OPTN Organ Procurement Organization Committee
Meeting Summary
October 23, 2025
Conference Call

PJ Geraghty, MBA, CPTC, Chair
Lori Markham, RN, MSN, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Teams teleconference on 10/23/2025 to discuss the following agenda items:

1. Welcome and Agenda
2. **Voting Item:** Health Resources and Services Administration (HRSA) Directive for OPTN Donation after Circulatory Death (DCD) Policy Development Workgroup: Policy Language Review

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

1. Welcome and Agenda

The Chair welcomed the members to the meeting and reviewed the agenda.

2. HRSA Directive for OPTN DCD Policy Development Workgroup: Policy Language Review

Decision: The Committee voted to approve the proposed language for the HRSA Directive for OPTN DCD Policy Development project.

The Chair and Vice Chair presented the proposed policy language developed by the OPTN DCD Policy Development Workgroup, and the Committee voted to approve the policy language. This proposed language will then be submitted to the OPTN Board of Directors for consideration to go out for public comment.

Presentation summary:

The Data Advisory Committee reviewed the project for the second time on October 20,2025 and decided to endorse it. The Committee meets today to review the proposal for voting. If approved, the policy language will be submitted to HRSA, and the full policy proposal submitted to HRSA on November 24, 2025. This project will go through special public comment; dates for this public comment period and Board of Directors (Board) approval target date are to be determined.

The Committee reviewed the proposed policy language, which includes:

- Addition of a definition of "unplanned DCD pause"
- Additional OPO responsibilities related to registering authorized potential deceased donors, informing stakeholders of the process for requesting unplanned DCD pause, and ensuring accuracy in neurological assessment and appropriate neurological reassessments
- Required information when requesting authorization for donation
- Updates to requirements for DCD protocols, including confirmation and documentation that the patient's healthcare team holds end-of-life discussions with the patient's agent and that withdrawal of life sustaining therapy decisions are not influenced by donation decisions

- Additional requirements for potential DCD donor evaluation
- Establishing a requirement for process for an unplanned DCD pause, including notification and response requirements
- DCD authorization and disclosure requirements, including explanation of normothermic regional perfusion practices if relevant
- Consent requirements for pre-DCD procedures
- Policies related to brain dead donors recovered using DCD protocols
- Additional reporting requirements

Summary of discussion:

"OPO Responsibilities: … 4. Registering all authorized potential deceased donors in the OPTN Donor Data and Matching System no later than the time at which the OPO decides to proceed with the donation process"

One member commented on the proposed responsibility for OPOs to register all authorized potential deceased donors in the OPTN Donor Data and Matching System when the OPO determines intent to recover organs for transplant. The member remarked that this is challenging with respect to the need for a donor ID. The Chair commented that registry of the donor creates the donor ID. The Chair noted that currently, different agencies have different points at which they require or create a donor ID for billing purposes or other things. The Chair noted that most OPOs register the donor earlier on, but technically, OPTN Policy does not require the OPO to register the donor until the OPO needs to run the match. The Chair explained that this policy designates a precise point in time that captures each of the authorized donors in the system, so that if a pause must be reported, there is a donor ID that is tied to it. A member explained that the Workgroup wanted this policy to capture the point at which the OPO makes the determination to move forward.

A member asked if a timeframe is set, would the OPO be prohibited from registering the potential donor earlier. The Chair remarked that this would not be the case. The Vice Chair added that the intent is to register the potential donor earlier in the process than when the match is run, because the pause may be called at any point after the OPO has determined it is appropriate to move forward. The member shared that their OPO considers the donation process to begin when the OPO takes over charges but noted that this may not be true for every OPO or appropriate for every referral.

One member recommended time of disclosure or authorization. Another member shared that their OPO registers donors in the OPTN System at time of sending blood for serological testing, but that other OPOs may register the donor sooner. The Vice Chair remarked that there is a moment in time when the OPO makes a conscious decision to move forward, and that is what needs to be captured here. The Chair reiterated that OPOs would not be prohibited from registering donors earlier, but that this point in time must ensure there is authorization and intent to move forward with the donation process. The Chair offered potential phrasing of "when the OPO determines intent to recover organs for transplant."

A HRSA representative remarked that the Committee's conversation mirrors those had in the Workgroup and noted that this is good. The HRSA representative remarked that HRSA will also review and may decide to recommend alternative language if it is determined to be appropriate. The HRSA representative shared that HRSA has discussed internally that OPOs have a threshold at which the intent to recover is determined. The HRSA representative added that HRSA directed changes regarding availability of data about patients who did not ultimately become donors. The HRSA representative remarked that the OPO Committee could approve the policy and move to implementation and later tweak the policy language to ensure consistency or provide clarity.

The Vice Chair offered language of "determined intent to proceed with the donation evaluation process." The Vice Chair explained that intent to recover could be interpreted as just before organ recovery, which is too late. One member expressed support, adding that an authorization is intent to recover, but here the evaluation shows that the OPO is moving forward. Another member expressed concern for using the term "evaluation," noting it may be too vague, as each referral is evaluated at some level. The Vice Chair offered that the term "evaluation" could be removed and instead recommended utilizing the "time at which the OPO determined intent to proceed with the donation process."

