OPTN

Public Comment Proposal

HRSA Directive for OPTN Donation after Circulatory Death Policy Development

OPTN Organ Procurement Organization Committee

Contents

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HRSA Directive for OPTN Donation after Circulatory Death Policy Development

Affected Policies:	*1.2: Definitions* *2.2: OPO Responsibilities* *2.3: Required Information when Requesting Authorization for Donation (new)* *2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* (*and all subsections*) *9.10.B: Expedited Liver Offers* *18.1: Data Submission Requirements* *18.5.C: Required Reporting by OPOs*
Sponsoring Committee:	*Organ Procurement Organization*
Public Comment Period:	*TBD*

Executive Summary

The number of patients for whom donation after circulatory death (DCD) is attempted continues to increase each year. The percentage of donors recovered under DCD protocols has grown to nearly half of all deceased donors from 12% (943 of all deceased donors) in 2010 to 43% (7,283 of all deceased donors) in 2024.[1] On May 28, 2025, HRSA directed the OPTN to propose policies focused on safeguarding patients entering the organ donation and procurement pathway through DCD and improving family communication with patient families.[2] The OPTN Organ Procurement Organization (OPO) Committee (the Committee) sponsored the HRSA Directive for OPTN DCD Policy Development Workgroup (the Workgroup). The Workgroup was tasked (at a high level) to propose changes that would:

- Describe the OPO's responsibility to ensure accuracy in patient neurological assessment and appropriate neurological reassessments
- Require a process for requesting an unplanned DCD pause
- Require OPOs to inform OPTN within 24 hours of any unplanned DCD pause
- Require OPOs to inform OPTN and HRSA if the donation process resumes following an unplanned DCD pause
- Requirements for family information about DCD organ procurement

Prior to the HRSA directive, the Committee sponsored a separate DCD Policy Review Workgroup to recommend updates to DCD policies. Those proposed changes included updates to policy regarding:

- Timing of family DCD donation discussion
- Use of DCD recovery protocols for brain death donors
- Updates to definitions and terminology for currency and clarity

This proposal incorporates these recommendations in addition to changes in response to the HRSA directive.

[1] OPTN data, accessed on November 7, 2025.
[2] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.

Purpose

The purpose of this proposal is to improve safeguards for patients who enter the donation after circulatory death (DCD) pathway in the organ procurement process and increase information shared with families of patients (both DCD and non-DCD) regarding potential organ procurement. The proposal also outlines requirements for the process for which a "pause" in procurement efforts can be undertaken should there be concern or a belief that the patient is experiencing increased neurological function or is at risk of experiencing pain. This proposal also includes changes to policy definitions and deceased donor organ procurement policies to provide more standardization in procurement practices across OPOs.

Background

The OPTN received a HRSA directive on May 28, 2025,[3] instructing the OPTN to propose policies within 180 days to focus on safeguarding DCD patients and improving family communication. At a high level, the directive stated that the proposed policies should address:

- The process by which a "pause" in procurement efforts can be undertaken if there is concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs
- Requirements for family information about DCD organ procurement to be provided at the time of organ donation authorization
- Policy describing the responsibility of the organ procurement organization (OPO) to ensure that the patient family, hospital staff, transplant center staff, and third-party procurement and preservation staff are empowered to call for a "pause" on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt
- Policy describing the OPO's responsibility to ensure accuracy in neurological assessment of patients and appropriate neurological re-assessments of patients who are potential DCD donors

The directive included additional information on what should be addressed by the proposed policies.

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) established the HRSA Directive for OPTN DCD Policy Development Workgroup (the Workgroup) to develop policies in accordance with the directive. As specified by HRSA, the Workgroup included representatives from the OPTN OPO, Patient Affairs, Ethics, Membership and Professional Standards, and Data Advisory Committees, as well as a critical care physician and additional donor family representatives.

HRSA's directive to the OPTN is the result of a special review of allegations of potential patient harm by an OPO and HRSA's identification of "patterns of risk across OPOs, often linked to staff practices, which included inconsistent assessments, coordination of care, data collection, and a lack of clarity on roles and responsibilities within the care team."[4] HRSA undertook its review under the authority of the OPTN Final Rule which states that the "Secretary or her/his designee may perform any reviews and evaluations

[3] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.
[4] OPTN Strengthening Organ Donation and Procurement Safety, https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/strengthening-organ-donation-and-procurement-safety/.

of member OPOs and transplant programs which the Secretary deems necessary to carry our her/his responsibilities under the Public Health Service Act and the Social Security Act." [5]

Prior to receipt of HRSA's directive, the Committee sponsored a DCD Policy Review Workgroup comprised of members from the OPTN Ethics, Membership and Professional Standards, and Operations and Safety Committees. The DCD Policy Review Workgroup was charged with reviewing all DCD policies and recommending updates to standardize procurement practices. This Workgroup had completed its work when the OPO Committee received the HRSA directive for DCD policy development. The Committee opted to wait on submitting updates to OPTN DCD policy for public comment until policies were developed in accordance with the directive.[6] This proposal addresses the requirements of the HRSA directive and incorporates some previous recommendations of the DCD Policy Review Workgroup.

Overview of Proposal

The Committee proposes updating OPTN DCD policies to improve safeguards for patients who are potential DCD donors. These proposed changes define an unplanned DCD pause and include additional requirements for OPOs to report any requests for an unplanned DCD pause to the OPTN through the Patient Safety Portal. The OPTN and HRSA will monitor the volume and frequency of unplanned DCD pauses reported and consider if further implementation within the OPTN Computer system is warranted. Additionally, the Committee proposes listing in policy the minimum information that must be shared with patient families regarding organ procurement for all patients for whom the OPO is seeking or confirming authorization for deceased donation, including information specific to DCD which must be shared with the families of potential DCD donors. Finally, the Committee proposes changes to policy definitions and deceased donor organ procurement policies to provide more standardization in procurement practices across OPOs.

Process for an unplanned DCD pause

Defining an unplanned DCD pause

HRSA's directive stated, "the proposed policies should address the process by which a 'pause' in procurement efforts can be undertaken if there is concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs."[7] The Workgroup discussed that donor hospital staff and OPO staff should routinely reassess patients for whom authorization is granted for DCD organ donation to confirm that the patient's prognosis remains consistent with plans to withdraw life-sustaining therapies and the patient meets the OPO's criteria for DCD donation. For example, an OPO may receive an initial referral from a hospital regarding a potential donor but should disengage if the patient does not meet the OPO's criteria for donation. The hospital may contact the OPO again if the patient's clinical presentation changes such that the patient does meet criteria for donation. At that point, the OPO may re-engage and continue the donation and procurement process. Neither HRSA nor the Workgroup intended such routine reevaluations to be considered unplanned DCD pauses for the purpose of this policy, as collaboration between the OPO and hospital care team should be expected as a standard of care. Instead, unplanned DCD pauses which must be reported to the OPTN

[5] 42 CFR §121.10 (a).
[6] Meeting Summary for June 12, 2025, OPTN Organ Procurement Organization Committee, https://optn.transplant.hrsa.gov/media/dupoztka/20250612-opo-committee-meeting-summary.pdf (accessed October 23, 2025).
[7] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf (accessed December 5, 2025).

are situations in which the DCD donation process is proceeding in an inappropriate or potentially unsafe manner, such that a stakeholder believes the process must be paused so that all stakeholders can reassess the patient and the clinical circumstances. Accordingly, the Committee proposes defining an unplanned DCD pause as "an unexpected suspension of the DCD process due to a difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies. An unplanned DCD pause is not intended to address issues or questions related to authorization for donation,"; the Committee notes that an unplanned DCD pause it is not intended to address issues or questions related to authorization for donation, as such issues and questions should be resolved prior to authorization for donation being granted. The Committee proposes adding the definition of an unplanned DCD pause to OPTN *Policy 1.2 Definitions*. Such a pause may be called between the time that authorization for DCD is granted and the time of cross clamp. **Appendix B** provides scenarios demonstrating a routine pause in the DCD process versus an unplanned DCD pause that would need to be reported to the OPTN. The Committee will describe education to be provided to the community to further clarify reportable cases of unplanned DCD pauses once the policy is finalized.

