

At-a-Glance

- **Proposal to Update and Clarify Language in the DCD Model Elements**
- **Affected/Proposed Bylaw:** Attachment III to Appendix B of the OPTN ByLaws
- **Organ Procurement Organization (OPO) and Organ Availability (OAC) Committees**

The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. As such, the name Model Elements has been changed to "Requirements." DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

- 1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
- 2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

Additionally, other policies that have the terms "Donation after Cardiac Death" will have to be modified for consistency.

- **Affected Groups**
 - Directors of Organ Procurement
 - General Public
 - OPO Executive Directors
 - OPO Medical Directors
 - OPO Coordinators
 - Transplant Administrators
 - Transplant Physicians/Surgeons
 - PR/Public Education Staff
 - Transplant Program Directors
 - Transplant Social Workers
 - Donor Family Members

- **Number of Potential Candidates Affected**

In 2009, there were 920 DCD donors, an 8.5% increase between 2008 and 2009. In addition, some OPOs have up to 32% of their donors recovered as DCD donors. By clarifying the Model Elements, OPOs and transplant centers can increase the number of organs procured from DCD donations and ultimately increase the number of transplants

- **Compliance with OPTN Strategic Goals and Final Rule**

The following two OPTN Strategic Goals and Priorities support the changes:

- Maximum Capacity – The proposed changes will help to maximize the number of donors and transplants by identifying the currently unrealized donor potential through the clarification and updating of language.
- Operational Effectiveness – The proposed changes will help to increase operational effectiveness by clarifying those elements required by OPOs, donor hospitals and transplant centers.

Additionally, these changes more accurately reflect language in sections 121.8 (Allocation of Organs) and 121.9 (Designated Transplant Program Requirements) of the OPTN Final Rule

- **Specific Requests for Comment**

Please comment on what impact the following changes in terminology might have on your institution:

- Changing “cardiac” death to “circulatory” death;
- Withdrawal of “life sustaining measures” to “medical treatment/support”; and
- The addition of the term “disease” which is included in the suitable candidate evaluation section.

Proposal to Update and Clarify Language in the DCD Model Elements

Affected/Proposed Bylaw: Attachment III to Appendix B of the OPTN Bylaws B

Organ Procurement Organization (OPO) and Organ Availability (OAC) Committees

Summary and Goals of the Proposal:

The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. The **Committees changed the name Model Elements to "Requirements."** DCD is redefined as Donation after Circulatory Death (DCD) in order to accurately reflect the definition of death determined by cardio-pulmonary criteria. The Committees also added the following language that mirrors the Centers for Medicare & Medicaid Services (CMS) requirements:

- 1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and
- 2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.

Additionally, other policies that have the terms "Donation after Cardiac Death" will have to be modified for consistency.

Background and Significance of the Proposal:

In 2009, the OPTN Board of Directors charged the OPO Committee and OAC with the goal of reviewing DCD policies to ensure that they were consistent with current practice. The Committees formed a joint Work Group and identified two areas that needed to be updated and clarified: 1) policy and bylaws and 2) definitions affecting DCD data reporting. Two subcommittees were formed to address issues for both areas; their work was approved by the Joint Work Group and ultimately approved by both committees.

The subcommittee spearheading the DCD policy review determined that existing policies were comprehensive; however, when they reviewed the DCD Model Elements that are included in the Bylaws, they concluded that they were out of date and should be modified. The OPTN Bylaws require that OPOs and transplant centers incorporate the DCD Model Elements into their DCD policies.