The Chair asked if work instructions outside of policy could be offered to clarify the intent. The HRSA representative noted that this is possible. The Chair continued that the OPO Committee agrees with respect to what that point in time is but could describe the intent further in guidance documentation. The HRSA representative remarked that this is policy making, and that it is important to protect against unintended consequences. The HRSA representative noted that it is important to understand the outer boundaries of what would be permissible under the language. The HRSA representative added that issuing interpretative guidance makes sense, but that it is important for the policy language to be written appropriately. The HRSA representative noted that it might be beneficial to develop an administrative definition for a potential donor at varying points in a process, and perhaps a new term could resolve confusion. The Chair offered that the Committee could request public comment feedback on the language as well.

Normothermic Regional Perfusion closure Requirements

The Vice Chair explained that the Workgroup's proposed requirements may change with recommendations by the OPTN NRP Workgroup but still felt it was necessary to include consent and authorization language related to thoracic-abdominal NRP (TA-NRP). The Vice Chair explained that the proposed requirements establish that, if an OPO anticipates TA-NRP may be utilized, the OPO must provide appropriate explanation for TA-NRP, including rationale, when organ function will occur, and safeguards to prevent blood flow to the brain. The Vice Chair added that how this is communicated to the family and any stakeholder in the DCD process is critical. The HRSA representative confirmed that the OPTN NRP Workgroup may make additional recommendations, but that proposed policy language is aligned with that work.

Proposed Data Collection Requirements

One member asked if the data collection requirements would apply to every referral, or just those cases where the OPO determined it was appropriate to move forward with the donation process. The Chair explained that it would be the latter, not necessarily every referral. The Chair explained that once a donor ID is generated, the OPO will have to close it out. The Chair continued that OPOs will now need to give organ-by-organ feedback, even in cases where the donation was not completed.

Waiting Period

One member asked if the Committee plans to make any recommendations regarding the minimum waiting period. The Chair remarked that this is being evaluated for future discussion but will not be discussed within this proposal. The Vice Chair offered that the Committee could guide that discussion, noting there is variation in the waiting period across the country. One member expressed support for including a minimum waiting period of 5 minutes within the current proposal. Another member agreed that the OPO Committee should offer a recommendation. A member shared that there is even variation in waiting periods within OPOs, and it would be helpful for the Committee to provide a standard or guidance for the minimum waiting period. The member continued that there needs to be rationale

provided, to explain why the time frame recommended is appropriate and necessary. Another member agreed.

One member asked if there is a definition of autoresuscitation. The Chair explained that it is understood to be coordinated pulsatile activity of the heart; not disorganized but visible fibrillation resulting in a pulse. The member explained that every person may have an understanding of autoresuscitation in mind, but there is an opportunity to provide a consensus definition. The member explained that all it takes is one episode where someone doesn't understand the physiology and processes for there to be widespread negative consequences. The member continued that it makes sense to develop a consensus definition and a minimum waiting time. The member added that the minimum waiting time contributes to warm ischemic time, and long waiting times due to lack of definition of autoresuscitation could result in non-use. The HRSA representative emphasized the potential for patient harm and remarked that this effort should be oriented toward preventing patient harm. The member agreed that medical professionals have to do what is right for the patient, but that there are times where what is right for the patient might not appear right to those who do not understand the donation process. The member continued that this would be an opportunity to educate the hospital staff and community about how organ recovery and transplantation work. The member continued that it is important to prevent misinformation and to ensure transparency. The HRSA representative agreed that there is an opportunity for the Committee to lead in educating hospital staff about what are safe and appropriate practices. The HRSA emphasized the importance of accountability and safety, and noted that the Committee is demonstrating this.

One member remarked that the importance of patient safety is not underestimated here, and that potential harm can occur in multiple ways. The member explained that there is harm when there are unnecessary or inappropriate delays, and that it is critically important to ensure the patient is declared appropriately and by protocol. The member added that there is harm to delays, such that potential recipients may not ultimately be transplanted due to error. The member explained that there's patient safety considerations for the potential donor, the potential recipient, and public perception that must be considered. The member offered that it is important to keep those in mind. The member added that the definition of circulatory death may be larger than the scope of this proposal, but that the Committee could recommend a minimum waiting time of 5 minutes within this proposal. The member expressed support for a 5 minute minimum waiting time. The member emphasized the opportunity for standardization.

The Chair noted that the recommendation for minimum waiting time is outside of the scope of the project and may constitute a big enough change to warrant its own policy development process, including research and public comment. OPTN Contractor Staff asked if the Committee would like to include a public comment question regarding minimum waiting time as part of this effort or wait until there has been more discussion and review. The Chair supported asking as part of public comment whether the OPTN should define the minimum waiting period for determination of circulatory cessation in OPTN policy, and if so, what should that definition be and why. The Vice Chair supported the inclusion of that question. The HRSA representative noted that the Committee is ahead of schedule, and that the Committee could gather evidence as they solicit feedback in public comment.

