OPTN Organ Procurement Organization Committee
HRSA Directive for OPTN DCD Policy Development Workgroup
Meeting Summary
September 11, 2025
Conference Call

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Introduction

The HRSA Directive for OPTN DCD Policy Development Workgroup (the Workgroup) met via Teams teleconference on 09/11/2025 to discuss the following agenda items:

1. Welcome & Agenda
2. Project Overview
3. Breakout #1: Pause Subgroup
4. Breakout #2: Family Education Subgroup
5. Next steps

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

1. Welcome & Agenda

Presentation Summary:

A co-chair welcomed the workgroup and reviewed the agenda. A Health Resources and Services Administration (HRSA) representative explained the use of new attestation forms for workgroup members.

2. Project Overview

Presentation Summary:

A co-chair reviewed the timeline, including an upcoming meeting with the Data Advisory Committee (DAC) for endorsement of the approach the workgroup is developing to collect information on pauses in the Donation after Circulatory Death (DCD) donation process.

Summary of discussion:

No decisions were made regarding this agenda item.

There was no discussion regarding this agenda item.

3. Breakout #1: Pause Subgroup

The Workgroup split into their assigned subgroups.

Presentation Summary:

A co-chair reviewed topics for discussion including the following:

- Additions to *Policy 2.2 Organ Procurement* Organizations (*OPO) Responsibilities*

- Empowering stakeholders to call for a pause
- Ensuring appropriate neurological assessment
- Pause data collection

Summary of discussion:

Topic #1: The subgroup discussed including the patient in the list of stakeholders who must be informed of the process for pausing the DCD donation process.

Topic #2: The subgroup agreed not to specify in policy how stakeholders are informed (e.g., verbal or written). However, the subgroup agreed that policy should specify that the family must be informed at the time of authorization and other stakeholders (e.g., donor hospital staff, third party perfusionists, recovery teams, etc.) should be informed when they become involved in the case, since there will be staff shift changes.

Topic #3: The subgroup discussed a requirement for the OPO staff and donor hospital staff to convene a minimum of every 12 hours, and within two hours of the planned withdrawal of life sustaining therapies, to confirm that both teams agree that withdrawal of life sustaining therapies remains appropriate.

Topic #4: The subgroup discussed the 2-phase data collection approach with reporting via the OPTN Patient Safety Portal to accommodate expeditious policy implementation.

The pause subgroup discussed the requirement for a policy on pausing procurement efforts if a patient shows increased neurological function or is at risk of experiencing pain during the process. The subgroup noted that all relevant stakeholders, including patients, their families, hospital staff, transplant center staff, and third-party procurement staff, need to be informed. One of the co-chairs pointed out that patients needed to be included because there are a few scenarios where the patient could be conscious prior to the withdrawal of life sustaining therapies. There was debate about whether policy should specify the timing and method of notification (written vs. verbal). The subgroup noted the practical challenges of staff turnover and varying involvement times, leading to a suggestion for notification "as soon as a particular individual is involved in the case" rather than at a fixed time or through a specific form of communication. A member noted that policy language referring to the family must be inclusive of potential authorizing parties e.g., the potential DCD donor's agent, if not a family member.

The subgroup debated the scope and responsibility for neurological assessments. There was consensus that while OPOs should verify that assessments are happening, the actual responsibility for performing them lies with the hospital care team. HRSA representatives clarified that the goal is not to mandate hospital actions, but to ensure care coordination between organ procurement organizations and hospitals, with protocols for reassessment and documentation at regular intervals (e.g., every 12 hours). The subgroup recommended that OPOs work with partner hospitals to develop protocols for regular neurological reassessments (minimum every 12 hours), with clear roles and responsibilities for care teams and OPOs. The importance of maintaining distinct roles for clinical teams and OPOs was emphasized, especially in low-volume donor hospitals.