The **Committees are now seeking public comment on proposed changes to these Model Elements.** The committees recommend specific changes to update terminology such as changing the terms "Model Elements" to "Requirements." Additionally, **the Committees agreed that the title "Donation after Cardiac Death" does not accurately reflect the Uniform Determination of Death Act's (UDDA) definition of death that states:**

"An individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. (Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West Suppl. 1997)

With this in mind, the Committees propose that the name “Donation after Cardiac Death” (DCD) be changed to “Donation after Circulatory Death (DCD)” to accurately reflect the intent of the UDDA. This change is particularly important because the heart is not dead (nor are other organs) when the heart stops, but when circulation and oxygenation to the tissues are irreversibly stopped. Organizations such as the Society of Critical Care Medicine (SCCM) use this terminology. The OPO Committee and OAC unanimously supported this change.

The name “Donation after Cardiac Death” appears in seven policies (2.7, 2.8, 3.5.3.3, 3.5.5, 3.5.11.5.1, 6.4.2, and 6.4.3) and in sections I and II of Appendix B, Attachment III of the Bylaws. If approved, the terms “cardiac” will be changed to “circulatory” and “Model Elements” will be changed to “requirements” in those policies and Bylaws as well to ensure consistency.

The phrase “withdraw life sustaining measures” was changed to “withdraw life sustaining medical treatment/support,” to reflect current language used by the community, the Society of Critical Care Medicine, and CMS.

While rare, DCD donation may occur in patients that do not have a neurological injury, but a disease that renders them ventilator dependent (i.e. amyotrophic lateral sclerosis). As such, the term “disease” was included in the language that describes suitable candidate conditions. This change will be more specific in allowing these candidates to grant first person consent for donation and make these Model Elements more consistent with current practice.

Language was also added that reflects the CMS requirements to have a written agreement with participating hospitals. These changes are consistent with CMS expectations and make the Model Elements more complete and inclusive.

The Model Elements currently require an assessment to determine whether death is likely to occur (after withdrawal of life sustaining medical treatment/support) within a timeframe necessary for organ donation. This language was deleted because there is no industry standard that allows for a true assessment of the likelihood of death within a specific time frame. Each hospital establishes its own timeframe for organ acceptability.

Terms like “heparin” and “regitine” were changed to “anticoagulant and /or vasodilator administration” as this new language is less prescriptive in the event that there are newer or more appropriate medications to be used.

Collaboration

The OPO Committee and OAC, as part of their annual goals, were tasked to review DCD policies and bylaws to ensure that they are consistent with current practice. A joint Work Group was formed that reviewed DCD policy and bylaws and the DCD Help Documentation in DonorNet®.

- **Collaboration:** Before distributing the proposed changes for public comment, the Committees sought input from the following committees and transplant organizations:
 - Pediatric Committee
 - Thoracic Committee
 - Liver Committee

- Kidney Committee
- Transplant Administrators Committee
- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- North American Transplant Coordinators Organization (NATCO)
- Association of Organ Procurement Organizations (AOPO)

Appropriate changes were made to the Model Elements based on recommendations that were received.

- **Strengths and weaknesses:** Strengths of the proposed changes:
 1. The language associated with DCD will be standardized.
 2. The language more accurately reflects the intent of the UDDA. The UDDA states that death occurs with the “irreversible cessation of circulatory and respiratory function.” This language does not indicate that the heart is dead.
 3. Some of the changes incorporate CMS language requirements making OPTN Bylaws and CMS regulations compatible.
 4. The Committees believe that clarification of the language will promote better compliance.

Weaknesses of the proposed changes:

1. There may be some confusion over terminology once implemented.
 2. Is unknown at this time if transplant centers and OPOs will incur a financial burden because it is unknown how many resources will be needed to bring their protocols in line with the protocol requirements.
 3. Since there will be programming changes, the OPTN will incur costs.
- **Description of intended and unintended consequences:** Members will have to align their institutional DCD policy with the changes to the Model Elements.

The intended consequences for this proposal are that the community will have a clearer understanding of DCD requirements. OPOs and transplant centers will need to align their individual DCD protocols and policies with the new language in the Model Elements.

An unintended consequence would be that each OPO and transplant center might incur a cost, as they will need to align their individual DCD protocols and policies with the new language in the Model Elements.

