ASTS
American Society of Transplant Surgeons

HRSA Directive for OPTN Donation after Circulatory Death Policy Development

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to provide public comment on the Health Resources and Services Administration (HRSA) directive to the Organ Procurement and Transplantation Network (OPTN) regarding Donation after Circulatory Death (DCD) policy development.

ASTS recognizes the seriousness of allegations made in recent media reports and Congressional hearings related to DCD organ donation. Many of these concerns reflect complex realities that can be difficult to fully convey outside of clinical context, and it is essential that the system respond to these allegations thoughtfully and transparently. The protection of organ donors and their families at the end of life and the preservation of public trust are foundational to the organ donation and transplantation system. Clear, consistent, and enforceable safeguards serve not only to protect vulnerable patients and families, but also to reinforce confidence in the professionals and organizations entrusted with this work.

ASTS commends the OPTN Committees and Workgroups for undertaking this exceptionally complex effort. DCD policy development exists at the intersection of ethics, critical care medicine, neurology, law, and transplantation. Balancing donor protection, family experience, clinical realities, and the urgent need for organs requires careful deliberation and collaboration. The committee's work reflects a sincere commitment to strengthening safeguards while recognizing the operational and ethical complexities inherent in end-of-life care and organ donation.

ASTS generally supports the direction of the proposed policies, recognizing their intent to enhance clarity, consistency, and transparency across DCD practices. ASTS offers several considerations intended to further strengthen patient protections, support shared accountability, and ensure continued public confidence in the donation system.

ASTS strongly affirms that informed consent standards must be explicitly and rigorously applied in all DCD scenarios. In instances of first-person authorization where the individual is mentally capable of making informed medical decisions, ASTS recommends that the informed consent standards currently applied to living organ donation serve as the appropriate benchmark. The potential donor should receive comprehensive education regarding the donation process, potential risks, uncertainties, and available alternatives. The potential donor must retain the unequivocal right to change their mind or withdraw authorization at any point, including up to the withdrawal of life sustaining therapies and/or death, for any reason. This right must be clearly communicated, thoroughly documented, and consistently respected. Similarly, when authorization is provided by a legally authorized representative, the authorizing individual should receive explicit education regarding the voluntary nature of donation, the right to pause or withdraw authorization at any time, and the clear separation between decisions related to life-sustaining treatment and decisions related to organ donation.

ASTS recognizes the essential role that organ procurement organizations play in facilitating safe, ethical, and effective organ donation. At the same time, policies governing unplanned DCD pauses and reconciliation prior to resumption should promote collaboration and shared responsibility between organ procurement organizations and donor hospitals and their medical personnel. Joint development of such policies, meeting defined minimum criteria and incorporated into formal operating agreements, would reinforce mutual accountability, and help ensure that safeguards are applied consistently across clinical settings.

ASTS supports the establishment of minimum standards governing the timing and sequencing of donation discussions. Donation discussions should occur only after the authorized agent has been fully informed of the potential donor's grave prognosis and the unlikelihood of meaningful recovery, preferably after the agent has already expressed intent toward withdrawal, comfort focused care or do not resuscitate status. Because it may be difficult or impossible to retrospectively assess whether the decision to donate influenced the decision to withdraw life-sustaining therapies, particularly during the natural grief process, clear standards for timing and sequencing serve to protect donors and patients alike. To support these safeguards, ASTS recommends clear documentation demonstrating that the decision to withdraw life-sustaining therapies preceded donation discussions. Responsibilities of donor hospital clinicians and organ procurement organization staff should be clearly delineated, with continued emphasis on ethical boundaries and role separation. Ensuring organ procurement organization compliance with communicating these standards to donor hospitals is achievable.

ASTS supports defining a minimum waiting period following circulatory cessation in OPTN Policy 2.15.J. A standardized minimum interval promotes consistency, transparency, and public confidence, while supporting donor protection. ASTS recommends alignment with existing medical evidence and ethical consensus, which is in support of a five-minute observation period.

ASTS supports the inclusion of automatic triggers for unplanned DCD pauses in limited and well-defined circumstances, particularly when there is uncertainty regarding neurological status, unexpected patient responsiveness, or discrepancies between anticipated and observed clinical progression. Supplemental education accompanying such triggers would further support appropriate clinical judgment and consistency; we do however also recognize that this may be difficult to codify in this initial iteration of policy. The Committee should continue to review data as it is submitted and consider policy revision as necessary based on learned experience.

Clear definitions of reportable events, standardized thresholds, and consistent reporting timelines would enhance transparency and support quality improvement efforts. The process of peer review and goal of process improvement and bringing members into compliance should remain a central goal, and an unplanned DCD pause should not automatically be viewed as a negative outcome, given the innate variability in the progression and pathophysiology of injury. It is difficult to determine if the proposed reporting requirements are appropriate given that the example form does not include all presumably pre-populated options for selection. ASTS believes the existing reporting

process is generally appropriate while recognizing that the OPTN or MPSC may seek additional information and clarification at any time. The community may benefit from additional lived experience with this new process to provide the clarity needed to ensure consistent understanding and application.

Given the importance of maintaining public trust and national consistency, ASTS supports submission of these policies to the Secretary of Health and Human Services for approval and enforceability in accordance with the OPTN Final Rule. Federal enforceability reinforces accountability while affirming the transplant system's commitment to donor safety and ethical practice. Prior to doing so, however, clarification around the language relating to member actions and potential penalties would be necessary. For example, donor hospitals would potentially be subject to investigation, but they are not considered OPTN members. Further, this raises concern that transplant hospitals, as OPTN members, may be found out of compliance for acts of omission or commission by donor hospitals or OPOs.

ASTS also encourages continued coordination between the OPTN and the Centers for Medicare and Medicaid Services, which maintains statutory oversight of organ procurement organizations. Alignment between OPTN policy requirements and CMS Conditions for Coverage is essential to ensure consistency in expectations, avoid duplicative or conflicting requirements, and reinforce shared accountability across the donation system. Such coordination would further support donor safety, operational clarity, and public confidence.

Based on these considerations, ASTS hesitantly recommends a position of Support for the proposed policies. This position reflects endorsement of the overall direction and intent of the proposals, while recognizing the value of continued refinement to ensure clarity, collaboration, and sustained public confidence in the organ donation and transplantation system.

☑ Support