The subgroup discussed a two-phase implementation approach for reporting pauses to the OPTN:

- Phase 1**:** Utilize the existing OPTN Patient Safety Reporting Portal for narrative reporting of unplanned pauses, capturing key information (e.g., who called the pause, rationale, notifications, actions taken, resolution) and facilitating quick policy implementation.

- Phase 2**:** Implement discrete data fields in the OPTN Computer System if the frequency and volume of reported pauses justify it. This would require a longer implementation timeframe and approval by the Office of Management and Budget but would provide more granular data for analysis and could require information to be reported before allocation could proceed e.g. reporting resolution of a pause.

Next steps:

The workgroup will continue to discuss the pause requirement elements at their next meeting.

4. Breakout #2: Family Education Subgroup

Presentation Summary:

The family education subgroup reviewed a suggested list of donation-related information that OPOs would be required to share with patient families that included the following:

- A list of organs that may be recovered
- A description of the evaluation and recovery process
- The possibility that organs may not be ultimately viable or transplanted
- Donation related charges are the responsibility of the OPO
- The potential impact donation may have on funeral preparations such as timing and viewing
- Contact information for individuals with questions or concerns
- A copy of a signed authorization form or first-person authorization (FPA) document
- The family's ability to call for a pause in the donation process

Summary of discussion:

Topic #1: The subgroup supported providing information to the family about the process of allocation, as well as keeping the family updated as allocation progresses.

Topic #2: The subgroup supported providing information related to normothermic regional perfusion and machine perfusion but recommended splitting out these topics separately and considering what families need to know about these topics.

Topic #3: The subgroup supported providing more information to the family about what a pause means, why it is important, what happens during the pause, and how a pause is resolved.

The family education subgroup discussed the importance of providing families with clear and comprehensive information about the donation process. This information includes the list of organs the recovery team may recover from the patient, the evaluation and recovery process, the allocation process, and the potential impact on funeral preparations. The subgroup agreed it would be beneficial to provide information on the allocation process to patient donor families, as well as updates to the family as allocation progresses. The subgroup also discussed how much information the OPOs should provide to the families, with some favoring as much information as possible, and others suggesting that information should be based on the needs of the family.

The subgroup discussed the need for clear policies and guidelines to ensure that the donation process is conducted transparently, including the use of normothermic regional perfusion (NRP) and machine perfusion. They emphasized the importance of developing policies that can be operationalized by the OPOs and ensuring compliance through audits. To help further the discussion, one member shared a patient-friendly explanation of the pause procedure. The subgroup discussed ways to incorporate this into the information to be disclosed to the family.

Next steps:

The workgroup will continue to discuss disclosure information and how pause information should be communicated to a patient's family members.

5. Next steps

Presentation Summary:

The workgroup reconvened and the co-chairs summarized the discussion from the subgroup breakouts.

Summary of discussion:

A member asked for summaries of the breakout discussions to be shared with the full workgroup.

Next steps:

The workgroup will receive a recap of the breakout discussions shortly after the meeting.

Upcoming Meetings

- October 9, 2025
- November 13, 2025

Attendance

- **Workgroup Members**
  - Andrew Flescher
  - Anji Wall
  - Cassie Hertert
  - Donna Smith
  - Doug Butler
  - Garrett Erdle
  - Kyle Herber
  - Lori Markham
  - Micah Davis
  - Patrice Ball
  - PJ Geraghty
  - Precious McCowan
  - Rachel Beekman
  - Rebecca Baranoff
  - Sanjay Kulkarni
- **HRSA Representatives**
  - Brianna Doby
  - Joni Mills
  - Luke Neureiter
  - Raymond Lynch
  - Sarah Laskey
  - Stephanie Grosser
- **SRTR Staff**
  - Katie Siegert
- **UNOS Staff**
  - Ethan Studenic
  - Houlder Hudgins
  - Joann White
  - Kaitlin Swanner
  - Kevin Daub
  - Lloyd Board
  - Susan Tlusty