The following programming changes would be required:

- Online Help documentation in DonorNet® and Tiedi® will need to be modified to reflect change from Donor after Cardiac Death (DCD) to Donor after Circulatory Death (DCD); all instances where Donor after Cardiac Death and/or DCD will need to be changed to reflect Donor after Circulatory Death and/or (DCD)
- Online Help documentation in DonorNet® and Tiedi® will need to be updated to define which donors could be classified as a DCD donor
- UNOS and OPTN web site glossaries will need to be updated to define Donor after Circulatory Declaration of Death (DCD)

Supporting Evidence and /or Modeling:

The Committee comprises experts in the field of procurement and DCD and agreed that the significant changes reflect current practice.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

In 2009, there were 920 DCD cases reported in the United States. This number represents an 8.5% increase in the number of DCD cases reported nationwide compared to 2008, and indicates improved understanding of donor hospital willingness to develop DCD policies; OPOs to facilitate DCD protocols; and transplant centers to accept DCD organs to treat end-stage organ failure. Furthermore, with some of the more successful OPOs achieving up to 32% of their donor base as DCD donors, there exists a significant gap in unrealized donor potential that can be better captured by using more complete and up-to-date DCD Model Elements.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The following two long-range Strategic Goals and Priorities support these changes:

- Maximum Capacity – The proposed changes will help to maximize the number of donors and transplants by identifying the currently unrealized donor potential through the clarification and updating of language.
- Operational Effectiveness – The proposed changes will help to increase operational effectiveness by clarifying those elements required by OPOs, donor hospitals and transplant centers.

Additionally, these changes accurately reflect language in sections 121.8 (Allocation of Organs) and 121.9 (Designated Transplant Program Requirements) of the OPTN Final Rule.

Plan for Evaluating the Proposal:

One year after the revisions are implemented, the Committees will review all policy violations related to non-compliance with the DCD Model Elements. The Department of Evaluation and Quality (DEQ) will collect the data. In reviewing the data, the committees will consider the following questions:

- *Has there been a decrease in the number of policy violations as demonstrated by complaints of policy violations?*
- *Has there been an increase in the number of DCD donations since the implementation of these revised Model Elements?*

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal does not require any programming changes to any of the data collection forms in UNetsm but will require programming to update the UNetsm glossaries and Online Help Documentation, and glossaries found on the public websites.

Operationally, transplant centers and OPOs will have to review and revise their current DCD protocols to align them with these changes. They will need to review their protocols, ensure that all elements are included, and proceed through their institutional structure to make the appropriate changes. All individuals involved in the practice of DCD will need to understand the changes.

The change is effective 30 days after Board approval and compliance will be enforced 90 days after the change takes effect.

Communication and Education Plan:

All transplant centers and OPOs are already required to have a DCD protocol in place. This policy change will require them to update their existing policy. They will require ample notice, however, in order to go through their internal processes of changing their institutional policies and procedures.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Transplant professionals within OPOs and Transplant Centers	Policy Notice is included with the monthly e-newsletter to members.	30 days after the board of directors approves the policy change.
System Notice	Same	Email	30 days before implementation and day of implementation
UNOS Update Article	Same	Print publication is mailed to members	Earliest issue after OPTN Board approves the policy change.
E-newsletter article	Same	Email	Several mentions in various e-newsletter beginning at least 3 months before OPOs and TX centers are required to implement the change.

Monitoring and Evaluation:

During on-site reviews, DEQ staff will require that OPOs and transplant centers sign an attestation to the existence of DCD protocols and verify knowledge of those protocols through staff interviews.

DEQ staff will request a corrective action plan if the OPO or transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy or Bylaw Proposal:

The following Bylaw proposal may appear different than what the reader is accustomed to seeing. Because of the large number of changes that were made (editorial and substantial content changes), much of the Bylaw would be crossed out making the proposal difficult to read and understand. In the new proposed language below, only those changes that are substantial content changes are either ~~crossed-out~~ if the language was eliminated or underlined if there is substantial new content added. Additionally, a "crosswalk" and original policy language that is crossed out can be found in Exhibit A. This document will assist the reader in identifying where changes occur and where content can be found if moved.

