

*Briefing to the OPTN Board of Directors on*

# **Clarify Requirements for Pronouncement of Death**

*OPTN Organ Procurement Organization Committee*

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# Clarify Requirements for Pronouncement of Death

<i>Affected Policies:</i>	<i>2.14.A: Conflicts of Interest</i> <i>2.15.G: Pronouncement of Death</i>
<i>Sponsoring Committee:</i>	<i>Organ Procurement Organization</i>
<i>Public Comment Period:</i>	<i>January 23, 2024 – March 19, 2024</i>
<i>Board of Directors Meeting:</i>	<i>June 17-18, 2024</i>

## Executive Summary

This proposal would clarify that donor hospital healthcare professionals who declare the death of a potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. The number of donation after circulatory death (DCD) donors has been increasing each year as organ procurement organizations (OPOs) focus efforts to increase the number of deceased donor organs available for transplant. In 2012, there were 1,107 DCD donors while in 2022 there were 4,777.<sup>1</sup> OPOs employ or contract with multiple physicians who are donor hospital intensivists to provide on-call medical director services. These physicians may need to participate in the pronouncement of death as part of the donor hospital healthcare team when not on-call for the OPO. Preserving the ability of these physicians to participate in the pronouncement of death of a DCD donor when not on-call for the OPO is important to prevent abandonment of a DCD donor, which may occur if there are not additional donor hospital staff who can pronounce death.

While there are existing policies that address the restrictions on donor hospital healthcare team members participating in the organ recovery and transplantation of organs if declaring death, there is a need to be consistent between the policies addressing DCD and donation after brain death (DBD). Additionally, avoiding any conflicts of interest during the pronouncement of death is a vital part of maintaining public trust in the organ donation, procurement, and transplantation system.

This proposal was not modified following public comment.

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<sup>1</sup> <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.

## Purpose

The Committee proposes updates to the current policies for consistency and to ensure a valid and unbiased pronouncement of death. These changes would clarify that donor hospital healthcare professionals who declare the death of the potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs.

## Background

OPOs employ or contract with multiple physicians who are hospital intensivists to provide on-call medical director services. These physicians may need to participate in the pronouncement of death as part of the donor's hospital healthcare team when not on-call for the OPO. The language in *Policy 2.15.G: Pronouncement of Death* states "The donor hospital healthcare team member who is authorized to declare death must not be a member of the OPO or the organ recovery team." This language is broad and does not cover the scenarios previously mentioned and does not provide adequate clarity for OPOs and the OPTN Membership and Professional Standards Committee (MPSC) to determine if the policy has been violated when these situations occur.

The MPSC is charged with monitoring compliance with OPTN obligations, including addressing risks to patient safety, public health, and the integrity of the OPTN. To address specific issues identified through routine monitoring activities, the MPSC refers potential project ideas to relevant OPTN Committees for evaluation and consideration for potential action. The Policy Oversight Committee collaborates with the MPSC and other OPTN Committees to ensure a formal documentation and review process for these referrals. The MPSC identified this issue and referred it to the OPTN OPO Committee for review.

The 2022 revised *Statement on Controlled Organ Donation after Circulatory Death* by the American Society of Anesthesiologists includes the principle that "in order to avoid potential conflict of priorities, the physicians caring for a donor should not be involved in any of the donation, organ procurement or transplantation procedures."<sup>2</sup> Additionally, the American Medical Association's *Code of Medical Ethics Guidelines for Organ Transplantation from Deceased Donors* includes language addressing conflicts of interest to ensure "healthcare professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor" and that "no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death."<sup>3</sup>

The Committee discussed several options to revise the policy language:

- *Consistent terminology* – The use of "declaration" versus "pronouncement" of death varies by state but appears to have the same meaning. For example, the Ohio Administrative Code uses "Pronouncement of Death" while New Jersey has the "New Jersey Declaration of Death Act."<sup>4, 5</sup> The Committee decided to maintain the current title of Policy 2.15.G as "Pronouncement of Death" to be consistent with the data collected in the OPTN Computer System.
- *Defining roles at the donor hospital and OPO* – The Committee considered adding language such as "actively serving in a role at the OPO" to clearly establish who cannot be involved in the end-of-life care and pronouncement of death. However, there were concerns about clearly defining the roles within OPTN policy and how it might lead to more confusion for members. Therefore,

<sup>2</sup> <https://www.asahq.org/standards-and-practice-parameters/statement-on-controlled-organ-donation-after-circulatory-death>.

