

**OPTN Patient Affairs Committee
Meeting Summary
December 12, 2023
Conference Call**

**Garrett Erdle, MBA, Chair
Molly McCarthy, Vice Chair**

Introduction

The OPTN Patient Affairs Committee (PAC), the Committee, met via WebEx teleconference on 12/12/2023 to discuss the following agenda items:

1. Board Debrief
2. CMS Pancreas Rule
3. eGFR Update

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

1. Board Debrief

A Board member provided an update on the Board of Directors (BOD) goals and areas of focus as it relates to efficiency and the modernization initiative.

Presentation summary:

A BOD and PAC member highlighted the BOD's focus on improving efficiency among Organ Procurement Organizations (OPOs), transplant centers, and the Centers for Medicare & Medicaid Services (CMS). The OPTN plans to slightly step back from continuous distribution to prioritize efficiency before continuing with more complex tasks like continuous distribution.

The Expeditious Task Force is actively meeting to optimize operational processes. Concerns have emerged regarding the Health Resources and Services Administration's (HRSA) modernization initiative. Notably, there's no plan for the unilateral continuation of the current contract, set to expire in March. A letter has also been sent to HRSA seeking more information, expressing worry about the lack of details and exposure for Board members once the Board separates. More specifically, there will be no indemnification once the Board separates which will provide a lot of exposure for Board members.

Summary of discussion:

The Committee did not make any decisions.

A member stated that the Expeditious Task Force has set ambitious goals, focusing on increasing donation after circulatory death (DCD), enhancing organs recovered per donor, and reducing discard rates, which is encouraging.

Regarding the HRSA and contract discussion, it was highlighted that there will be multiple contracts. One side will handle operations, while the other will be involved in support functions. A member expressed concerns about the support side of the contract but agreed that this matter can be addressed in a future discussion.

2. CMS Pancreas Rule

The Committee reviewed the CMS pancreas rule and discussed their thoughts and concerns on the matter.

Presentation summary:

- *Procurement of Pancreatic Tissue for Research from Deceased Donors Before vs After the CMS Final Rule in 2020*¹
- Examined data from October 1, 2018, to March 31, 2023
- Findings:
 - Rapid increase in research pancreas procurement (RPP)
 - Over representation of tier 2 and 3 OPOs
- The Pancreatic Islet Cell Transplantation Act of 2004
 - Added to the Public Health Service Act – “Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).”
 - Stated intent: “Increase the supply of pancreatic islet cells for research”
- CMS final rule for OPO Conditions for Coverage updated in 2020. The update includes “pancreas for research” as a transplanted organ.
 - While CMS agrees with commenters that pancreata for research are specific to the local research demands and may not reflect universal OPO practice, they state that their inclusion in the outcome measures is consistent with the requirements of the statute and are finalizing them as such.

Summary of discussion:

The Committee did not make any decisions.

During the discussion, a member inquired about the verification process for researchers accepting pancreata for research purposes. The presenter indicated that, in her organization, researchers are verified, but she was uncertain about a system-wide process. The member pointed out a significant increase in the number of pancreas donations for research, as indicated by SRTR data, questioning the reasons behind certain OPOs experiencing a surge from ten or fewer to over 100 pancreas donations for research in a year.

In response, another member highlighted that there is currently no formal approval program determining who can or cannot receive islet cells. The decision is left to the discretion of individual OPOs which may contribute to the observed fluctuations.

3. eGFR Update

The committee received an update on the estimated glomerular filtration rate (eGFR) race-inclusive calculation.

¹ Goldberg DS, Lahrman DD, Wadsworth M. Procurement of Pancreatic Tissue for Research from Deceased Donors Before vs. After the CMS Final Rule in 2020. *JAMA Netw Open.* 2023 Sep 5;6(9):e2332395. doi: 10.1001/jamanetworkopen.2023.32395. PMID: 37672275; PMCID: PMC10483317.