Attachment III to Appendix B of the OPTN Bylaws

Model Elements-Requirements for Controlled Donation after Cardiac Circulatory Death Recovery (DCD) Protocols

Introduction: Donation after Cardiac Circulatory Death (DCD) describes the organ recovery process that may occur when a death is 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. A DCD donor may also be called a non-heartbeating or asystolic donor. The Institute of Medicine, along with the transplant community, recognizes DCD as an ethical and viable option for patients and families making end-of-life decisions.

These guidelines will help OPOs and transplant centers develop the necessary DCD protocols and may be helpful in analyzing existing protocols for process improvement. These guidelines 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 and transplant centers. OPTN members that experience difficulty in adopting a DCD protocol may consult with the joint OPO committee/MPSC working group for assistance.

A. Agreement

The OPO must have a written agreement with hospitals that participate in DCD recovery. The participating hospital must be a Medicare and Medicaid participating hospital or a Critical Access Hospital as certified by Medicare. The participating hospital must also have a ventilator and a functional operating room.

B. Protocols

OPOs and transplant centers shall establish protocols that define the roles and responsibilities of

the OPO and transplant centers for the evaluation and management of potential donors, organ recovery and organ placement in compliance with OPTN policy.

C. Candidate Evaluation

~~Before evaluating a patient as a DCD candidate, the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment and that decision must be documented in the patient's chart.~~ A potential DCD donor should ~~then~~ be evaluated by the primary healthcare team and the local OPO to determine if the candidate meets the following criteria:

1. ~~A patient, from age newborn to the Donation Service Area's (DSA) defined upper age limit, with a permanent and irreversible neurological injury (i.e. upper spinal cord injury), or permanent and irreversible disease (i.e. end-stage musculoskeletal or pulmonary disease) that results in necessary life-sustaining medical treatment or ventilated support but who does not fulfill the neurologic criteria for death,~~ may be a suitable candidate for DCD.
2. ~~A patient with end-stage musculoskeletal disease, pulmonary disease or upper spinal cord injury may also be a suitable DCD candidate.~~
5. ~~An assessment should be made as to whether death is likely to occur (after the withdraw life sustaining measures) within a time frame that allows for organ donation.~~

The OPO may also consult with the OPO Medical Director and the Transplant Center team that may be considering the organs for transplantation.

D. Consent/Authorization

For the purpose of obtaining consent and authorization for a DCD recovery, "legal next of kin" can include any of the following:

1. the patient who consents to be an organ donor candidate
2. the next of kin as defined by state or local law ~~or the Uniform Anatomical Gift Act~~
3. the designated health care agent

The legal next of kin may consent to procedures or drug administration to prepare the patient for a DCD recovery. Some examples of procedures or drugs may include, but are not limited to, femoral line placement, lymph node excision, ECMO circuit cannulation, bronchoscopy, anticoagulants, and vasodilators.

A medical examiner or coroner must give clearance, when applicable.

Create a plan for patient care in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support. This plan should include provisions for ~~continued~~ end of life care and the immediate notification of the patient's next of kin.

E. Withdrawal of Life Sustaining Medical Treatment/Support Measures/Patient Management

Before withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to:

1. Verify the patient's identification.

2. Determine the process and location for withdrawing life-sustaining treatment or ventilated support. Items to be considered may include ETT removal or termination of blood pressure management medications.
3. Review the roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
4. Review the plan for patient care in the event that death does not occur within the established time period after the withdrawal of life-sustaining medical treatment or ventilated support.

No member of the Transplant Center surgical team may be present for the withdrawal of life-sustaining medical treatment or ventilated support.

