

HRSA Directive for OPTN DCD Policy Development

OPTN Organ Procurement Organization (OPO) Committee

Purpose of Proposal

- On May 28, 2025, the OPTN received a directive to propose policies to strengthen safeguards for DCD patients and improve family communication
- The proposal seeks to
 - Describe OPOs responsibility to ensure accuracy in neurological assessment and appropriate neurological reassessments
 - Require a process for requesting an unplanned DCD pause and inform
 - Require OPOs to inform OPTN within 24 hours of any unplanned DCD pause
 - Require OPOs to inform OPTN and HRSA when the donation process resumes following an unplanned DCD pause
 - Require OPOs to provide specific information to families about DCD organ procurement

Proposal

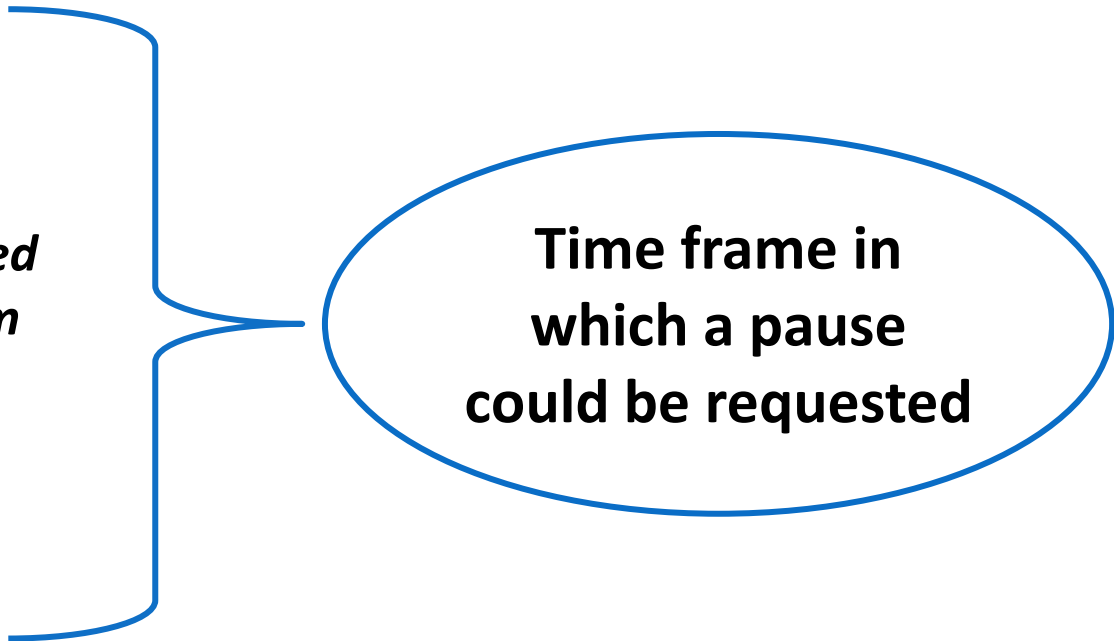
- Requirements prior to proceeding with DCD
 - Require OPOs to ensure accuracy in neurological assessment and appropriate neurological reassessments
 - OPO and primary healthcare team must confirm that the patient continues to meet the donor hospital's criteria for DCD:
 - At least every 12 hours
 - Within 2 hours prior to the planned withdrawal of life sustaining therapies
 - Following authorization for DCD – new requirement for consent if premortem cannulation occurs

Proposal

- Unplanned DCD Pause
 - Definition: An unexpected suspension of the DCD process due to a difference of opinion as to whether a patient meets the OPOs criteria for DCD or donor hospital criteria for withdrawal of life sustaining therapies.
 - **Please note:** This definition is not intended to address issues or questions related to authorization for donation

Proposal: Timeframe to request unplanned DCD pause

- Patient referred
- Patient not medically ruled out
- ***Patient authorized***
- ***Matches are run***
- ***Offer are made***
- ***Offers are accepted***
- ***Operating room arranged***
- ***Donor to operating room***
- ***Withdrawal of support***
- ***Cardiac arrest***
- ***Stand-off period***
- ***Declaration of death***
- ***Cross clamp***
- Recovery
- Packaging and labeling of organs
- Transportation of organs



