BRIEFING PAPER **OPTN/UNOS**

Proposal to Update and Clarify Language in the DCD Model Elements

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Organ Procurement Organization Committee

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 do not change any current level of oversight by the donor hospital to ensure that appropriate practices are following for a patient's end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support. 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 be modified for consistency. These proposed changes will help provide a common understanding of DCD protocols for the transplant community and the public.

Background and Significance of the Proposal:

In 2009, the OPTN Board of Directors charged the OPO Committee and Organ Availability Committee with the goal of reviewing DCD policies to determine if 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 the Bylaws 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 Committee is now seeking public comment on proposed changes to these Model Elements. The Committee recommends specific changes to update terminology such as changing the terms "Model Elements" to "Requirements." Additionally, the Committee 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 the definition 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 promote 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.

This proposal was first distributed for public comment during the March 11, 2011 to June 10, 2011 period. Prior to the Nov. 14-15, 2011 Board of Directors meeting, several letters were submitted to the OPTN contractor requesting that the public comment period be reopened to allow the requesting organizations to provide comments. The Executive Committee directed the OPO Committee to review the comments outlined in the letters, revise the proposal if necessary, and resubmit the proposal for public comment during the Spring 2012 cycle. While reviewing the proposal it was discovered that some of the language was incorrectly presented in the previous version of the document. This included some language that was deleted (shown with strikethroughs) that are not in the current bylaws. These mistakes have been corrected

and the policy language included in this proposal shows all the changes to the bylaws with proposed new language underlined and proposed deletions with strikethroughs.

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- Provide an unmistakably clear markup document to show the entirety of the changes.
    - The OPO Committee modified the proposed language to address this concern. The new language is underlined and deleted language is identified by strikethroughs.
- Explicitly clarify the intent of the change from Model Elements to Requirements as to whether there is prescriptive intent that the language must be followed by OPOs and transplant hospitals without flexibility by locality.
    - The OPO Committee noted that upgrading the model elements to "requirements" is in accordance with the CMS regulations for OPOs and hospitals. This requirement makes it more protective for those patients involved. The requirement is designed to provide for flexibility depending on the state and local laws and regulations and the hospital specific policies and procedures.
- Eliminate any provision that prescribes that an OPO or transplant center provide DCD options to a conscious patient.
    - The OPO Committee noted that there have been cases when the OPO is contacted by the hospital when patients have irrecoverable, ventilator dependant, devastating neurologic injuries or illness and the patient is making the decision to withdraw the ventilator or cardiopulmonary assist device. This level of autonomy is consistent with the Federal Patient Self Determination Act of 1990[1]. In these cases, the OPO and hospital have a legal obligation to honor the patients advance directive which may include organ donation. Good end-of-life care would dictate that if the patient has questions or requests information regarding the donation process, then both the OPO and the hospital should cooperate to ensure that the patient receives the information required to make an informed decision.
- Develop and endorse recommendations for specific procedural safeguards for the application of DCD in conscious ventilator-dependent patients, to include psychiatric evaluation, a waiting period after the first patient request, and the requirement that a second patient request be made at the end of the waiting period. The proposed Requirements broaden donor criteria to include patients without cognitive neurological injury. As physicians, we are greatly concerned that patients with chronic illnesses such as spinal cord injury or amyotrophic lateral sclerosis (ALS) would be vulnerable to real or perceived pressure to decline further treatment in order to donate their organs, especially since the Requirements would permit evaluation of their eligibility for organ donation in advance of a decision whether to withdraw ventilatory or other life-sustaining support.
    - The OPO Committee agrees that these are important considerations for conscious patients making decisions to withdraw support and are advocates that hospitals should have appropriate procedures in place to assess the patient's

[1] Patient Self-Determination Act-Omnibus Budget Reconciliation Act of 1990. Pub L No. 101-508

mental capacity to make critical decisions for their own healthcare. Independent of the option for organ donation, these are hospital specific policies and procedures. The separation of the OPO and Hospital responsibilities related to these assessments further safeguards patient autonomy and decision-making.