HRSA's directive called for the proposed policies to address "any automatic triggers for a pause in procurement efforts if the patient shows objective signs of improving neurologic status."[8] HRSA's directive stated "potential triggers could include changes in brain stem reflexes, change or minimum threshold for [Glasgow Coma Scale], or planned DCD procurement in the setting of self-determined withdrawal of care."[9] The Workgroup considered whether automatic triggers should be incorporated into the policy but noted that a patient may seem to show a change in neurologic status that is not indicative of a recovery and it may not be appropriate to call an unplanned DCD pause in those cases.[10] The Workgroup discussed that there may be circumstances in which more caution by the OPO and donor hospital should be deployed in assessing the patient's neurologic status. These circumstances include when a patient was admitted due to a drug overdose or anoxic injury, or when the patient otherwise has a poor neurologic exam without correlating neuroimaging. After thoughtful deliberations, the Committee decided not to propose incorporating specific automatic triggers for an unplanned DCD pause into the policy due to the variability and applicability of various circumstances. To strengthen donor patient safety and help ensure that any potential changes are recognized, the Committee is proposing required check-ins regarding neurological status. In addition, the Committee does seek community feedback on the topic of specific automatic triggers and whether the OPTN should provide any supplemental guidance or education regarding situations that may warrant additional caution when assessing patient neurological status.

As noted, the proposed policy will require routine check-ins between the donor hospital and OPO staff regarding patient neurologic status (detailed further below) and maintains the existing policy requirement for the OPO to conduct a timeout prior to the donor hospital withdrawing life sustaining therapies. These standardized check-ins throughout the DCD donation process provide opportunities for stakeholders to raise and resolve any concerns. If concerns are not resolved, then stakeholders may request an unplanned DCD pause.

[8] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf (accessed December 5, 2025).

[9] *Ibid.*

[10] Meeting Summary for August 14, 2025, HRSA Directive for OPTN DCD Policy Development Workgroup, https://optn.transplant.hrsa.gov/media/lodeotmh/20250814-hrsa-directive-for-optn-dcd-policy-develop (accessed November 12, 2025).

Process for informing stakeholders

HRSA's directive required that the proposed policies address "a process for informing all stakeholders, including patient family, hospital staff, transplant center staff, and third party procurement and preservation staff that they are empowered to call for a pause on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt."[11] Furthermore, the directive required "an addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure that the patient family, hospital staff, transplant center staff, and third party procurement and preservation staff are empowered to call for a 'pause' on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt."[12] The Workgroup discussed these requirements and recommended that "patient" should also be included in the policy as a stakeholder who must be notified to account for cases in which the patient is conscious prior to withdrawal of life sustaining therapies. For example, a conscious, ventilator-dependent patient suffering from late-stage amyotrophic lateral sclerosis (ALS) or a high cervical spine fracture may make their own decisions related to DCD donation.[13] Regarding the process for informing stakeholders, the Workgroup agreed not to specify a particular format for informing stakeholders (e.g. verbal or written) but recommended time points within the donation process when stakeholders should be notified. Accordingly, the Committee proposes requiring the OPO to inform the patient, if applicable, or the patient's agent of the process for requesting an unplanned DCD pause at the time of authorization. The Committee proposes that the OPO must inform other stakeholders, including donor hospital staff, transplant center staff, OPO staff, and third-party procurement and preservation staff of the process for requesting an unplanned DCD pause as they become involved in the DCD process for a given patient. This will ensure that hospital staff and staff supporting organ donation who work in shifts are informed as shifts change over throughout the donation process.

HRSA's directive stated that proposed policies should address "requirements for informing legal next of kin (LNOK), primary healthcare team, hospital leadership team, and any transplant centers with provisional acceptances if a pause in DCD organ procurement is triggered or requested."[14] The Workgroup discussed the use of the term "legal next of kin" as being outdated due to the fact that not every decision maker is legally kin. The Workgroup proposed replacing references to "legal next of kin" to "agent" to broaden and capture these other possibilities.[15,16] The Workgroup discussed that a "requested" pause should be considered a "triggered" pause. In other words, the request for a pause from any stakeholder triggers specific actions, including suspending the DCD donation process, suspending allocation, and informing all existing stakeholders of the unplanned DCD pause.

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[11] *Ibid.*

[12] *Ibid.*

[13] American Society of Transplant Surgeons (ASTS), ASTS Statement on Conscious DCD, https://www.asts.org/docs/default-source/position-statements/asts-statement-on-conscious-dcd5e0ecdf3-86dd-4e4c-af02-5eea6e3433f7.pdf?sfvrsn=c6a4ed3_3 (Accessed November 12, 2025).

[14] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.

[15] Meeting Summary for April 16, 2025, OPTN Donation after Circulatory Death Policy Review Workgroup, https://optn.transplant.hrsa.gov/media/nmlnok2y/20250416_optn-opo_dcd-policy-review-workgroup_meeting-summary.pdf (accessed November 11, 2025).

[16] Meeting Summary for May 21, 2025, OPTN Donation after Circulatory Death Policy Review Workgroup, https://optn.transplant.hrsa.gov/media/ilgoy353/20250521_optn-opo_dcd-policy-review-workgroup_meeting-summary.pdf (accessed November 11, 2025).

Neurological assessments

HRSA's directive required "an addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure accuracy in neurological assessment and appropriate neurological re-assessments."[17] The Workgroup discussed that while OPOs should verify that neurological assessments are being conducted, the donor hospital staff hold the responsibility to perform the neurological assessments. To ensure appropriate care coordination between donor hospital staff and OPO staff, the Workgroup recommended that the OPO and primary healthcare team must confirm that withdrawal of life-sustaining therapies remains appropriate. This reassessment must occur at least every 12 hours from the time the OPO initiates the donation process, and within 2 hours prior to the planned withdrawal of life sustaining therapies. The Committee proposes incorporating these requirements into OPTN *Policy 2.15.C Potential DCD Donor Evaluation*.

Requirements for resuming procurement efforts following a pause

HRSA's directive stated that proposed policies should address "requirements for the OPO to fulfill prior to resuming procurement efforts, such as convening with the legal next of kin and primary healthcare team to discuss the patient's suitability for continued procurement efforts." Recognizing that the specific actions an OPO might take to resolve a pause may be in part dependent on state and local laws and regulations, the Workgroup recommended that OPTN policy requires OPOs to have a documented process that specifies how the OPO determines if the DCD donation process can proceed following a request for an unplanned DCD pause. The Committee proposes incorporating this requirement under OPTN *Policy 2.15.D Process for Unplanned Pause*.

HRSA's directive required that "in cases where procurement efforts are resumed after a pause has been triggered and discussed, the OPO must obtain acknowledgement from all transplant teams and their contracted representatives (i.e. procurement and preservation contractors) that they are aware of the pause and its resolution prior to the surgical procedure."[18] The Committee proposes incorporating this requirement under OPTN *Policy 2.15.E Response to a Request for an Unplanned DCD Pause*.

Reporting to the OPTN

HRSA's directive stated that proposed policies should address "a requirement for the OPTN to be informed within 24 hours of any requested or triggered pause, including specific data elements or records that should be included in the notification. MPSC [The OPTN Membership and Professional Standards Committee] will review the cadence and outcome of pauses during regular monthly meetings."[19] Per the directive, the Workgroup also considered data that should be collected regarding any pauses via an OPTN data collection instrument. Given that unplanned DCD pauses are expected to be rare, emergent events, the Workgroup recommended requiring reporting of such pauses via the OPTN Patient Safety Reporting Portal to facilitate more rapid implementation of these policies. The Workgroup suggested that the OPTN can monitor the volume and frequency of unplanned DCD pauses reported through the Patient Safety Portal and consider if further implementation within the OPTN Computer System is warranted.