<sup>3</sup> <https://code-medical-ethics.ama-assn.org/ethics-opinions/guidelines-organ-transplantation-deceased-donors>.

<sup>4</sup> <https://codes.ohio.gov/ohio-administrative-code/rule-4731-14-01>.

<sup>5</sup> [https://www.thaddeuspope.com/images/NJ\\_Decl\\_Death\\_Act.pdf](https://www.thaddeuspope.com/images/NJ_Decl_Death_Act.pdf).

the Committee deferred to hospital and OPO practices and procedures to ensure a clear separation between the donation process and patient care.

- *Personnel authorized to pronounce death* – This is another issue that varies by state and local statutes and regulations. Some states such as Kentucky allow nurses and nurse practitioners to pronounce death.<sup>6</sup> Currently, *Policy 2.14.A: Conflicts of Interest* references physicians so the Committee agreed to modify the language to state, “donor hospital healthcare team member.” This change will cover all personnel who might have the authority to declare death and make the language consistent with *Policy 2.15.G: Pronouncement of Death*.

The Committee ultimately determined that avoiding unnecessary complexity in the policy would be the best approach. OPOs and donor hospitals will maintain the ability to develop their own institutional policies to ensure protection from conflicts of interest.

## Proposal for Board Consideration

The Committee is proposing the following changes to OPTN Policy:

### Policy 2.14.A: Conflicts of Interest

*Current Policy Language:*

The organ recovery procedure and the transplantation of organs must *not* be performed by *either* of the following:

1. The potential deceased donor’s attending physician at the time of death
2. The physician who declares the time of the potential deceased donor’s death

*Proposed Changes:*

- Removed “time of death” to be consistent with *Policy 2.15.G: Pronouncement of Death*.
- Added reference to hospital policy and state/local statutes or regulations to be consistent with *Policy 2.15.G: Pronouncement of Death*.
- Removed reference to physician and attending physician since various healthcare professionals are authorized to declare death. It is important to note that this does not impact patient care because these policies establish a clear separation between patient care and donor evaluation, including pronouncement of death.

### Policy 2.15.G: Pronouncement of Death

*Current Policy Language:*

The donor hospital healthcare team member who is authorized to declare death must not be a member of the OPO or the organ recovery team. Circulatory death is death defined as the irreversible cessation of circulatory and respiratory functions. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

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<sup>6</sup> <https://kbn.ky.gov/KBN%20Documents/aos36-resuscitation-orders-death.pdf>.

*Proposed Changes:*

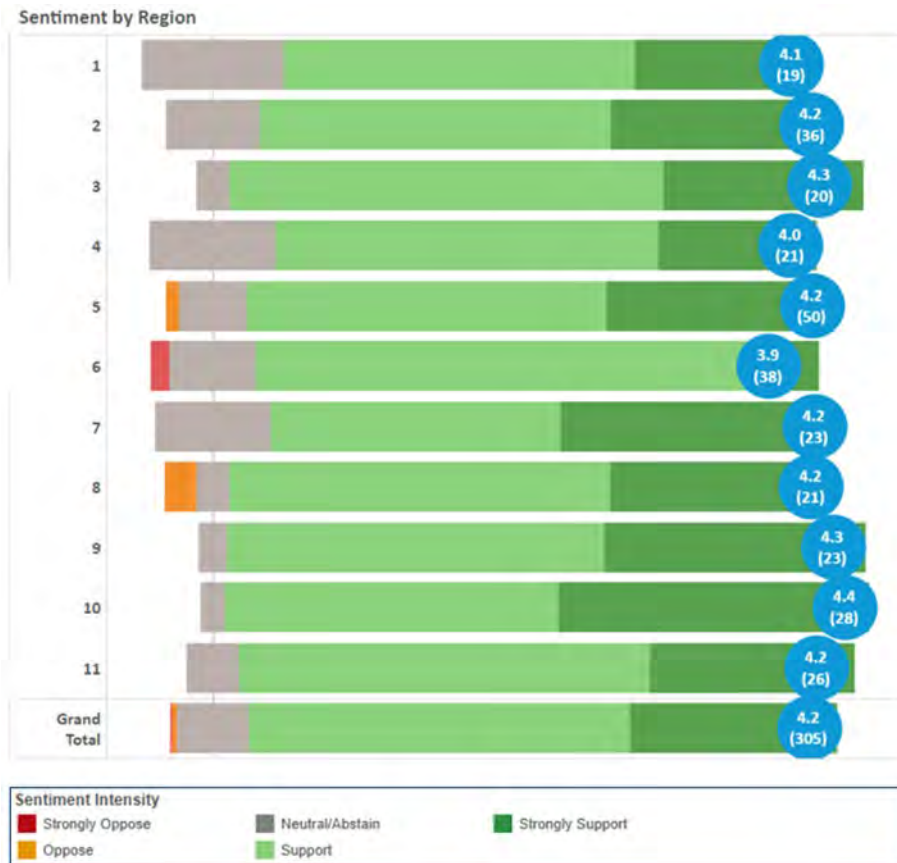
- Modified language to be donor-specific. For example, the donor hospital healthcare team member who declares death cannot be involved in any aspect of the organ recovery procedure or transplantation of *that* donor’s organs.
- Replaced donor hospital healthcare team member who “is authorized to declare death” with “who declares death” to be specific to that donor. There are various donor hospital personnel who might be “authorized” but are not involved in the potential donor’s care.