No member of the Organ Recovery team or OPO staff may guide or administer palliative care or declare death.

F. Pronouncement of Death

The patient care provider who is authorized to declare death must not be a member of the OPO or the surgical 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.

Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy.

G. Organ Recovery

The surgical recovery of organs may not be initiated until the patient is declared dead.

~~A. Financial Considerations~~

- ~~1. OPO policy to ensure no donation related charges are passed to the donor family.~~

Resources:

**** Maastricht Classification – Definition of Controlled DCD Donors***

DCD donors are grouped by the Maastricht classification (1995; amended 2003):

- I Dead on arrival to hospital
- II Unsuccessful resuscitation
- III Awaiting cardiac arrest – In-Patient (w/d of support)
- IV Cardiac arrest after brain-stem death
- V Cardiac arrest in a hospital inpatient

Controlled DCD donors would include those outlined in classification III of the Maastricht criteria.

Sources:

- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death* (Washington: Government Printing Office, 1981), p. 73.

- Uniform Determination of Death Act. 12 Uniform Laws Annotated 320 (1990 Supp). Uniform Determination of Death Act, 12 uniform laws annotated 589 (West 1993 and West Suppl. 1997)

How is irreversibility defined?

From the Report of a National Conference on Donation after Cardiac Death.
Am J Transplant. 2006 Feb; 6 (2):281-91.

Irreversibility is recognized by persistent cessation of function during an appropriate period of observation. Based on a cardiopulmonary criterion, DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function *will not resume spontaneously*. This meaning of “irreversibility” also has been called the “permanent” cessation of respiration and circulation.

If data show that auto-resuscitation (spontaneous resumption of circulation) cannot occur and if there is no attempt at artificial resuscitation, it can be concluded that respiration and circulation have ceased permanently.

In clinical situations in which death is expected, once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (auto-resuscitation) may be only a few minutes. Current data on auto-resuscitation indicate that the relevant event is cessation of circulation, not cessation of electrical activity.

When life-sustaining therapy is withdrawn, based on the limited data available (presented by Michael DeVita at the National Conference), spontaneous circulation does not return after 2 minutes of cessation of circulation.

How is the permanent absence of circulation determined?

From the Report of a National Conference on Donation after Cardiac Death.

Cessation of functions is recognized by an appropriate clinical examination that reveals the absence of responsiveness, heart sounds, pulse and respiratory effort.

In applying the circulatory criterion of death in non-DCD circumstances, clinical examination alone may be sufficient to determine cessation of circulatory and respiratory functions. However, the urgent time constraints of DCD may require more definitive proof of cessation of these functions by the use of confirmatory tests.

Confirmatory tests (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital protocol to assure the family and the hospital professional staff that the patient is dead.

***** Other Important Determination of Death Resources**

1. Recommendations for non-heart-beating organ donation, A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, *Critical Care Medicine*, 2001 Vol. 29, No. 9, pp. 1826-1831.
2. Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement, Institute of Medicine, December 1997.
3. Non-Heart-Beating Organ Transplantation: Practice and Protocols, Institute of Medicine, 2000.

Below is the policy language for those OPTN and UNOS Policies and Bylaws that will also need to be changed to be consistent with the changes proposed to the Model Elements. Only the section that includes

information on DCD is included here to eliminate the need to have entire policies listed when only a small portion of the policy requires a change.

APPENDIX B TO BYLAWS

OPTN/UNOS

Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

I. Organ Procurement Organizations.

Donation After Cardiac Circulatory Death: OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements ~~and model elements~~ set forth in Attachment III.

II. Transplant Hospitals.

Donation After Cardiac Circulatory Death. Transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the requirements ~~and model elements~~ set forth in Attachment III.