The Committee proposes adding a requirement to OPTN *Policy 18.5.C Required Reporting by OPOs* for OPOs to report any request for an unplanned DCD pause to the OPTN Patient Safety Reporting Portal within 24 hours after the OPO becomes aware of the request. The Committee proposes specifying the

[17] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.
[18] *Ibid.*
[19] *Ibid.*

information that must be included in the patient safety report in OPTN *Policy 18.5.C.1 Required Reporting of Unplanned DCD Procurement Pause*. This information would include the OPTN donor ID, when the OPO began evaluating the donor, the role of the stakeholder requesting the pause and the rationale for requesting the pause, and verification that stakeholders were notified of the pause. **Appendix A** includes a template that OPOs may use to submit the required information to the OPTN. If it takes longer than 24 hours from the request for the pause for the OPO to determine whether the DCD donation process can resume or must be stopped, then the OPO must follow up within 24 hours of resumption of the case or submitting the donor organ disposition to provide more information on why the DCD donation process was resumed or stopped. This information can be provided as a follow-up to the original report to the OPTN Patient Safety Reporting Portal and should not be reported separately within the portal unless a subsequent pause was requested after the case resumed.

The Workgroup considered that an unplanned DCD pause could be requested for a patient who does not go on to donate any organs. Additionally, the Workgroup considered that an unplanned DCD pause could be requested early in the donation process, shortly after authorization for DCD donation was granted but prior to the OPO generating a donor ID for the patient in the OPTN Computer System. To ensure that a donor ID is generated for any patient who could have a requested unplanned DCD pause, the Committee proposes an addition to OPTN *Policy 2.2 OPO Responsibilities* requiring the OPO to register all authorized potential deceased donors in the OPTN Donor Data and Matching System. This change will allow any unplanned DCD pause reported via the OPTN Patient Safety Reporting Portal to be linked with data in the OPTN Donor Data and Matching System via the donor ID.

Furthermore, the Committee proposes expanding the scope of the donor organ disposition form to require completion of the form for all individuals, except living donors, from whom authorization for donation is granted. Currently, the donor organ disposition feedback form is only required to be completed for donors from whom at least one organ is recovered. For patients who do not go on to donate, the OPO would be obligated to complete the donor organ disposition form within 5 business days after the OPO determined no organs would be recovered from the patient. This timeline is similar to current reporting requirements, as the donor organ disposition form must be completed within 5 business days after the procurement date for patients from whom at least one organ is recovered. The Committee proposes incorporating this requirement into OPTN *Policy 18.1 Data Submission Requirements*. To accommodate the expanded scope, the Committee proposes adding two new disposition codes to the donor organ disposition form:

- Outside expiration time for DCD recovery
- Donation process stopped due to unplanned DCD pause

Taken together, these requirements will ensure the OPTN can link data and track outcomes for all of the following DCD scenarios:

- Patient with authorization for DCD donates one or more organs after an unplanned DCD pause
- Patient with authorization for DCD does not donate any organs due to unplanned DCD pause
- Patient with authorization for DCD does not donate any organs for other reasons

Finally, in addition to the requirements for reporting unplanned DCD pauses, the Committee proposes adding a requirement to OPTN *Policy 18.5.C Required Reporting by OPOs* for OPOs to report any auto-resuscitation event (spontaneous return of cardiac or respiratory activity) that occurs beyond the waiting period required by *Policy 2.15.J Organ Recovery.* The Committee considered whether OPTN policy should define a minimum waiting period of circulatory cessation before organ recovery can

proceed after circulatory death is determined.[20] The OPTN and HRSA issued a safety alert as a resource to provide awareness and guidance on best practices during rare cases of autoresuscitation during DCD processes, including suggestion of a waiting time of five minutes.[21] The Committee requests feedback from the community on whether the OPTN should define the minimum waiting period for determination of circulatory cessation in OPTN policy, and if so, how the OPTN might define that waiting period.

Requirements for family information

HRSA's directive called for the OPTN to propose requirements for family information about DCD organ procurement to be provided at the time of organ donation authorization, noting that "this education should include descriptions of any actions to be taken by the hospital and OPO should the patient not expire within the operative time limit or if organ procurement attempts are aborted in the operating room."[22] OPO professionals and patient and donor family representatives on the Workgroup collaborated to develop a set of required elements that must be included in this education. Recognizing that some of the information would be applicable to families of brain death donors as well as to families of potential DCD donors, the Committee proposes establishing a new policy outlining information that must be provided when requesting authorization for donation for any potential deceased donor patient. This information must include:

- List of organs that may be recovered and most likely uses for recovered organs
- Description of how the patient will be evaluated for donation and organ recovery process, to include:
    - Estimated time frames for donor evaluation and organ recovery
    - The need and process for a donor risk assessment interview
    - Laboratory evaluations including testing for infectious diseases according to Policy *2.9 Required Deceased Donor Infectious Disease Testing*
    - Description of procedures and medications that may be administered to the patient during the organ evaluation process
    - Allocation process and time frames for updates on allocation progress
- The possibility that organs may ultimately not be transplanted
- That any financial charges related to the donation process are the responsibility of the OPO
- The potential impact donation may have on funeral preparations such as timing and viewing
- Contact information for OPO staff if questions or concerns arise following authorization
- Copy of signed authorization form or first person authorization document

The Committee proposes required consent for certain procedures that may be done prior to withdrawal of live saving therapies such as cannulation that include that the:

- Patient or the patient's agent must specifically consent to cannulation and must be advised of complications that may occur during these procedures or that may occur if the patient does not expire in a timeframe that allows for organ donation to occur
- The OPO must confirm that the patient or the patient's agent has given consent for any DCD related procedures or drug administration that occur prior to patient death. If any premortem

[20] Meeting Summary for October 23, 2025, OPTN Organ Procurement Organization Committee, https://optn.transplant.hrsa.gov/media/dupoztka/20250612-opo-committee-meeting-summary.pdf (accessed November 7, 2025).
[21] John Magee, message to the OPTN community, November 11, 2025, Ensuring Safety and Reliability in DCD Protocols. https://optn.transplant.hrsa.gov/media/t4gb4okl/optn-autoresuscitation-safety-notice-11062025.pdf (accessed December 5, 2025).
(accessed December 5, 2025).

cannulation occurs, the patient or the patient's agent must specifically consent to the cannulation and must be advised of complications that may occur during these procedures, or that may occur if the patient does not expire in a time frame that allows for donation to occur.

For potential DCD donors, the Committee proposes requiring the additional information specific to the DCD process, including:

- Location in the donor hospital where withdrawal of life sustaining therapies will occur
- Time frame between withdrawal of life sustaining therapies and declaration of death for DCD to occur
- Plan for continued patient care if the patient does not expire in a time frame that allows for donation to occur
- Appropriate explanation of the potential for normothermic regional perfusion (NRP) if the OPO anticipates that NRP may be used in the organ recovery process, including:
    - The rationale for the recovery technique
    - That select organ function will likely occur
    - The safeguards that will be taken to prevent blood flow to the brain
- That any stakeholder in the DCD donation process, including the patient or patient's agent, may request an unplanned DCD pause according to *Policy 2.15.D Process for Unplanned DCD Pause*
- Reasons why a stakeholder may request an unplanned DCD pause
- That the donation process will stop if there is a decision not to move forward with withdrawal of life sustaining therapies

Standardizing procurement practices

The previous work done by the DCD Policy Review Workgroup identified additional opportunities to update OPTN DCD policies to standardize DCD procurement practices. The Committee proposes updates to policy on the following topics:

- Timing of family DCD donation discussion
- Use of DCD recovery protocols for brain death donors
- Updates to definitions and terminology for currency and clarity

Timing of Family DCD donation discussion

The Workgroup discussed the timing of discussions with potential donor families regarding donation. Current policy creates a clear division between care for a patient and the possibility of organ donation by requiring that discussions of organ donation could not take place until after the decision to withdraw life supporting therapies. The Workgroup believed this requirement was established to maintain individual and public trust. They acknowledged that it creates issues for potential donor families, as this requirement creates situations where they must make difficult decisions at the last minute. These last-minute changes can extend the timeline of events and alter the families' plans, resulting in additional grief for the family.