- Eliminate any reference to ECMO or EISOR in the Proposal, and refer the many ethical and legal concerns raised by use of ECMO and EISOR in DCD practice to the OPTN/UNOS Ethics Committee for review and recommendation.
    - The OPO Committee noted that these were included as examples and were not endorsing the given use of these procedures. Instead the proposed requirements provide a safeguard for appropriate authorization in the case that these procedures are to be considered. Any of these procedures should be approved according to hospital policy. However, these examples have been removed from the proposal to eliminate any confusion.
- Eliminate any definition of death from the Proposal, as the definition of death is a matter of applicable state statutory or case law.
    - The OPO Committee agrees and the proposed requirements state that “death is declared in accordance with hospital policy and applicable state and local statues or regulation.”
- Reconsider the traditional terminology of "Non-Heart-Beating Donation" as a clarifying designation for the practice in consideration.
    - The OPO Committee disagrees. The language has been changed to represent current clinical nomenclature.
- Explicitly endorse in the Proposal the longstanding ethical safeguard that the donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures has been agreed to by the patient's next of kin, as recommended by the Institute of Medicine. The proposed Requirements remove the important stipulation separating patient care from donation solicitations. Whereas previously the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate, under the proposed policy a patient may be evaluated as a DCD candidate *prior* to a decision by family members and caregivers, which ought to be free from external pressure. Gone is the crucial wall separating patient care from donation solicitations. Such undue influence on difficult decisions at a heart-wrenching time is ethically unacceptable.
    - The OPO Committee noted that the deleted language “the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate” in the original proposal was included then deleted during the drafting of the original proposed changes. That language has never been included in any version of the bylaws. The OPO Committee disagrees with the position that a patient may not be evaluated as a DCD candidate prior to a decision by family members and caregivers to withdraw life sustaining measures, or the position that a donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures have been agreed to. Under CMS regulation, hospitals are obligated to notify OPOs about “individuals whose death is imminent, or who have died” (CFR 42, Volume 3,Revised October 1, 2004, Chapter IV, Part 482: Sec.482.45). The timely referral of a potential organ donor occurs prior to family knowledge of donation options for two primary purposes: 1) the evaluation of a patient as a potential organ donor can be facilitated without OPO communication with the

family, and 2) the patient may have already been registered as an organ donor, which requires no further authorization by a surviving family or caregiver. By not allowing for an OPO's evaluation for donor candidacy prior to a decision to withdrawal, the health care system may expose families to the following misrepresentations: 1) to imply that their loved one is not a donor candidate, when in fact they might be a candidate; 2) to cause a delay in carrying out patient withdrawal procedures as agreed to by a surviving family, but prior to OPO involvement (The 2006 version of the UAGA allows for an OPO to "conduct any reasonable examination necessary to ensure the medical suitability." The UAGA has been enacted in 44 of 50 states and legislation pending in three states; www.nccusl.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006); 3) The surviving family may be lead to believe that they are authorized to make donation decisions for the individual at or near death, while in fact they may not be (all 50 states have passed legislation allowing for a first person authorization (FPA) for organ donation) and more than one hundred million persons are registered. The surviving family would not have access to information available through an OPO which is authorized to access FPA records.

The OPO Committee agrees that the ethical concerns and safeguards are paramount in the organ donation process. The changes to the model elements are intended to increase those patient protections and safeguards by ensuring that hospital have specific policies and procedures for donation after circulatory death. These proposed changes should serve to guide the process and ensure that each patient is treated with the dignity, respect and compassionate end-of-life care. These requirements serve to ensure hospitals and caregivers have a policy and to ensure that OPOs and Transplant Centers abide by the policies developed.

- ***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 Committee believes 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. It 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****:* The intended consequences for this proposal are that the community will have a clearer understanding of DCD requirements.

  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.

Supporting Evidence and/or Modeling:

The Committee comprises donor family representation and experts in the field of procurement and DCD and agreed that the 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 OPTN Key Goals and Adherence to OPTN Final Rule:

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

- 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 Committee 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 UNet[sm] but will require programming to update the UNet[sm] glossaries and Online Help Documentation, and glossaries found on the public websites. The following programming changes would be required:

- Online Help documentation in DonorNet® and Tiedi® will need to be modified to reflect the change from Donor after Cardiac Death (DCD) to Donor after Circulatory Death (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)

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.

Communication and Education Plan:

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	Transplant professionals within OPOs and Transplant Centers	Email	30 days before implementation and day of implementation
UNOS Update Article	Transplant professionals within OPOs and Transplant Centers	Print publication is mailed to members	Earliest issue after OPTN Board approves the policy change.

E-newsletter article	Transplant professionals within OPOs and Transplant Centers	Email	Several mentions in various e-newsletters beginning at least 3 months before OPOs and TX centers are required to implement the change.

Compliance Monitoring:

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 modifications to Policy 7.16 and 7.17 appear below with new language underlined and deleted language marked with ~~strikethroughs~~.