One member asked if OPOs that experienced concerning events changed their minimum waiting period policies. The HRSA representative remarked that they cannot share specific events or corrective actions, as this is sensitive information. The member shared that it is important for OPOs and transplant programs to share their changes in practices that are effective in solving problems or improving outcomes and processes. The HRSA representative agreed that HRSA supports dissemination of corrective actions is important. The HRSA representative explained that it is important for OPOs to know

what good practices should be disseminated. The HRSA representative offered that HRSA could come up with an interim summary document describing actions taken by those involved in potentially preventable adverse events to provide to the OPTN in the interim, and asked if that would be helpful. The HRSA representative continued that the MPSC could also put out an advisory. The member expressed support. The Vice Chair iterated that currently, this information is only shared via word of mouth.

Data Reporting Requirements

One member asked if the policy language should include verification of the dates and times that the "patient, if applicable," was notified of the unplanned DCD pause. The Chair agreed, but noted that if the patient themselves was notified, then the patient would be their own agent, and the family wouldn't necessarily need to be notified. The Chair continued that the patient's decision-making ability is also highlighted elsewhere.

A member asked if there was concern for the vagueness of the term "patient's family," also asking how that would be defined. The Chair agreed, noting that it could be defined as the patient's legal next of kin. The Vice Chair recommended removing the "patient's family" if the patient's decision making agent is being communicated with. The Vice Chair continued that may be a holdover. The Chair remarked that the patient could have an agent responsible for donation decisions but also have family members present and aware who should not necessarily be excluded. The Chair noted that it could be removed as a required element, but noted that the patient's family should not be excluded in that circumstance. The Vice Chair remarked that "patient family" is too open ended and could include both those who should be involved or those who shouldn't, like a distant cousin. The HRSA representative offered that OPO discretion could be appropriate, to allow the OPO to include the family if subject to the conversation. The Chair continued that may be an OPO level decision and thus wouldn't need to be described in policy. The Vice Chair recommended using "at minimum" and then removing the requirement for "patient's family".

A member asked if patient's healthcare team is also defined, noting that could be considered too broad. The Chair responded that it is not defined, but that could be the providers directing care of the patient. The Vice Chair offered that the language could say "healthcare team guiding care." OPTN Contractor Staff noted that OPTN Policy 2.15 uses "patient healthcare team" or "primary healthcare team." The OPTN Contractor Staff noted that, if the Committee chooses to use more specific language here, the OPO Committee may want to consider making more specific language in other parts of policy as well to ensure alignment. Another member recommended that this could be clarified in a guidance document, noting that the intent is clear. The Chair agreed, noting the same for the hospital leadership team. The Vice Chair agreed this is a reasonable place for guidance.

One member recommended aligning language in proposed OPTN Policies 2.2 and 2.15 to ensure language using "patient's family" aligns with "patient's agent," for consistency. The Chair agreed.

A member asked if there should be a timeframe for retaining records in order to provide them upon request. The Chair remarked that this should be part of the donor's records and utilize the same timeframes.

The Vice Chair remarked that "medical records" should just include "records," to ensure inclusiveness. One member agreed. The Chair responded that could be expanded to include all communications related to the donor, and that the idea of the "medical records" requirement would be to capture hospital records and donor records maintained according to OPO record retention policy. The Chair continued that relevant notes should be maintained in the hospital record and copied by the OPO into the donor's records. The HRSA representative noted that HRSA and MPSC ask if there were any after-

action reviews, and records related to that. The HRSA representative continued that additional actions, process changes, and reviews should be captured. The HRSA representative noted that may be a question for public comment as to how to capture other documentation that resides outside of the electronic medical record related to review of a pause or changes in process. The Chair agreed that it is a standard request for action review or root cause analysis. The Chair noted that "preserve any records" could be appropriate, but there may be pushback. The HRSA representative offered that root cause analysis and other post-event documentation could be clarified in the guidance documentation. The Chair recommended updating the language to "records" and allowing public comment feedback. One member offered that there could be a way to upload root cause analysis documentation, similar to the patient safety process. The Chair responded that there could be OPO discretion as to whether it is appropriate or necessary to include, noting that those are usually not completed until more than 24 hours after the event. The Chair continued that a patient safety report can only be opened on the OPO side by the person who submitted it, so that type of documentation would be than likely be submitted via email to the patient safety team.

VOTE: 11 approve, 0 oppose, and 0 abstain

Upcoming Meetings

- TBD

Attendance

- **Committee Members**
  - PJ Geraghty
  - Lori Markham
  - Micah Davis
  - Ann Rayburn
  - Shane Oakley
  - Stephen Gray
  - Judy Storjfell
  - Micah Davis
  - Kerri Jones
  - Daniel DiSante
  - Greg Veenendaal
  - Rachel Markowski

- **HRSA Representatives**
  - Brianna Doby

- **SRTR Staff**
  - Jon Miller
  - Katie Siegert

- **UNOS Staff**
  - Kaitlin Swanner
  - Houlder Hudgins
  - Kevin Daub
  - Jesse Howell
  - Carly Rhyne
  - Rebecca Murdock
- **Other**
  - Doug Fesler