The Workgroup considered changing the policy to require that healthcare teams and organ procurement organizations collaborate to determine the best time for donation discussions with families based on the individual circumstances of each case.[23] This option was ultimately rejected, as the Workgroup felt that the use of collaboration was ill-defined and too vague for policy. The Workgroup felt the policy needed

[23] Meeting Summary for January 22, 2025, OPTN OPO Committee DCD Policy Review Workgroup, https://optn.transplant.hrsa.gov/media/wv3mi53k/20250122_optn-opo_optn-dcd-workgroup_meeting-summary.pdf (accessed October 23, 2025).

to have a specific point in time at which it would be acceptable for OPOs to discuss donations with donor families. They settled on altering the language to allow discussions for organ donation to take place once end of life discussions are taking place with the potential deceased donor's agent. The Workgroup determined that this would enable OPOs to speak to potential donor families and provide them with all the necessary information to make an informed decision without allowing discussions to occur too early.

There were additional discussions emphasizing the importance of ensuring conversations with potential donor families not being subjected to undue influence by the donation decision. Undue influence is a term to describe a family or community member who intentionally or unintentionally influences a patient to choose a treatment plan the patient does not truly desire.[24] The Committee proposed including language stating, "the decision to withdraw life sustaining therapies should not be influenced by the donation decision." The Committee seeks feedback from the community on how the OPTN may be able to identify, report, or evaluate instances of undue influence in the donation decision and further defining the responsibilities related to the timing of the family discussion for donation.

The proposed changes include:

- Replace "the OPO must confirm that the legal next of kin has elected to withdraw life sustaining medical treatment" with "the host OPO must confirm with the patient's healthcare team and document that end-of-life discussions have been initiated with the patient or patient's agent" to allow potential donor families to make informed decisions
- Add "the decision to withdraw life sustaining therapies should not be influenced by the donation decision" to ensure appropriate medical care of the patient

Use of DCD recovery protocols for brain death donors

There are some instances where a patient has experienced brain death and the family members express a desire to be with the patient until their heart stops beating. Currently, policy does not specify whether organs from these donors should be allocated under policies for brain death donors or policies for DCD donors. The Workgroup discussed that while these cases are not frequent, there should be a standardized approach for addressing these scenarios.[25] Transplant surgeons participating in the Workgroup advised that donors undergoing DCD recovery should be allocated as DCD donors, given the potential for the donor's organs to incur additional ischemic time. The Committee proposes adding new *Policy 2.15.L Brain Dead Donors Recovered Using DCD Protocols* to require the OPO to take the following actions in these cases:

1. Document in the OPTN Donor Data and Matching System the justification for undergoing DCD recovery
2. Notify transplant programs that a DCD match run will be used for the donor
3. Execute the match run as a DCD donor

The Committee recommends that this documentation should be made in Donor Highlights in the OPTN Donor Data and Matching System. The Committee also proposes adding language to *Policy 2.15.J Organ Recovery* to indicate that a predetermined waiting period of circulatory cessation is not required when

[24] Fuller T, Hendrick J, Beck AC. Undue Influence versus Relational Autonomy in Clinical Decision Making #439. J Palliat Med. 2022 Jun;25(6):996-997. doi: 10.1089/jpm.2022.0089. PMID: 35647638. (Accessed November 7, 2025).
[25] Meeting Summary for May 21, 2025, OPTN OPO Committee DCD Policy Review Workgroup, https://optn.transplant.hrsa.gov/media/ilgoy353/20250521_optn-opo_dcd-policy-review-workgroup_meeting-summary.pdf (accessed October 23, 2025).

the patient has been declared brain dead but their organs are subsequently recovered under DCD protocols.

Updates to definitions and terminology for currency and clarity

The Committee proposes several updates to policy definitions and terminology for clarity and to reflect preferred terminology. Proposed changes include:

- Remove reference to the term "consent" from the definition of "authorization"
- Revise policies related to authorization and consent for DCD to distinguish between authorization for DCD donation broadly, and specific consent for any DCD related procedures or drug administration that occur prior to patient death
- Replace references to life sustaining "medical treatment or ventilated support" to "life sustaining therapies"

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of NOTA, which requires the OPTN to "adopt and use standards of quality for the acquisition … of donated organs,"[26] and to "provide information to physicians and other health professionals regarding organ donation."[27] This proposal would update standards in OPTN policy for acquiring DCD organs. Additionally, this proposal would add requirements for providing information to donor hospital physicians and other health professionals regarding safeguards for patients in the organ donation process.

The Committee also submits this proposal under the OPTN Final Rule that states, "policies on such other matters as the Secretary directs."[28] This proposal was developed in accordance with the HRSA directive received by the OPTN on May 28, 2025.[29]

Implementation Considerations

Member and OPTN Operations

This proposal is primarily anticipated to affect the operations of organ procurement organizations and the OPTN. The proposal may also affect operations of transplant hospitals but is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

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, confirming the plan for continued patient care if a potential DCD donor does not expire in a time frame that allows for DCD donation to occur, ensuring appropriate neurological reassessments, and reporting unplanned DCD pauses to the OPTN. OPOs must provide this information to all stakeholders which include the patient or patient's agent, donor hospital staff, transplant center

[26] 42 USC §274(b)(2)(E).
[27] 42 USC §274(b)(2)(H).
[28] 42 CFR §121.4(a)(6).
[29] Suma Nair, letter to Richard N. Formica, Jr., and Rexanah Wyse Morrissette, May 28, 2025, https://optn.transplant.hrsa.gov/media/j3zpoia2/opo-corrective-action-plan-and-optn-directive_5282025_redacted_508.pdf.

staff, OPO staff, and third-party procurement and preservation staff. OPOs may need to modify existing workflows to support their updated protocols and provide training to staff on the changes. OPOs may also need to modify existing workflows to ensure all authorized donors are registered in the OPTN Computer System, and that the donor organ disposition is submitted for all patients, except living donors, for whom or from whom authorization for donation is granted.

Operations affecting Transplant Hospitals

Transplant hospitals will need to inform staff of the policy changes. While this proposal would not require action from transplant hospitals to implement, transplant hospitals should be aware of the policies regarding unplanned DCD pauses in the event they are contacted about an unplanned DCD pause for a donor from which their transplant program(s) has accepted one or more organs. Additionally, transplant hospital staff should be aware that organs from brain dead donors whose families request recovery via DCD protocols will be allocated as DCD organs.

Operations affecting the OPTN

The OPTN will implement changes to donor disposition reporting in the OPTN Donor Data and Matching System. The OPTN will provide a template for reporting unplanned DCD pauses via the OPTN Patient Safety Reporting Portal. The OPTN will update OPTN policies and the OPTN member evaluation plan and communicate changes to members.

Potential Impact on Select Patient Populations

This proposal is intended to improve safeguards for patients in the donation after circulatory death (DCD) pathway in the organ procurement process and increase information shared with patient families regarding DCD organ procurement. This proposal would also require additional information sharing with families of patients who are approached for authorization for organ donation following brain death. This proposal is not expected to impact transplant candidates or transplant recipients.