Presentation summary:

Background:

- Programs must review their waiting lists and request eGFR waiting time modifications for registered Black kidney candidates impacted by race-inclusive eGFR calculations.
- All kidney transplant programs must submit an attestation to the OPTN by January 3, 2024, affirming that the program has completed the process above and sent patient notifications.
- This policy was implemented on January 5, 2023

Data:

- Median time of 1.7 years awarded.
- 491 candidates with an eGFR waiting time modification received a deceased donor transplant and 15 received a living donor transplant (as of 7/5/2023)
- 14,774 eGFR waiting time modifications have been submitted (as of 12/12/2023)
- 14,003 eGFR waiting time modifications have been processed (as of 12/12/2023)
- 138 attestations received out of 232 active kidney programs (as of 12/12/2023)

Summary of discussion:

The Committee did not make any decisions.

During a discussion regarding waiting time modifications submitted, a member highlighted a notable concern that only approximately half of Black/African American candidates have submitted for this modification. The OPTN contractor staff stated that it is important to understand that the OPTN does not track the specific calculation used for qualifying time, creating challenges in adequately estimating the number of eligible candidates for submission.

The Committee chair emphasized this issue, noting that only half of the kidney programs have reported. He reminded the Committee that a 90-day turnaround time for program reporting had been previously recommended, as opposed to the current 12-month period. Noting the urgency of the situation, he stressed the importance for programs to promptly submit their attestations, as this issue has already persisted for quite some time.

In the discussion about the Member and Professional Standards Committee (MPSC) process for handling non-compliance, a member asked whether it is possible for centers to submit required information after the designated time period has elapsed.

The OPTN contractor clarified that, even if past the due date, centers are obligated to take the necessary steps to achieve compliance. This includes submitting attestations and reviewing all candidates, and she emphasized that wait time modifications and attestations can still be submitted even after the deadline has passed.

Expressing the need for oversight in ensuring proper implementation, the member suggested the necessity for an individual or entity to oversee compliance. He voiced concern about the prolonged duration of this process.

A member sought clarification on the meaning of submitting an attestation, questioning whether it signifies an understanding and agreement to comply with a policy change or if it indicates that the transplant center has addressed all candidates affected by the race-based eGFR calculation. Aligning with a previous comment, this member emphasized the need for an urgent response from all centers to achieve compliance and benefit eligible candidates with the wait time modification. Stressing the

importance of actions beyond mere attestation, the member highlighted the necessity to rectify the situation and ensure eligible candidates are transplanted promptly.

The OPTN contractor acknowledged and concurred with the member's points. She clarified that attestation signifies the center's notification to all candidates regarding their eligibility for waiting time modifications and the actual submission of eGFR waiting time modifications for these candidates.

In a conversation addressing the repercussions for centers not in compliance with the policy, a member expressed the belief that there should be more of a push and urgency on this matter. She emphasized that this issue has been a point of advocacy by the PAC, spanning several years. The member underscored the urgency of addressing this issue, characterizing it as a known moral and ethical concern that requires prompt attention and decisive action.

Upcoming Meeting

- January 16, 2023

Attendance

- **Committee Members**
 - Garret Erdle
 - Molly McCarthy
 - Denise Abbey
 - Cheri Denise Coleman
 - Tonya Gomez
 - Lorrinda Gray-Davis
 - Calvin Henry
 - Andreas Price
 - Cathy Ramage
 - Kristen Ramsay
 - Julie Spear
 - John Sperzel
 - Jenny Templeton
 - Steve Weitzen
 - Justin Wilkerson
- **HRSA Representatives**
 - Mesmin Germain
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Alex Carmack
 - Kaitlin Swanner
 - Kim Uccellini
 - Desiree Tenenbaum
 - Jesse Howell
 - Houlder Hudgins
 - Robert Hunter
 - Krissy Laurie
 - Rebecca Murdock
 - Jenn Musick
 - Kelley Poff
 - Sharon Shepherd
 - Betsy Warnick
- **Other Attendees**
 - Jessica Yokubeak
 - Kurt Shutterly