicare conditions of participation, TCs continue to be strongly motivated to attain (or retain) near perfect patient and graft survival as the result of outcomes-based performance measures used by HRSA contractors (the Organ Procurement Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR)). See ASTS correspondence dated February 4, 2021 to Lee A. Fleisher, MD, Chief Medical Officer and Director of the Center for Clinical Standards & Quality (CCSQ).

In addition, such performance metrics should be risk adjusted to account for differences in the population of potential donors in each Donor Service Area. To fail to do so as proposed in the current CMS OPO metrics, will mislabel some OPOs as performing well and performing poorly without accounting for the differences in the populations that are dying as potential donors in the different DSA.

For example, performance on outcomes measures are reported publicly by the SRTR in the form of "star ratings" on each Transplant Center's Program Specific Report (PSR). Just to maintain a "three star" outcomes rating, 96% of a TC's kidney transplant recipients must have a functioning transplant at one year. The five-star rating system for TC outcomes is so volatile that almost half of kidney programs have a change in ratings within six months and more than half shift by two stars within four years.[2] Adverse outcomes for only one or two patients can have a major impact on star ratings, and thus on the TC's eligibility for third party contracts, on patient referrals, and on the TC's local reputation. Considering that TCs—not OPOs—make (and should make) clinically complex decisions regarding whether to accept an organ for transplantation, so long as outcomes measures continue to play an outsized role in TC performance evaluation, requiring OPOs to substantially increase their Transplant Rates sets up a potentially adversarial relationship between TCs and their area OPOs that is not in the best interests of transplant patients.

> *Additional Recommendation: If CMS determines that some measure focusing on OPO performance in placing organs for transplantation is appropriate, we urge adoption of a*

[2] Jesse D. Schold, Kenneth A. Andreoni, Anil K. Chandraker, Robert S. Gaston, Jayme E. Locke, Amit K. Mathur, Timothy L. Pruett, Abbas Rana, Lloyd E. Ratner, Laura D. Buccini, Expanding clarity or confusion? Volatility of the 5-tier ratings assessing quality of transplant centers in the United States. American Journal of Transplantation. 09 January 2018.

measure that focuses on improvements in performance rather than a comparative Transplant Rate measure.[3] (We likewise favor an absolute rather than relative metric.) We also believe it is critical that any new metrics be developed with the input of the entire transplant community and include input from associations representing transplant surgeons, transplant physicians, OPOs, patient organizations, and other affected stakeholders to achieve outcomes for which the metrics were designed.

II. **The Final Rule precludes CMS from recertifying or contracting with any OPO that fails to meet outcomes requirements regardless of whether any alternative is available, thus potentially leaving many areas of the country at risk of not having any OPO. For this reason, CMS should modify the Final Rule to give itself the flexibility to re-certify and contract with an underperforming OPO under specified conditions.**

The de-certification of an area OPO has the potential to result in extraordinary disruption in access to transplantation for considerable periods, potentially denying entire populations the opportunity to obtain life-saving treatment. For this reason, we are extremely concerned that the OPO CfC Final Rule places CMS in a regulatory straightjacket that will preclude the agency from retaining an underperforming OPO even if it commits to making any changes required by CMS and even if there is no other alternative available.

In particular, under the OPO CfC Final Rule, OPOs that fail to meet the outcome requirements in effect for the 2018-2022 certification cycle and Tier 3 OPOs identified based on their performance for the last assessment period for the 2022-2026 certification period must be decertified and are precluded from retaining their contracts. The Final Rule essentially assumes that at least one other OPO will bid for the contract for the service area of any OPO that is de-certified as the result of a failure to meet the outcomes requirements in effect for the 2018-2022 certification cycle and that at least one Tier 1 or Tier 2 OPO will bid for the contract for the service area of any OPO assigned to Tier 3 as the result of its performance during the final assessment period for the 2022-2026 certification cycle.

But what happens if no OPO wants to take over? The Final Rule—which is equally binding on CMS as on the affected OPOs—precludes the agency from allowing the de-certified OPO to maintain the contract, even if it were willing to make whatever organizational or operational changes CMS may demand. In this case, it appears that the de-certified OPO's service area will be left without any OPO unless and until a new organization that is eligible for certification materializes. (And since the CfC Final Rule does not exempt new organizations from the outcomes requirements, it is unclear how any new organization – which necessarily lacks an outcomes track record--could ever become eligible for certification.)

ASTS strongly believes that it is highly imprudent for CMS to so tightly constrain its own flexibility to meet the needs of potential recipients who happen to reside in areas served by underperforming OPOs. We believe that this problem could be addressed in either of two ways. First, we have drafted proposed modifications of the Final Rule that we believe would allow CMS the flexibility to work with an underperforming OPO if the agency concludes that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems Improvement Agreement satisfactory to the Secretary (see Attachment A).