Projected Fiscal Impact

Projected Impact on the OPTN [30]

It is estimated that $(**redacted**) - $(**redacted**) would be needed to implement this proposal. Implementation would involve updates to the OPTN Computer System that include developing the solution, coding, and testing to support the updated policy requirements and associated system tools. In addition, implementation would include building communications and education materials, updating process documents, and community outreach. It is estimated that $(**redacted**) - $(**redacted**) would be needed for ongoing support. Ongoing support includes member support and education, compliance monitoring, system maintenance, and answering member questions as necessary. In addition, ongoing support will include a monitoring report at the 6-month, 1-year, and 2-year timeframes. The total for implementation and ongoing support is estimated to be $(**redacted**) - $(**redacted**).

[30] Unredacted cost information has been made available to OPTN Board members.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews."[31] During site surveys, an OPTN Contractor, on behalf of the OPTN, will review a sample of deceased donor medical records, and any material incorporated into the medical record by reference, as well as any required written protocols and related internal polices for compliance with updated OPO responsibilities related to deceased donor organ procurement and requirements for controlled DCD protocols. This may include:

- Verification of written protocols that specify the required disclosure information for the donor or donor's agent as specified in *OPTN Policy 2.3*, and in the case of authorization for DCD, the additional information required per *OPTN Policy 2.15.F.*
- Documentation confirming that the patient's healthcare team initiated end-of-life discussions with the patient or patient's agent, prior to the OPO initiating any discussion about organ donation.
- Documentation related to potential DCD donor evaluation including:
    - Confirmation of the plan for continued patient care if the patient does not expire in a time frame that allows for DCD to occur.
    - Confirmation from the OPO and primary healthcare team that withdrawal of life-sustaining therapies remains appropriate. This reassessment must occur at least every 12 hours from the time the OPO initiates the donation process, and within 2 hours prior to the planned withdrawal of life sustaining therapies.
- Verification of documented processes for unplanned DCD pauses including:
    - Informing the patient or patient's agent and all stakeholders of the process for requesting an unplanned DCD pause.
    - Convening all existing stakeholders, including the individual who requested the unplanned DCD pause, to consider the rationale for requesting the pause and actions to be taken to address the unplanned DCD pause.
    - How the OPO determines if the DCD process can proceed following a request for an unplanned DCD pause.
- Confirmation that the patient or the patient's agent has given consent for any DCD related procedures or drug administration that occur prior to patient death, including specific consent for premortem cannulation.
- Documentation of the deceased donor's agent's direction in cases of brain dead donors that are recovered using DCD protocols.

Any data entered into OPTN Computer System may be reviewed by the OPTN, and members are required to provide documentation as requested. Additionally, an OPTN Contractor will continue to send inquiries on behalf of the Membership and Professional Standards Committee (MPSC) to OPTN members who report patient safety events. This includes all required reporting events such as requested unplanned DCD pauses according to *Policy 2.15.D,* and auto-resuscitation events that occur beyond the waiting period required by *Policy 2.15.J.* Information about the event will be requested, such as:

- Procedures and protocols

[31] 42 CFR §121.8(a)(7).

- Quality review processes
- Plans for improvement
- Specifically for unplanned DCD pause events:
    - Any missing required data per *OPTN Policy 18.5.C.1*
    - Any required data related to the resumption or termination of cases following an unplanned pause event, if not submitted in the initial report.

The MPSC will continue to review the information submitted by the member and may request that the member submit additional information about certain aspects of the program or submit a plan for quality improvement. The MPSC may also request that a member participate in additional engagement with the MPSC, such as an informal discussion or a peer visit. In rare circumstances where the MPSC identifies a potential ongoing risk to patient health or public safety, the MPSC may request that a member inactivate to mitigate the risk.

Policy Evaluation

The Committee considers the number of unplanned DCD pauses the key metric to assess the outcome of the proposed change.

Metrics to be evaluated include:

1. The number of unplanned DCD pauses
2. Other metrics as requested by the Committee

These metrics will be reviewed at approximately six months, one year, and two years post-implementation.

Conclusion

As the number of patients for whom DCD is attempted continues to increase, it is imperative to improve safeguards for potential DCD patients, improve family communication, and update policies that will promote standardization in DCD practices. This proposal updates policies that will further define and provide more standardization in DCD practices across OPOs. Additionally, this proposal will require OPOs to report cases of unplanned DCD pauses that could potentially inform future considerations.

Considerations for the Community

- 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?
- Are the requirements for OPOs to report unplanned DCD pauses clear? Are there areas where the OPTN should consider improvements to make the language clearer?

- Should the OPTN recommend these proposed OPTN polices be approved by the Secretary of Health and Human Services and made enforceable by HHS, in accordance with the process outlined in the OPTN Final Rule?[32]

[32] 42 CFR §§ 121.4(b)(2)-(c), available at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1.2 Definitions

Agent

A person legally authorized to act on behalf of another person.

Authorization

The act of granting permission for a specific act. ~~This is sometimes called consent, which is not to be confused with informed consent.~~ Authorization for organ donation may be given by a patient (commonly known as First Person Authorization, or FPA) or by the patient's agent.

Donation after Circulatory Death (DCD)

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. A DCD donor may also be called a non-heart beating, asystolic, or donation after cardiac death donor.

Unplanned DCD pause

An unexpected suspension of the DCD process due to a difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies. An unplanned DCD pause is not intended to address issues or questions related to authorization for donation.

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating referred patients for potential deceased ~~donors~~ donation.
4. Registering all patients authorized for deceased donation in the OPTN Donor Data and Matching System no later than the time at which the OPO decides to proceed with the donation process.
5. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
6. Verifying that death is pronounced according to applicable laws.
7. Informing all stakeholders involved in the donation after circulatory death (DCD) process of the process for requesting an unplanned DCD pause in accordance with *Policy 2.15.D: Process for an Unplanned DCD Pause*. Stakeholders include the patient or patient's agent, donor hospital staff, OPO staff, and third-party procurement and preservation staff.
8. Ensuring accuracy in neurological assessment and appropriate neurological reassessments in accordance with *Policy 2.15.C: Potential DCD Donor Evaluation*.
9. Establishing and then implementing a plan to address organ donation for diverse cultures and

ethnic populations.

10. Ensuring the clinical management of the deceased donor.
11. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
12. Assessing deceased donor organ quality.
13. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
14. Executing the match run and using the resulting match for each deceased donor organ allocation.
15. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
16. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information*, is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
17. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
18. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The samples must be collected within 24 hours prior to organ procurement. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.3 Required Disclosure Information for the Donor or Donor's Agent

The OPO must have a written protocol specifying the information that must be provided to the donor or the donor's agent when the authorization for donation is confirmed. At a minimum, this information must include the following:

1. List of organs that may be recovered and most likely uses for recovered organs
2. Description of the donor evaluation and organ recovery process, to include:
    a. Estimated time frames for donor evaluation and organ recovery
    b. The need and process for a donor risk assessment interview
    c. Laboratory evaluations including testing for infectious diseases according to Policy *2.9: Required Deceased Donor Infectious Disease Testing*

d. Description of procedures and medications that may be administered during the organ evaluation process

e. Allocation process and time frames for updates on allocation progress

3. The possibility that organs may ultimately not be transplanted

4. That any financial charges related to the donation process are the responsibility of the OPO

5. The potential impact donation may have on funeral preparations such as timing and viewing

6. Contact information for OPO staff if questions or concerns arise following authorization

7. Copy of signed authorization form or first person authorization document

When requesting authorization for donation after circulatory death (DCD), the OPO must provide additional information according to *Policy 2.15.F: Authorization for DCD*.