**Time frame in
which a pause
could be requested**

Patients for whom a pause
is called may not proceed
to donation until pause is
resolved

Proposal

Process for requesting unplanned DCD pause:

- OPO must inform all stakeholders of the process for requesting a pause
 - Patient or patient's agent: At the time of authorization
 - Donor hospital staff, transplant center staff, OPO staff, and third-party procurement and preservation staff: As they become involved in the DCD process
- OPO must establish and document a process by which an unplanned DCD pause can be requested
 - Process must specify how the OPO determines if the DCD process can proceed
 - Process must include convening all existing stakeholders to consider the rationale for requesting the pause and actions to be taken to address the pause

Proposal

Response to an unplanned DCD pause

- OPO suspends DCD process, suspends allocation, and informs stakeholders
- OPO and hospital care team assess if patient still meets criteria for withdrawal of life sustaining therapies
- If DCD process resumes:
 - OPO must obtain acknowledgement prior to organ recovery from all transplant programs that accept an organ from the donor and any contracted representatives that they are aware the pause occurred and acknowledge the decision to proceed

Proposal

- OPO reporting requirements
 - Require a donor ID and disposition for all authorized potential deceased donors to capture outcomes for patients who do not donate
 - Require reporting of unplanned DCD pauses via OPTN Patient Safety Reporting Portal
- Unplanned DCD pause reports provided to HRSA
- Membership & Professional Standards Committee (MPSC) will review reports monthly

Proposal

- Requirements for family information
 - Identified minimum requirements for informing families of all potential donors and additional requirements specific to potential DCD donors
 - Incorporates existing CMS requirements for informing donor families
 - DCD-specific requirements include:
 - Process for requesting unplanned DCD pause and reasons why one might be requested
 - Location in donor hospital where withdrawal of life sustaining therapies will occur
 - Plan for continued patient care if patient does not expire in a time frame for donation
 - Explanation of potential for thoracoabdominal normothermic regional perfusion, if applicable
 - That the DCD donation process will stop if there is a decision not to move forward with withdrawal of life sustaining therapies

Incorporation of Previous Policy Recommendations

- Prior to directive, OPO Committee sponsored a separate DCD Policy Review Workgroup to recommend updates to DCD policies
- Proposed changes include updates to policy regarding:
 - Timing of family DCD donation discussion
 - Use of DCD recovery protocols for brain dead donors
 - Updates to definitions and terminology for currency and clarity
- Public comment proposal includes these recommendations

Implementation

- **Members**
 - OPOs will need to establish and document processes by which an unplanned pause in the DCD donation process may be requested
 - OPOs will need to update their written protocols with donor hospitals to align with new policy requirements for notifying stakeholders about the process for requesting an unplanned pause
 - OPOs may need to modify existing workflows
 - Transplant hospitals will need to be aware and inform staff of the policy changes

Implementation

- OPTN will:
 - Implement changes to donor disposition reporting in the OPTN Donor Data and Matching System
 - Provide a template for reporting unplanned DCD pauses via the OPTN Patient Safety Reporting Portal
 - Update policies and the OPTN member evaluation plan and communicate changes to members

What do you think?

- Should the proposed policies be approved by the Secretary and made enforceable by HHS, in accordance with the process outlined in the OPTN regulations at 42 CFR 121.4(b)(2) and (c) ?
- How might the OPTN identify, report, or evaluate whether the decision to withdraw life sustaining therapies was subjected to undue influence by the donation decision? Is there a clearer way to define responsibilities regarding the timing of the family discussion for donation?
- Should the OPTN add any automatic triggers for an unplanned DCD pause into policy, or provide any supplemental guidance or education regarding situations that may warrant additional caution when assessing patient neurological status?
- Should the OPTN define a minimum waiting period of circulatory cessation in *Policy 2.15.J: Organ Recovery*? If so, how long should the minimum waiting period be, and why?