

January 16, 2026

Health Resources Services Administration
5600 Fishers Lane
Rockville, MD 20852

(submitted via OPTNWeb@hrsa.gov)

The Association of Organ Procurement Organizations (AOPO) welcomes the opportunity to comment on the Health Resources Services Administration (HRSA) Directive for Organ Procurement and Transplantation Network (OPTN) Donation after Circulatory Death (DCD) Policy Development to improve the safety of organ donation and transplantation in the United States.

AOPO collectively represents 46 federally designated, non-profit Organ Procurement Organizations (OPOs) in the United States, which together serve millions of Americans. As an organization, AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaboration with OPOs, other stakeholders, and federal agencies to continue this nation's transplantation success while consistently improving towards the singular goal of saving as many lives as possible.

DCD continues to grow year after year, enabling life-saving transplants for thousands of patients who might otherwise miss a chance at a new life. AOPO believes that maintaining access to DCD is critical and agrees that all OPTN members must collaborate with donor hospitals and donor families to ensure the safety of donors throughout the process, with OPOs most affected by this new rule.

The decision to withdraw life-sustaining therapy (WLST) is one that lies with the patient's family/agent and the patient's health care team. OPTN members must not influence decisions regarding WLST. AOPO believes in offering all patients and their loved ones the opportunity to save and heal lives regardless of whether life sustaining measures are being withdrawn due to neurologic death or other nonsurvivable, catastrophic illnesses or injuries. Prematurely and needlessly restricting a patient's opportunity to become a donor hinders the mission of AOPO, OPTN, CMS and the entire system's goal of saving more lives through organ donation and transplantation. Families/agents who are considering WLST must be informed about donation and how the donor evaluation process may affect the timing of the WLST. Many families have expressed frustration with learning about this timing impact after planning for other family members to be present at the time of WLST. Waiting until the family has made the decision is too late, and AOPO supports this change in policy as well.

At present, there is no reliable way to predict whether a patient will die within a time frame that allows for donation. Accordingly, AOPO does not believe there should be specific clinical requirements in policy that trigger a DCD pause. As part of ongoing educational efforts, OPOs and donor hospitals can describe patients who may be at greater risk of inaccurate neurologic assessment and offer guidance on how to properly assess such patients. However, specific neurologic deficit requirements for DCD could risk excluding donors with sustained neurologic function who cannot survive without artificial support (e.g., ventilator, mechanical circulatory assist device, medications, etc.). The current neurologic-deficit requirement excludes potential donors whose life support is being withdrawn for other irreversible and non-survivable conditions, such as end-stage cardiovascular or respiratory failure, which do not meet the neurologic criteria but are nonetheless terminal.

Increasing experience with DCD suggests that observation periods (from the time of pulselessness to the time of incision) of less than five minutes may be inadequate to exclude autoresuscitation. In the era of machine preservation and normothermic regional perfusion (NRP), the warm ischemic time argument in favor of shortened observation periods is increasingly indefensible. Accordingly, AOPO supports an OPTN policy mandating a five-minute period of continuous observation following circulatory arrest prior to organ recovery. AOPO notes that declaring providers may not feel that this entire observation time is necessary or warranted, and thus, if the provider refuses to observe the patient for the full five minutes of pulselessness, the OPO must complete this observation period and document this in the donor record.

AOPO is unsure of the necessity of the requiring OPOs to report pauses within 24 hours of their origination. OPOs navigate tenuous situations with families and donor hospitals routinely, and singling out this one particular type of incident and requiring reporting seems overly burdensome and excessive. However, if OPOs must report, it is recommended the reporting requirement be a single report within 24 hours of the outcome of any pause, not to exceed 72 hours. Pauses without defined outcomes could be reported within 72 hours of the start of the pause (to allow time for resolution of the pause). Once such an extended pause is resolved, OPTN could require a report within 24 hours of the resolution.

We agree that key individuals involved in the DCD process should be informed that they can request an unplanned pause at any time; however, to what level is this expected? To notify every new nurse, RT, physician, etc. that comes on shift throughout the process will be difficult and onerous to document. Could a solution be for hospital and OPO policies to outline an unplanned pause protocol, and for staff to be educated on it?

OPOs should have a policy that requires them to provide every hospital staff member involved with a document on the DCD pause process, without having to document that step for every hospital staff member in every case.

AOPO understands the appeal of the requirement that any stakeholder in the process (donor or donor's agent, donor hospital staff, OPO staff, and third-party procurement and preservation staff) have the authority to pause the DCD process. AOPO agrees this pause cannot be attributed to anyone's objection to donation, but rather to a concern that WLST is inappropriate for this patient. It is important to reiterate that OPOs are not involved in the decision to withdraw life support, this is the prerogative of the donor family and the hospital's patient care team. OPO staff should defer to the patient care team and the patient/patient's agent regarding the suitability of WLST, as OPO staff are not experts in this area and should not be involved in these decisions for patients who are potential donors. All stakeholders also have the option to request a consultation with the hospital's in-house ethics team. OPOs should have a policy for informing these stakeholders of this requirement but should have broad leeway in how they meet it. Further, transplant centers should be required to educate their own staff on this topic so that OPOs are not required to do so.

AOPO feels that OPO staff cannot be responsible for the neurological assessment of the donor nor for "ensuring the accuracy" thereof. We recommend rephrasing this requirement in 2.15.C to require that the OPO document the exam performed by a member of the patient care team. Further, we recommend that the frequency of documented assessments not be prescribed in policy, only that continued assessment of WLST suitability is required.

Lastly, AOPO supports the clarifications to existing policy regarding brain dead donors whose organs are recovered under DCD protocols, usually at family/agent request.

We agree that these proposed OPTN policies should 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.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Jeffrey Trageser', with a stylized, flowing script.

Jeffrey Trageser
AOPO President
Executive Director, Lifesharing