

**OPTN Executive Committee
Meeting Minutes
February 11, 2020
Teleconference**

**Maryl Johnson, M.D., Chair
David Mulligan, M.D., FACS, Vice Chair**

Introduction

The Executive Committee (EC) met via teleconference on 02/11/2020 to discuss the following agenda items:

- 1) Request for approval of the OPTN Response to HRSA Request for Public Comment: Removing Financial Disincentives to Living Organ Donation (Living Donor Committee)
- 2) Request for approval of the OPTN Response to CMS Request for Public Comment: OPO Conditions for Medicare/Medicaid Coverage: Revisions to the Outcome Measure Requirements for OPOs (MPSC and OPO Committees)

The following is a summary of the Committee's discussions.

1. OPTN Response to HRSA Request for Public Comment: Removing Financial Disincentives to Living Organ Donation

The Vice Chair of the Living Donor Committee (LDC) presented the Committee's final draft of their response to a rules proposal from HRSA following the July 2019 Executive Order on advancing American kidney health. HRSA proposes a regulation allowing living organ donors to be reimbursed for related lost wages, child care expenses, and elder care expenses. The reimbursed expenses would be included in the current NLDAC process that offers financial support for living donors. The proposal does not change criteria eligibility based on income of donor and recipient.

The LDC was asked to identify any other potential financial barriers to organ donation, including the challenges related to employer-provided medical insurance benefits while out of work during donation and recovery. The letter underscores the LDC's support of this and any effort that reduces financial barriers and brings donors as close as possible to financial neutrality in donation. It also encourages HRSA and the transplant community at large to use the OPTN as a resource for data and information as needed.

Several members voiced strong support of the response as written, and no edits were offered. In a unanimous vote, the Committee approved the statement for submission.

100% aye; 0 abstentions; 0 nays.

Next Steps:

The letter will be submitted on behalf of the OPTN via the Federal Register no later than Feb. 18, 2020.

2. OPTN Response to CMS Request for Public Comment: OPO Conditions for Medicare/Medicaid Coverage: Revisions to the Outcome Measure Requirements for OPOs

UNOS staff presented the draft letter to the Committee. The EC approved a letter of response from the OPTN to CMS' initial request for information in September 2019. On December 23, 2019, CMS released

its proposed rules for public comment. The Executive Committee met in January to review initial feedback from the MPSC and OPO Committees and offer directional guidance to staff and Committee members supporting the drafting of the response, due Feb. 21st, 2020. The draft presented to the Committee covered the following key points:

- Reaffirm the need for a more comprehensive “denominator” for assessing OPOs performance on converting a death to a donor
- Restate the need for death data, with sufficient clinical detail, transmitted preferably directly for donor hospitals’ EMR should be used to assess actual donor potential for regulatory purposes
- Appropriate risk adjustment is necessary to properly assess performance
- The two metrics should measure two distinctly different things. As proposed, the metrics use the same denominator, and do not adequately offer differentiated performance indicators
- The combination of a shortened assessment window (from 36 months to 12) with an unstable metric increases the likelihood an OPO will fail by chance
- The proposed calculation of donor potential is not appropriate for regulatory purposes
- Reiterated concerns about limitations of CDC death data in first OPTN letter (Sept. 2019)
- Object to the proposed change to the definition of “donor”
- Concern over flagging methodology
- Request clarity on intended process following decertification of ~30 OPOs
 - Based on the 2017 data provided, more than half of the 58 OPOs would be flagged for decertification
 - No apparent defined appeals process
 - Request details on how to manage the disruption to the transplant system and the recovery of organs for the patients that need them

The Chair began discussion by reiterating the need for the Committee to carefully consider this letter given its importance to the transplantation and donation system as a whole. One member asked why the letter specifically mentions the proportion of donor deaths due to drug intoxication, including but not limited to opioid overdoses. The Chair explained that the increase in transplants over the past several years is due to several factors, and that the impact of the opioid epidemic accounts for less than 13% of those deaths, so the Committee felt it important to include that data in the beginning of the letter.