RESOLVED, that modifications to Policy 2.8 (Model Elements for Controlled DCD), Appendix B to the OPTN Bylaws (Criteria for OPO, Transplant Hospital and Histocompatibility Laboratory Membership), Policies 2.7 and 2.8 (Removal of non-renal organs), 3.5.3.3 (Sharing), 3.5.5 (Payback Requirements), 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years), 6.4.2 (Developmental protocols in International Organ Exchange), and 6.4.3 (Ad Hoc Organ Exchange), is modified, as set forth below, effective September 1, 2013.

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

Introduction: ~~Donation after Cardiac Death (DCD) has been accepted by the Institute of Medicine and the transplant community as an ethically and medically acceptable option for patients and families making end of life decisions.~~

~~The intent of developing model elements for OPO and transplant hospital DCD recovery protocols is to establish model elements for OPOs and transplant hospitals to meet in developing, reviewing and improving their respective DCD recovery protocols. This outline is intended to set standards of what must be addressed in a DCD recovery protocol by OPOs and hospitals without being prescriptive regarding practice; each hospital and each DSA is specific in its practice, culture, and resources. The continuing collaboration between OPOs and transplant hospitals is encouraged to allow for the constant development of DCD best practices. The joint OPO Committee/MPSC Working~~

~~Group is available as a continuing resource for OPTN member hospitals that experience delay or difficulty in adopting a DCD recovery protocol.~~

Introduction: 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 whose medical treatment no longer offers a medical benefit as determined by the patient's primary healthcare provider, and in consideration of any available advanced directive executed by the patient. Any planned withdrawal of life sustaining medical treatment/support will be carried out in accordance with hospital policy. The timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy. Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statues 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 centers 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 centers, and donor hospitals.

A. Agreement

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

B. Protocols

OPOs and donor hospitals must establish 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.

C. ~~A. Suitable Candidate Selection~~ 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.

1. ~~A patient (from age newborn to the DSA's defined upper age limit, if applicable) who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for DCD.~~

2. ~~Other conditions that may lead to consideration of DCD eligibility include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.~~
3. ~~The decision to withdraw life sustaining measures must be made by the hospital's patient care team and legal next of kin, and documented in the patient chart.~~

4. ~~The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO and the patient's primary health care team. The OPO determination of donor suitability may also consult with the include consultation from the OPO Medical Director and Transplant Center teams that may be considering the donor organs for transplantation.~~

~~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.~~

D ~~B~~. ~~Authorization/Approval~~ Consent for DCD

Conditions involving a potential DCD donor being medically treated/supported in a conscious mental state shall 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.

~~1.~~ The OPO must confirm that consent has been obtained for any DCD related procedures or drug administration that occur prior to patient death. ~~The legal next of kin may elect to consent to procedures or drug administration for the purposes of organ donation (e.g. heparin, regitine, femoral line placement, lymph node excision, ECMO, and bronchoscopy). No donor related medications shall be administered or donation related procedures performed without consent.~~

~~2. For purposes of these model elements, "legal next of kin" shall also include the patient, a designated health care representative, legal next of kin, or appropriate surrogate.~~

E. Authorization for 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 ~~consents to be an organ donor candidate~~
2. ~~the next of kin as defined by state or local law~~ persons defined by state/local laws to authorize organ donation.
3. ~~the designated health care agent~~

~~Clearance from medical examiner/coroner must be obtained when applicable~~

F. ~~C.~~ Withdrawal of Life Sustaining Medical Treatment/Support ~~Measures/Patient Management~~

Prior to the donor hospital withdrawing life-sustaining medical treatment or ventilated support, 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.
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 in the event that the patient does not become a donor and appropriate communication with the next of kin.

~~1. A timeout is recommended prior to the initiation of the withdrawal of life sustaining measures. The intent of the timeout is to verify patient identification, roles and the respective roles and responsibilities of the patient care team, OPO staff, and organ recovery team personnel.~~

~~a.~~ No recovery personnel (surgeons and other recovery practitioners) ~~member of the transplant team~~ may ~~shall~~ be present for the withdrawal ~~of~~ life-sustaining ~~measures.~~ medical treatment or ventilated support.

~~b.~~ No member of the organ recovery team or OPO staff may guide or administer ~~participate in the guidance or administration of~~ palliative care, or declare ~~the declaration of~~ death.