The proposed new policy language is available on page 9 of this document.

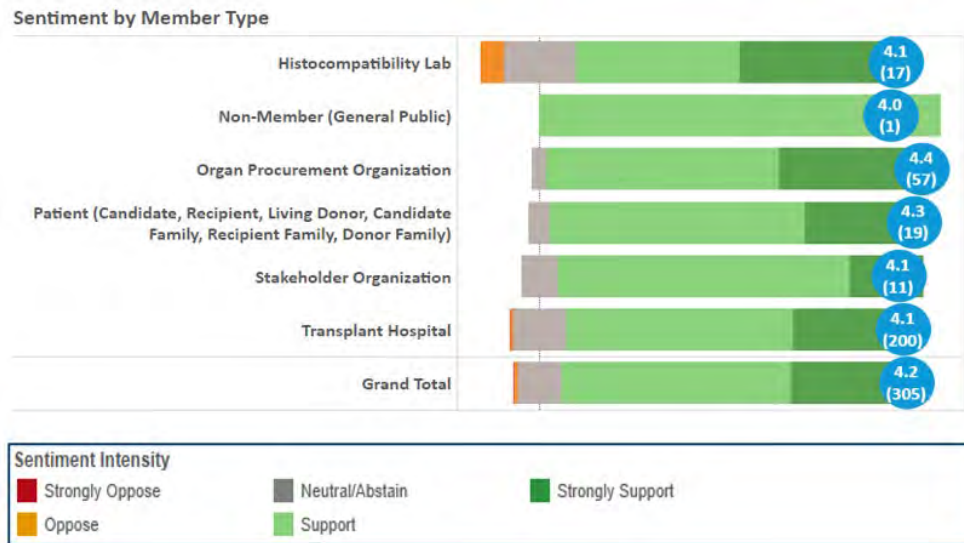
## Overall Sentiment from Public Comment

Generally, public comment sentiment was supportive of this proposal, as indicated by the total sentiment score of 4.2. Sentiment is collected from participants who submit an individual public comment and from regional meeting participants. Participants are asked to provide their feedback on “What is your opinion of this proposal?” There are five Likert scale response choices with 1 representing strongly oppose up to 5 representing strongly support. **Figures 1 and 2** below illustrate the sentiment received by region and member type.

**Figure 1: Sentiment by Region, Clarifying Requirements for Pronouncement of Death, 2024**



**Figure 2: Sentiment by Member Type, *Clarifying Requirements for Pronouncement of Death, 2024***



There were twenty-five written comments received on this proposal. The following themes were identified and aligned with the specific questions for consideration by the community that were included in the public comment document.

### *Adequate Clarity for Proposed Policy Language*

Most commenters agreed that the proposed policy language changes clearly outline the separation between healthcare provider roles and participation in the recovery and transplant of that donor’s organs. Various professional societies, including the American Society of Transplant Surgeons (ASTS), the Association of Organ Procurement Organizations (AOPO), and NATCO expressed support for clarifying the policies.

### *Concerns about Patient/Donor Impact*

Most commenters agreed these proposed changes will have minimal impact on patients and donors, although the University of Arkansas Medical Services commented that “creating clearer guidelines will have a positive impact on our patient population and transplant center.”

### *Ethical Considerations*

Most commenters agreed that consistent policy language will ensure clear boundaries between patient care/pronouncement of death and the procurement and transplantation of organs. The American Society of Transplant Surgeons (ASTS), the Association of Organ Procurement Organizations (AOPO), and NATCO expressed support for clarifying the policies to reduce ethical concerns.