Following a question from the Vice Chair, the POC Chair commented on the suggestion in the proposed rules that OPOs would subsume another OPOs service area in the event of decertification. She expressed concern that there is no incentive for higher performing OPOs to consolidate with lower performing OPOs as there is no regulatory relief for an otherwise severe performance threshold, which serves as a disincentive for any voluntary affiliation. In the instance of an involuntary affiliation in which CMS assigns new territory to an OPO, there are resources – both physical, human and financial – that are not moved with CMS designation. Rather, as OPOs are charitable not for profits overseen by their state, this change in designation does not commandeer the OPOs assets and could have the unintended consequence of leaving the system without OPOs willing to seek to affiliate with the territory or in which CMS requests an OPO do so without any regulatory relief. Overall, this would serve to cause seismic disruption to a system, and to no achievable or meaningful end. As written, the proposed rules increase

the likelihood of “false positives,” resulting in the decertification of an OPO that likely was not low performing, and with an OPO asked to consolidate a territory that may not be set up for success and may even not perform any better. Decertification is CM’ key accountability component to the system and it should be able to help enforce continuous improvement, but changes to that mechanism should be carefully planned, be sensitive to the realities of the donation and transplantation environment, and can actually successfully affiliate and consolidate OPOs with the goal of better performance. The Immediate Past President supported these comments, and the Chair asked for the Chairs of the MPSC and OPO Committees to offer comment. The Chair of the MPSC noted that her own OPO would struggle to affiliate with nearby OPOs as her own is hospital-based and much smaller than others. She also indicated her concern with the perverse incentives possible with the proposed new definition of “donor.” The Chair of the OPO Committee agreed with the previous comments, and reiterated her support for maintaining a 36 month review window and the current observed-to-expected metric as a measure of performance in the absence of directly-report hospital data.

A member of the Committee offered that perhaps a summary statement offering an overview of the OPTN’s efforts to move from a punitive to a “just” culture focused on improvement in an environment of peer review, and that these changes could serve to upend these improvements to the system.

A member asked whether decertifications had occurred in the past. The POC Chair offered that there have not been any decertification in the past. To the best of her knowledge, there was an instance approximately a decade ago in which an OPO was headed down a decertification path with CMS. The OPO filed suit and claimed the regulation in place was likely arbitrary and capricious and won the suit. More recently, the New York OPO, as publicly reported, established a negotiated path for improvement, a path not contemplated by the regulation. She added that in her perspective, without adequate rationale for any new regulation, in particular surrounding the selection of the top 25% performance threshold, the same circumstance is likely to occur. Other members commented in support of this sentiment.

The member asked about the recent letter from U.S. Senator Grassley et al and how that might impact the OPTN’s response, if at all. The Chair responded to say that much of the content of that letter is tangential to this topic and also largely outside of the scope of the OPTN. The Executive Director noted that the OPTN would answer all questions possible and refer Grassley and his colleagues to other sources of information as needed. The letter does inquire after a theme that suggests that the OPO community is failing because so many of its members would fail to meet the proposed metric. The metric itself is a comparative metric, which by definition ensures that some will be under the line and some will be over, regardless of the relative performance of the group as a whole. Others have indicated that CMS’ threshold means that 75% of OPOs are “failing” and that this is a problem to be fixed. However, this metric simply is intended to compare them to one another. The member thanked the Chair and Executive Director for the answer and stated he perceived these efforts to be attacks on the OPO community. The POC Chair added that, from her perspective, the best way to hold OPOs accountable is to develop a very accurate, clear metric with a rationale that has been carefully articulated.

The Chair thanked the attendees for their comments and discussion. The draft response was approved by a vote of the Committee with all edits incorporated from the Committee and other nonsubstantive or clerical edits as needed.

Next Steps:

The Chair thanked members for their comments and noted that she would review the final draft of the letter. If any of the subsequent changes are substantive in nature, the Chair noted she would reconvene

the Committee to review. The response document will be finalized and submitted via the Federal Register no later than February 21, 2020.

Upcoming Meetings

- February 25, 2020 at 11 am ET
- April 20, 2020 at 9am ET