[3] For reasons also stated in our initial comments we also favor use of an absolute rather than a relative donation rate performance threshold.

Alternatively, if CMS needs additional time to address this issue but does not wish to delay implementation of new OPO outcomes measures, we urge the agency to finalize new definitions set forth at **42 CFR§ 486.302;** new outcomes measures set forth in **42 CFR § 486.318;** conforming amendments set forth at **42 CFR § 486.328**; and amendments of the QAPI requirements set forth at **42 CFR§ 486.348** but to refrain from finalizing the changes set forth in 42 CFR **§ 486.316 (Re-certification and competition processes)**, pending further consideration. In this manner, CMS can effectively provide OPOs with notice of the outcomes standards that will apply in the 2022-2026 certification cycle without putting itself in a regulatory straightjacket that has the potential to disrupt, delay, or completely deny access to transplantation in areas serviced by underperforming OPOs.

We appreciate the opportunity to re-engage with CMS on these important issues. Please contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870 if you have any questions regarding our comments or any other issues relating to transplantation system improvements.

Sincerely,

Marwan S. Abouljoud, MD, FACS, CPE, MMM
President
American Society of Transplant Surgeons

Cc:
Lee Fleisher, MD, Chief Medical Officer and Director, Center for Clinical Standards & Quality (CCSQ)
Diane Corning, Division of Non-Institutional Quality Standards, Clinical Standards Group
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Kristin Shifflett, Life Safety Code Subject Matter Specialist, CMS
Captain James Cowher, Director, Division of Continuing Care Providers (DCCP)
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Attachment A: Proposed Modifications of OPO CfC Final Rule

§ 486.316 Re-certification ~~and competition processes~~.

(a) *Re-certification of OPOs.* Based upon performance on the outcome measures set forth in § 486.318 and the re-certification survey, each OPO will be designated into either Tier 1, Tier 2, or Tier 3. The tier in which the OPO is designated will determine whether the OPO is re-certified ~~(Tier 1)~~, must compete to retain its DSA (~~Tier 2~~), or will receive an initial de-certification determination ~~(Tier 3~~).

(1) *Tier 1*. An OPO is re-certified for at least an additional 4 years, the OPO's DSA is not opened for competition, and the OPO can compete for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, and

(ii) It meets the outcome requirements as described in § 486.318(e)(4) for the final assessment period of the agreement cycle.

(2) *Tier 2*. An OPO is re-certified for at least an additional four years, the ~~An~~ OPO's DSA is open for competition and the OPO is eligible to compete to retain its DSA and for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, and

(ii) It meets the outcome requirements as described in § 486.318(e)(5) at the final assessment period of the agreement cycle.

(3) *Tier 3*. An OPO will receive a notice of de-certification determination under § 486.314 and cannot compete for any open DSA if it meets either of the following:

(i) Has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; or

(ii) Has outcome requirements as described in § 486.318(e)(6) at the final assessment period of the agreement cycle; provided, however, that final assessment period outcomes requirements as described in § 486.318(e)(6) shall not serve as a basis for decertification if the Secretary determines that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems Improvement Agreement satisfactory to the Secretary.

(b) *De-certification and competition.* If an OPO receives an initial notice of decertification: ~~fails to meet the outcome measures set forth in § 486.318(e)(6) at the final assessment period prior to the end of the agreement cycle, or it meets the requirements described in paragraph (a)(3) of this section:~~

(1) ~~CMS will send the OPO a notice of its initial de-certification determination and~~ The OPO has the right to appeal as established in § 486.314;

(2) If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas set forth in (c) of this section. The de-certified OPO is not permitted to compete for its open area or any other open area.

(3) The OPO competing for the open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open DSA, an OPO must meet the performance requirements of the outcome measures for Tier 1 or Tier 2 at § 486.318(e)(4) and (5), and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

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(f) *Extension of the agreement cycle for extraordinary circumstances*. OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period.

(g) For the 2022 recertification cycle only, if an OPO does not meet one of the outcome measures as described in paragraphs §486.318(a)(1), (a)(3), (b)(1), or (b)(3), or has been shown by survey to not be in compliance with the requirements for certification at §486.303, including the conditions for coverage at §§486.320 through 486.360, ~~the OPO is de-certified.~~ CMS will send the OPO a notice of its initial de-certification determination; provided, however, that failure to meet one of the outcomes measures described in paragraphs §486.318(a)(1), (a)(3), (b)(1), or (b)(3) shall not serve as a basis for decertification if the Secretary determines that the OPO is the sole OPO option reasonably available for the OPO's service area or that recertification of the OPO is in the best interests of potential recipients in the OPO's service area and the OPO enters into a Systems

Improvement Agreement satisfactory to the Secretary. If an OPO that receives an initial decertification determination does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.