2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. Potential DCD donors are limited to patients who have died, or whose death is imminent, whose medical treatment no longer offers a medical benefit to the patient as determined by the patient, the patient's ~~authorized surrogate~~agent, or the patient's advance directive if applicable, in consultation with the patient's healthcare team. Any planned withdrawal of life sustaining ~~medical treatment/support~~ therapies will be carried out in accordance with hospital policy. Prior to the OPO initiating any discussion with the ~~legal next-of-kin~~ patient's agent about organ donation ~~for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment.~~ the host OPO must confirm with the patient's healthcare team and document that end-of-life discussions have been initiated with the patient or patient's agent. The timing of a potential DCD donor evaluation and donation discussion will be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy. The decision to withdraw life sustaining therapies should not be influenced by the donation decision. Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statutes or regulation. A DCD donor may also be called a non-heartbeating, asystolic, or donation after cardiac death donor.

These policies will help OPOs and transplant hospitals develop necessary DCD protocols. These set the minimum requirements for DCD recovery but do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs, transplants hospitals, and donor hospitals.

2.15.A Agreement

The OPO must have a written agreement with all hospitals that participate in DCD recovery.

2.15.B Protocols

OPOs and donor hospitals must establish written protocols that define the roles and responsibilities for the evaluation and management of potential DCD donors, organ recovery, and organ placement in compliance with OPTN Policy. OPOs must make their written protocols available to the OPTN on request.

2.15.C Potential DCD Donor Evaluation

The primary healthcare team and the OPO must evaluate potential DCD donors to determine if the patient meets the OPO's criteria for DCD ~~donation~~. If the patient meets the OPO's criteria for DCD, the OPO must confirm the plan for continued patient care if the patient does not expire in a time frame that allows for DCD to occur. The OPO and primary healthcare team must confirm that withdrawal of life-sustaining therapies remains appropriate. This reassessment must occur at least every 12 hours from the time the OPO initiates the donation process, and within 2 hours prior to the planned withdrawal of life sustaining therapies.

2.15.D Process for Unplanned DCD Pause

2.15.D.i Process for a Pause

OPOs must establish and document a process by which an unplanned pause in the DCD process may be requested due to an unresolved difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies. Such an unplanned DCD pause may be requested by any stakeholder as defined per *Policy 2.2: OPO Responsibilities* in the DCD process between the time that authorization for DCD is granted per *Policy 2.15.F: Authorization for DCD* and the time of cross clamp. The process must specify how the OPO determines if the DCD process can proceed following a request for an unplanned DCD pause. At a minimum, this process must include convening all existing stakeholders, including the individual who requested the unplanned DCD pause, to consider the rationale for requesting the pause and actions to be taken to address the unplanned DCD pause.

2.15.D.ii Required Notification of the Process for a Pause

At the time of authorization, the OPO must inform the patient, if applicable, or patient's agent of the process for requesting an unplanned DCD pause. As they become involved in the DCD process, the OPO must inform donor hospital staff, transplant center staff, OPO staff, and third-party procurement and preservation staff of the process for requesting an unplanned DCD pause.

2.15.E Response to a Request for an Unplanned DCD Pause

Once the OPO is made aware of a request for an unplanned DCD pause, the OPO must suspend the DCD process, suspend allocation, and inform all existing stakeholders of the unplanned DCD pause. The OPO and donor hospital care team will collaborate to determine whether the patient still meets the donor hospital's criteria for withdrawal of life sustaining therapies. If the patient no longer meets the donor hospital's criteria for withdrawal of life sustaining therapies, the OPO will stop the DCD process. This shall not preclude the OPO from restarting the DCD process if the patient is later found to be a suitable candidate for withdrawal of life sustaining therapies, and the patient or patient's agent and donor hospital care team elect to withdraw life sustaining therapies.

When the OPO determines that the DCD process can resume following an unplanned DCD pause, the OPO must obtain acknowledgment prior to organ recovery from all transplant programs that accept an organ from the donor and any contracted representatives, such as third party contractors, involved in organ recovery that they are aware that the unplanned DCD pause occurred and acknowledge the decision to proceed.

The OPO must inform the OPTN of any unplanned DCD pause and its outcome according to *Policy 18.5.C: Required Reporting by OPOs*.

2.15.~~D~~F ~~Consent for DCD~~ Authorization for DCD

~~Conditions involving a potential DCD donor being medically treated/supported in a conscious mental~~

~~state~~
~~will require that the OPO confirms that the healthcare team has assessed the patient's competency and capacity to make withdrawal/support and other medical decisions.~~

~~The OPO must confirm that consent has been obtained for any DCD related procedures or drug administration that occur prior to patient death.~~

Authorization for a DCD recovery must be obtained from *either* of the following:

1. The patient
2. Persons defined by state/local laws to authorize organ donation, such as the patient's agent

In addition to the requirements in *Policy 2.3: Required Disclosure Information for the Donor or Donor's Agent*, the OPO must provide to the patient or the patient's agent, at a minimum, the following:

- Location in the donor hospital where withdrawal of life sustaining therapies will occur
- Time frame between withdrawal of life sustaining therapies and declaration of death for DCD to occur
- Plan for continued patient care if the patient does not expire in a time frame that allows for DCD to occur
- Appropriate explanation of the potential for normothermic regional perfusion (NRP) if the OPO anticipates that NRP may be used in the organ recovery process, including:
    - The rationale for the recovery technique
    - That select organ function will likely occur
    - The safeguards that will be taken to prevent blood flow to the brain
- That any stakeholder in the DCD process, including the patient or patient's agent, may request an unplanned DCD pause according to *Policy 2.15.D Process for Unplanned DCD Pause*
- Reasons why a stakeholder may request an unplanned DCD pause
- That the donation process will stop if there is a decision not to move forward with withdrawal of life sustaining therapies

2.15.~~E~~G ~~Authorization for DCD~~ Consent for Procedures Pre-DCD

~~For the purpose of obtaining authorization for a DCD recovery, "legal next of kin" can include *any* of the following:~~
~~1. The patient who authorizes deceased donation.~~

~~2. Person defined by state/local laws to authorize organ donation.~~

The OPO must confirm that the patient or the patient's agent has given consent for any DCD related procedures or drug administration that occur prior to patient death. If any premortem cannulation occurs, the patient or the patient's agent must specifically consent to the cannulation, and must be advised of complications that may occur during these procedures, or that may occur if the patient does not expire in a time frame that allows for DCD to occur.

2.15.~~F~~H Withdrawal of Life Sustaining ~~Medical Treatment or Support~~ Therapies

Prior to the donor hospital withdrawing life sustaining ~~medical treatment or ventilated support~~

therapies, the OPO is required to conduct a timeout to confirm:

1. The patient's identification.
2. The process for withdrawing life sustaining ~~treatment or ventilated support.~~ therapies
3. Roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
4. The hospital's plan for continued patient care if the patient does not become a donor, and appropriate communication with the next of kin.

No recovery personnel (surgeons and other recovery practitioners) may be present for the withdrawal of life sustaining ~~medical treatment or ventilated support~~ therapies. No member of the organ recovery team or OPO staff may guide or administer palliative care or declare death.

2.15.~~G~~I Pronouncement of Death

The donor hospital healthcare team member who declares death cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

2.15.~~H~~J Organ Recovery

Organ recovery will only proceed after circulatory death is determined, inclusive of a predetermined waiting period of circulatory cessation to ensure no auto-resuscitation occurs. unless the recovery is made pursuant to *Policy 2.15.~~J~~L: Brain Dead Donors Recovered Using DCD Protocols*.

2.15.~~I~~K Potential DCD ~~Potential~~ Donor Who Converts to Brain Death after an Organ Offer Has Been Made

When a potential DCD donor converts to brain death, the host OPO must re-execute the match system and allocate the organs according to the organ allocation policies. *Policy 5.4: Organ Offers* does not apply when a DCD donor converts to brain death. Additionally, OPOs should initiate allocation of organs that may have been ruled out due to the donor's initial DCD status.

However, the host OPO may choose not to reallocate organs from a DCD donor who converts to brain death for any one of the following reasons:

1. Donor instability
2. Lack of donor family approval and authorization
3. Other extraordinary circumstances

The host OPO must document the reason for not reallocating organs when a DCD donor converts to brain death and make this documentation available to the OPTN on request.