### *Increase/Maintain Public Trust in Declaration of Death*

Commenters agreed that public trust is critical to the lifesaving mission of organ donation and transplantation. AOPO in particular stated that “OPOs understand their obligations regarding death declaration in the donation process and are committed to ensuring that death is declared in accordance with law and by individuals who do not have an interest in the outcome of the declaration.”

## Compliance Analysis

### NOTA and OPTN Final Rule

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "adopt and use standards of quality for the acquisition and transportation of donated organs."<sup>7</sup> The Final Rule requires OPTN members to perform "clinical examinations of potential donors.....to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN."<sup>8</sup> This proposal will ensure the roles of healthcare teams and OPO personnel are clearly defined to avoid conflicts of interest during patient care and potential donor evaluation, which could compromise the examination of the donor. This will help support public trust in the organ donation process and provide OPTN members with clear rules and responsibilities for the pronouncement of death.

### OPTN Strategic Plan

This proposal supports the strategic goal of increasing the number of transplants. Increased clarity of the requirements surrounding who can pronounce death could lead to more DCD donor procurements. For example, an individual not actively serving in a role with the OPO may be available to pronounce death.

## Implementation Considerations

### Organ Procurement Organizations

#### *Operational Considerations*

OPOs may need to evaluate their internal policies and procedures to account for this policy change.

#### *Fiscal Impact*

This proposal is not anticipated to have any fiscal impact on OPOs.

### Transplant Programs

#### *Operational Considerations*

Transplant hospitals may need to evaluate their internal policies and procedures to account for this policy change.

#### *Fiscal Impact*

This proposal is not anticipated to have any fiscal impact on transplant programs.

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<sup>7</sup> 42 USC 274(b)(2)(E).

<sup>8</sup> 42 CFR 121.6(a).

## Histocompatibility Laboratories

### *Operational Considerations*

There is no anticipated impact on histocompatibility laboratories.

### *Fiscal Impact*

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

## OPTN

### *Operational Considerations*

There is no anticipated impact on OPTN operations.

### *Resource Estimates*

It is estimated that 145 hours would be needed to implement this proposal. Implementation would involve updates to current policies, education, and communication efforts to OPOs and transplant hospitals about the proposed changes. It is estimated that 20 hours would be required for ongoing support, which includes answering member questions, as necessary.

## Potential Impact on Select Patient Populations

There is no anticipated impact to transplant candidates.

## Post-implementation Monitoring

### Member Compliance

This proposal will not change the current routine monitoring of OPTN members. Members will be expected to comply with requirements in the proposed policy language.

### Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”<sup>9</sup> As the changes seek to clarify policy, the policy will be monitored as requested by the OPO Committee.

## Conclusion

With the annual increase in the number of DCD donors, efforts should be made to avoid any restrictions that might limit the use of DCD donors while also maintaining a clear separation between the pronouncement of death and participation in organ recovery and transplantation of organs. Clarifying roles that are specific to individual donors will reduce unnecessary prohibitions on hospital personnel

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<sup>9</sup> 42 CFR §121.8(a)(6).



not actively serving in a role with an OPO. Additionally, this proposal will update the policies to ensure consistency between DCD and DBD policies addressing the pronouncement of death.

Following review of public comments, the Committee determined that no post-public comment changes were needed.

## 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, cross-references, and footnotes affected by the numbering will be updated as necessary.

1 **2.14.A Conflicts of Interest**

2 The organ recovery procedure and the transplantation of organs must not be performed by the donor  
3 hospital healthcare team member who declares the death of the potential deceased donor. ~~either of the~~  
4 ~~following:~~ Death is declared in accordance with hospital policy and applicable state and local statutes or  
5 regulation.

- 6 ~~1. The potential deceased donor's attending physician at the time of death~~  
7 ~~2. The physician who declares the time of the potential deceased donor's death~~

8

9 **2.15.G Pronouncement of Death**

10 The donor hospital healthcare team member who ~~is authorized to~~ declares the death of the potential  
11 deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of  
12 that donor's organs. ~~must not be a member of the OPO or the organ recovery team. Circulatory death is~~  
13 ~~death defined as the irreversible cessation of circulatory and respiratory functions.~~ Death is declared in  
14 accordance with hospital policy and applicable state and local statutes or regulation.

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