POLICY 2.0

MINIMUM PROCURMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

Policy 2.7 and 2.8

- 2.7 REMOVAL OF NON-RENAL ORGANS.** When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. This policy also applies to non-renal organs from controlled donation after cardiac circulatory death (DCD) donors.
- 2.7.1 Multiple Abdominal Organ Procurement.** It is expected that all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. Cooperation between all organ recovery teams is required.
- 2.8** In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the ~~standards of the DCD Model Elements~~ Requirements for Controlled Donation after Cardiac Circulatory Death Recovery (DCD) Protocols as adopted in the OPTN Bylaws, Appendix B, Attachment III.

POLICY 3.0

ALLOCATION OF DECEASED KIDNEYS

- 3.5.3.3 Sharing.** With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Circulatory Death donors¹ if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom

there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after ~~Cardiac~~ Circulatory Death donors¹, if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after ~~Cardiac~~ Circulatory Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after ~~Cardiac~~ Circulatory Death donors shall be defined as follows: (1) A controlled Donation after ~~Cardiac~~ Circulatory Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

Policy 3.5.5

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), ~~3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata Time Limit), 3.8.3.4 Organ Offer Limit),~~ 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after ~~Cardiac~~ Circulatory Death donor¹, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after ~~Cardiac~~ Circulatory Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after ~~Cardiac~~ Circulatory Death donors shall be defined as follows: (1) A controlled Donation after ~~Cardiac~~ Circulatory Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after ~~Cardiac~~ Circulatory Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

Policy 3.5.11.5.1

3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with

the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after ~~Cardiac~~ Circulatory Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

POLICY 6.0 TRANSPLANTATION OF NON-RESIDENT ALIENS

Policy 6.4.2

6.4 EXPORTATION AND IMPORTATION OF ORGANS-DEVELOPMENTAL STATUS.

International exchange of organs for transplantation is technically feasible but remains an uncommon procedure. The OPTN regards international sharing of organs to be in an early phase of development.

6.4.1 Exportation. [No Change]

6.4.2 Developmental Protocols in International Organ Exchange. After prior approval by the OPTN, members may enter into formal organ exchange arrangements, each not to exceed two years in duration, with a foreign transplant program or programs. Negotiations with foreign transplant programs or foreign agencies which include importing organs must be approved by the Ad Hoc International Relations Committee. Importation of organs is defined in Policy 6.4.5 (Importation). Proposed protocols must be submitted to the OPTN describing the basis for such arrangements, expected benefits to both foreign and domestic participants, credentials of the foreign source, number and type of organs anticipated to be involved, and plans for allocation procedures and reporting of results. Proposed protocols must include a requirement for the donor organization to submit documentation certifying the informed consent of the donor or his or her legal representative. Proposed protocols must also include a requirement for the donor organization to submit documentation certifying that the donor has met the brain death or donation after ~~cardiac~~ circulatory death (DCD) protocols that are in compliance with recognized U.S. standards for domestic organ procurement. Proposed protocols must include a requirement for the donor organization to submit documentation of the donor's ABO. Proposed protocols will be reviewed by the Ad Hoc International Relations Committee, which will then make recommendations to the Board of Directors.

Policy 6.4.3

6.4.3 Ad Hoc Organ Exchange. Except as provided for in approved international exchange protocols, all offers of organs for human transplantation from foreign sources must be made to the Organ Center. If a member is contacted by a foreign source with an organ offer, that member must notify the Organ Center of that offer. No more than six exchanges by any member with any foreign program(s) will be allowed on an ad hoc basis. Additional

exchanges must be made as part of an international organ exchange protocol approved by the Ad Hoc International Relations Committee and Board of Directors.

Imports of organs from foreign sources on an ad hoc basis must meet the requirements for importing organs and allocation of those organs under organ exchange protocols found in Policy 6.4.2.1. Additionally, organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after ~~cardiac~~ cardiac circulatory death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement. Organs imported by OPOs must include documentation from the donor organization certifying the informed consent of the donor or his or her legal representative. Organs imported by OPOs must include documentation from the donor organization verifying the donor's ABO.