2.15.~~J~~L Potential Brain Dead Donors Recovered Using DCD Protocols

When a potential donor is declared brain dead and the deceased donor's agent directs that recovery be done under DCD protocols the OPO must do all of the following:

1. Document in the OPTN Donor Data and Matching System the justification for undergoing DCD recovery
2. Notify transplant programs that a DCD match run will be used by documenting that notification in the OPTN Donor Data and Matching System

3. Execute the match run as a DCD donor

9.10.B Expedited Liver Offers

The host OPO or the Organ Center is permitted to make expedited liver offers if both of the following conditions are met:

1. The donor has entered the operating room or, in the case of a DCD donor, withdrawal of life sustaining ~~medical support~~ therapies has been initiated, whichever occurs first.

2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential transplant recipient will no longer accept the liver.

Prior to sending expedited liver offers, the host OPO or Organ Center must report all of the following information to the OPTN:

1. Date and time donor entered the operating room or withdrawal of life sustaining ~~medical support~~ therapies was initiated, whichever occurs first.

2. Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient.

3. Reason for organ offer refusal by the primary potential transplant recipient.

Expedited liver offers will be made to potential transplant recipients on the match run who are eligible to receive expedited liver offers as described in OPTN *Policy 9.10.A: Expedited Liver Placement Acceptance Criteria*.

Transplant hospitals must accept an expedited offer within 30 minutes of notification to be eligible to receive the liver. Once this time limit has expired, the host OPO or Organ Center must place the liver with the potential transplant recipient with the provisional yes that appears highest on the match run.

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

The following member:	Must submit the following materials to the OPTN:	Within:	For:
		list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	
OPOs, all	*Death notification records* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	*VCA Candidate List*	30 days after the procurement date	Each covered deceased donor VCA organ that is offered to a potential covered VCA recipient
Host OPO	*Donor organ disposition (feedback)*	*Either* of the following: • 5 business days after the OPO determined no organs would be recovered from the individual • 5 business days after the procurement date	Individuals, except living donors, ~~from~~for whom ~~at least one organ is recovered~~ authorization for donation is granted

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Host OPO	*Deceased donor registration* (DDR)	30 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor feedback* Members must amend the form or contact the OPTN Contractor to amend this form according to *Policy 18.6: Reporting of Living Donor Adverse Events*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the recovery hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA, domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	Either of the following: • 30 days after the six-month and annual	Each recipient followed by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
		anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital submits the *recipient feedback* form	Each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	*Candidate Removal Worksheet*	1 day after the transplant	Each covered VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.5.C Required Reporting by OPOs

OPOs must report the following events to the OPTN according to *Table 18-5* below.

Table 18-5: Required Reporting by OPOs

Host OPOs must report if:	To the:	Within:	~~Within 72 hours after:~~ After:
An unplanned pause is requested in the DCD process according to *Policy 2.15.D: Process for Unplanned DCD Pause*	OPTN Patient Safety Reporting Portal	24 hours	The OPO becomes aware
An auto-resuscitation event occurs beyond the waiting period required by *Policy 2.15.J: Organ Recovery*	OPTN Patient Safety Reporting Portal	24 hours	The OPO becomes aware
Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required	OPTN Patient Safety Reporting Portal	72 hours	The OPO becomes aware
An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in *Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype*, and after the OPO has executed a match run	OPTN Patient Safety Reporting Portal	72 hours	The OPO becomes aware

18.5.C.1 Required Reporting of Unplanned DCD Procurement Pause

When an unplanned pause is requested in the DCD process according to *Policy 2.15.D: Process for Unplanned Pause*, the notification to the OPTN must include:

- OPTN donor ID
- Date and time the OPO decided to proceed with the donation process
- Date and time the OPO became aware of the request for an unplanned DCD pause
- Role of the stakeholder requesting the unplanned DCD pause
- Rationale for requesting the unplanned DCD pause
- Verification of dates and times that the following individuals, at a minimum, were notified of the unplanned DCD pause:
    - Patient, if applicable, or patient's agent
    - Patient's healthcare team
    - Hospital leadership team

- OPO leadership team
- Any transplant programs with an organ offer acceptance

When the DCD process resumes following an unplanned pause, the OPO must provide the following information to the OPTN within 24 hours of resumption of the DCD process:

- OPTN donor ID
- Actions taken by the OPO to address the unplanned DCD pause
- The transplant programs and procurement staff notified of the unplanned DCD pause
- Date and time when the DCD process resumed
- Rationale for resuming the DCD process

When the DCD process is stopped due to an unplanned DCD pause, the OPO must provide the following information to the OPTN within 24 hours of submitting the donor organ disposition:

- OPTN donor ID
- Actions taken by the OPO to address the unplanned DCD pause
- Date and time when the DCD process was stopped
- Rationale for stopping the DCD process
- The transplant programs and procurement staff notified that the DCD process was stopped

The OPO must preserve any records related to the pause and make those records available to the OPTN on request.

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Appendix A: Unplanned DCD Pause Reporting Template

The following is a template that OPOs may use to submit the required reporting information to the OPTN. This information can be provided as a follow-up to the original report to the OPTN Patient Safety Reporting Portal and should not be reported separately within the portal unless a subsequent pause was requested after the case resumed.

Report Unplanned Donation after Circulatory Death (DCD) Pause to the OPTN

OPTN donor ID: Enter OPTN donor ID

Date and time the OPO decided to proceed with the donation process:

Click or tap to enter a date.

HH:MM

Date and time the OPO became aware of a request for an unplanned DCD pause:

Click or tap to enter a date.

HH:MM

Role of the stakeholder requesting the unplanned DCD pause: Choose an item.

Rationale for requesting the unplanned DCD pause: Enter rationale

Verification of dates and times that the following individuals were notified of the unplanned DCD pause:

Patient Click or tap to enter a date. HH:MM **Not applicable** ☐

Patient's agent Click or tap to enter a date. HH:MM **Not applicable** ☐

Hospital leadership team Click or tap to enter a date. HH:MM

OPO leadership team Click or tap to enter a date. HH:MM

Any transplant programs with an organ offer acceptance

Heart: Click or tap to enter a date. HH:MM **Not applicable** ☐

Lung: Click or tap to enter a date. HH:MM **Not applicable** ☐

Liver: Click or tap to enter a date. HH:MM **Not applicable** ☐

Pancreas: Click or tap to enter a date. HH:MM **Not applicable** ☐

Kidney: Click or tap to enter a date. HH:MM **Not applicable** ☐

VCA: Click or tap to enter a date. HH:MM **Not applicable** ☐

Actions take by the OPO to address the unplanned DCD pause: Click or tap here to enter text.

Transplant programs and procurement staff notified of the unplanned DCD pause: Click or tap here to enter text.

Date and time when the DCD process resumed: Click or tap to enter a date. HH:MM **Not applicable** ☐

Rationale for resuming the DCD process: Click or tap here to enter text.

Date and time when the DCD process was stopped: Click or tap to enter a date. HH:MM **Not applicable** ☐

Transplant programs and procurement staff notified that the DCD process was stopped: Click or tap here to enter text.

Appendix B: DCD Pause Scenarios (Reportable versus Non-Reportable)

The following are scenarios demonstrating examples of pauses in the DCD process. For each scenario, an explanation is included to distinguish which types of cases would be considered an unplanned DCD pause that would need to be reported based on the proposed requirements outlined above.

The proposed policy definition of an "unplanned DCD pause" is "an unexpected suspension of the DCD process due to a difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies. An unplanned DCD pause is not intended to address issues or questions related to authorization for donation."

Scenario 1

A hospital refers a patient to the OPO as a potential donor. The OPO checks the state donor registry and determines that the patient is registered as an organ donor. Hospital reports to the OPO that the patient's agent is considering withdrawal of support. The OPO and hospital collaborate to explain to the patient's agent that the patient is a registered donor, and to explain how donation will affect the withdrawal process. The OPO provides information about donation after circulatory death, including how and why to initiate an unplanned DCD pause, and information about normothermic regional perfusion.

Scenario 1A: The patient's agent expresses concern about the process and leaves the hospital. The OPO begins the formal donor workup, registers the donor with the OPTN Donor Data and Matching System, and begins evaluation. The patient's agent returns to the hospital and states that she wants life-sustaining therapy withdrawn immediately and she does not want the patient to be a donor. The OPO and hospital staff explain that the patient's organ donor registration is binding under state law and that withdrawal of life-sustaining therapy will occur as soon as the resources for organ recovery are in place. The patient's agent announces that she is declaring a pause as the OPO had explained to her earlier.

*This **is not** an unplanned DCD pause per the proposed OPTN policy. Pauses undertaken for issues relating to authorization are not reportable as an unplanned DCD pause. Hospitals and OPOs should work collaboratively to address issues regarding authorization with donor agents consistent with state law and local policy.*

Scenario 1B: The patient's agent agrees with the process and leaves the hospital. The OPO begins the formal donor workup, registers the donor with the OPTN Donor Data and Matching System, and begins evaluation. The OPO coordinator documents the patient's initial presenting neurologic status (as examined by the bedside nurse) in the OPO record. Eight hours later, the patient's bedside nurse notifies the OPO coordinator that the patient is now opening his eyes and following commands. The OPO coordinator recommends that the nurse notify the patient's attending physician. The physician examines the patient and confirms the nurse's findings. The physician contacts the patient's agent and reports this change. The physician also recommends that the patient's agent reconsider the decision to withdraw life-sustaining therapy, which will also have the effect of stopping the donation evaluation process. The agent agrees, and the physician notifies the OPO coordinator that life-sustaining therapies will continue. The OPO coordinator confirms the decision with the patient's agent, offers gratitude for the patient's donation decision, and offers additional support, if needed.

*This **is not** an unplanned DCD pause. All stakeholders agree that withdrawal of life-sustaining measures is not appropriate and agree to stop the DCD process. This pause does not need to be reported.*

Scenario 2

A hospital refers two patients to the OPO as potential donors as follows:

- **Patient A (refer to Scenario 2A for additional description):** The OPO checks the state donor registry and determines the patient is registered as an organ donor. The hospital reports to the OPO that the patient's agent is considering withdrawal of support. OPO and hospital collaborate to explain to the agent that the patient is a registered donor, and to explain how donation will affect the withdrawal process. The OPO provides information about donation after circulatory death, including how and why to initiate a pause, and information about normothermic regional perfusion.
- **Patient B (refer to Scenario 2B for additional description):** The OPO determines that the patient is not registered as an organ donor. The hospital reports to the OPO that the patient's agent is considering withdrawal of support. The OPO and hospital collaborate to offer the patient's agent the option of organ donation after circulatory death (DCD), and to explain how donation will affect the withdrawal process. The OPO discloses information about DCD, including how and why to initiate a DCD pause, and information about normothermic regional perfusion.

Scenario 2A: The patient's agent gives authorization for DCD and consent for procedures needed for DCD and leaves the hospital. The OPO begins the formal donor workup, registers the donor with the OPTN Donor Data and Matching System, and begins evaluation. The OPO coordinator documents the patient's initial presenting neurologic status (as examined by the bedside nurse) in the OPO record. Eight hours later, the patient's bedside nurse notifies the OPO coordinator that the patient is now opening his eyes and following commands. The OPO coordinator recommends that the nurse notify the patient's attending physician. The physician examines the patient and confirms the nurse's findings. The physician contacts the patient's agent and reports this change. The physician also recommends that the patient's agent reconsider the decision to withdraw life-sustaining therapy, which will also have the effect of stopping the donation evaluation process. The agent agrees, and the physician notifies the OPO coordinator that life-sustaining therapies will continue. The OPO coordinator confirms the decision with the patient's agent, offers gratitude for the patient's donation decision, and offers additional support, if needed.

*This **is not** an unplanned DCD pause. All stakeholders agree that withdrawal of life-sustaining measures is not appropriate and agree to stop the DCD process. This pause does not need to be reported.*

Scenario 2B: The patient's agent gives authorization for DCD and consent for procedures needed for DCD. The OPO begins the formal donor workup, registers the donor with the OPTN Donor Data and Matching System, and begins evaluation. At shift change, the OPO coordinator meets with the new shift patient care team and reminds them of the option to request a DCD pause. An hour later, the patient's bedside nurse expresses concern to the patient's physician that the patient's true neurologic status may be obscured by the medications given to prevent the patient's seizures. The physician states that the previous shift's physician felt that withdrawal of life support was acceptable and is not willing to overturn that decision. The nurse notifies the OPO coordinator that she is calling for a pause because of her concern.

*This **is** a reportable unplanned DCD pause. There is a difference of opinion among the stakeholders that the patient may be at risk for inappropriate withdrawal of life-sustaining therapies.*

Scenario 3

A hospital refers a patient to the OPO as a potential donor. The OPO determines that the patient is not registered as an organ donor. The hospital reports to the OPO that the patient's agent is considering withdrawal of support. The OPO and hospital collaborate to offer the patient's agent the option of organ donation after circulatory death (DCD), and to explain how donation will affect the withdrawal process. The OPO provides information about DCD, including how and why to initiate a pause, and information about normothermic regional perfusion.

The patient's agent gives authorization for DCD and gives consent for pre-recovery procedures (including bronchoscopy and coronary angiography) as part of the donor evaluation process. The OPO begins the formal donor workup, registers the donor with the OPTN Donor Data and Matching System, and begins evaluation. At shift change, the OPO coordinator meets with the new shift patient care team and reminds them of the option to request a pause. During the organ allocation process, a lung center requests a bronchoscopy. The OPO coordinator requests this procedure through the hospital's usual process. A consulting physician arrives to perform a bronchoscopy. The OPO coordinator, while observing the procedure, notes that the patient is presenting signs of increased neurological function and mentions this to the physician. The physician states that these are reflexes and not reflective of increased neurological function. The OPO coordinator announces that she is requesting a DCD pause because of her concern.

*This **is** a reportable unplanned DCD pause. There is a difference of opinion among the stakeholders that the patient may be at risk of experiencing increased neurological function during the DCD evaluation process and may not be appropriate for withdrawal of life-sustaining care.*

Scenario 4

A hospital refers a patient to the OPO as a potential donor; the patient's injury is related to an overdose of a narcotic. The OPO determines that the patient is not registered as an organ donor. The hospital reports to the OPO that the patient's agent is considering withdrawal of life sustaining therapies. The OPO and hospital collaborate to offer the patient's agent the option of organ donation after circulatory death (DCD), and to explain how donation will affect the withdrawal process. The OPO provides information about DCD, including how and why to initiate a pause, and information about normothermic regional perfusion.

The primary care team notes changes in the patient's neurologic assessment on the third day of the patient's stay, after authorization has been provided and the donor OR has been scheduled. The bedside nurse voices concern that withdrawal of life-sustaining therapies may not be appropriate, that psychoactive substances in the overdose and/or sedation may have been inhibiting the accuracy of the neurologic assessment around the time when the primary healthcare team and patient's agent had a discussion of changing goals of care. The attending physician concurs and wants to delay further action in organ procurement. The OPO coordinator tells the patient's agent and bedside nurse that the OR will continue, and that the changes in the patient's status are not meaningful. The OPO coordinator states that the patient's agent had made a decision which is final. The attending physician announces that she is requesting a DCD pause because of her concern.

*This **is** a reportable unplanned DCD pause. There is a difference of opinion among the stakeholders that the patient may not be appropriate for withdrawal of life-sustaining care and therefore not appropriate for a planned withdrawal in a DCD OR.*