~~c. There must be a determination of the location and process for withdrawal of life sustaining measures (e.g. ETT removal, termination of blood pressure support medications) as a component of the patient management.~~

~~d. If applicable, placement of femoral cannulas and administration of pharmacologic agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed in the consent process.~~

G. ~~D.~~ Pronouncement of Death

~~1. The patient care team member that is authorized to declare death must not be a member of the OPO or organ recovery team.~~

~~2. The method of declaring cardiac death must comply in all respects with the legal definition of death by an irreversible cessation of circulatory and respiratory functions **before** the pronouncement of death. ** / ***~~

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.

H. ~~E.~~ Organ Recovery

~~1. Following the declaration of death by the hospital patient care team, the organ recovery may be initiated.~~

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.

~~**F. Financial Considerations**~~

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

Below is the bylaw and policy language for those policies and bylaws that need to be changed to be consistent with the changes proposed to the DCD 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 will 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 ~~d 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 ~~d model elements~~ set forth in Attachment III.

2.0 MINIMUM PROCURMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

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.

3.5 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 donors[1] 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 donors[1], 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:

[1]For 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.

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 donor[1], 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.

[1]For 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.

3.5.11.5 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

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. Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

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.

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~~ 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.

Public Comment Responses:

1. **Public Comment Distribution**
   Date of distribution: *03/16/2012*
   Public comment end date: *06/15/2012*

Public Comment Response Tally					
Type of Response	**Response Total**	**In Favor**	**In Favor as Amended**	**Opposed**	**No Vote/ No Comment/ Did Not Consider**
Individual	270	28 (10%)		235 (87%)	7
Regional	11	10 (91%)		1 (9%)	
Committee	4	3 (75%)		0 (%)	1

2. **Primary Public Comment Concerns/Questions**

   - The key issues raising during public comment can be found in **Section 5**.

3. **Regional Public Comment Responses**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	3/26/2012	11 yes, 0 no, 0 abstentions		In Person
2	3/30/2012	26 yes, 0 no, 2 abstentions		In Person
3	5/11/2012	17 yes, 0 no, 1 abstentions		In Person
4	5/11/2012	14 yes, 0 no, 0 abstentions		In Person
5	5/10/2012	19 yes, 0 no, 0 abstentions		In Person
6	5/4/2012	44 yes, 0 no, 0 abstentions		In Person
7	6/15/2012	14 yes, 0 no, 0 abstentions		In Person
8	5/11/2012	19 yes, 0 no, 0 abstentions		In Person
9	5/2/2012	17 yes, 0 no, 0 abstentions		In Person
10	5/4/2012	19 yes, 0 no, 0 abstentions		In Person
11	5/18/2012	1 yes, 16 no, 0 abstentions		In Person

Regions 1-10:
No Comments

Region 11:
The region did not approve this proposal and mentioned the following concerns during discussion:

- This proposal will require significant re-work for OPO/donor hospital policies and Memorandums of Agreement as policies would need to be reviewed by hospital committees and should be cardiac or circulatory death which would not require the automatic re-work for the policies and procedures.
- Will this proposal actually increase the number of DCD donors as the proposal documents an increase in donation under the name of Donation after Cardiac Death?
- The CMS regulations indicate the verbiage Donation after Cardiac Death and not Circulatory Death. This change will create a conflict between CMS and OPTN policies
- Under the revised section "D" authorization for DCD recover, legal next of kin is not the patient who consents. This section should just indicate "authorization" is obtained according to state and/or local law. Under this same section the OPO must receive authorization from the legal next of kin for procedures. Also donor designation is not acknowledged in this section and should just say legal next of kin or via donor designation per state and local law.

Committee Response: The change from cardiac to circulatory updates the OPTN policies and bylaws and does not include a requirement that OPOs and transplant centers change this within their policies, unless it is referencing OPTN policies/bylaws. The Committee acknowledges that the changes may not affect the number of DCD donors. The Committee is proposing a delay in implementation until alignment with CMS regulations can be coordinated. Finally, the Committee made revisions to the proposed language regarding authorization and consent.

4. Committee Public Comment Responses

Ad Hoc Disease Transmission Advisory Committee:
Upon review, the Committee determined that it had no comment regarding this issue.

Ethics Committee: The first issue discussed by the Committee involves the change from cardiac death to circulatory death. This change is based on the Uniform Determination of Death Act (UDDA) definition, which defines "death" by cardiac criteria as the irreversible cessation of circulatory or pulmonary functions. It was agreed that the change to circulatory is appropriate, and that it is a good change because it makes the terminology of the bylaws and the community consistent with the UDDA. It is potentially problematic that literature suggests that DCD donors do not have the *irreversible* cessation of circulatory function but rather the *permanent* cessation of circulatory function. The proposed language confirms that DCD describes death as the irreversible cessation of circulatory function, while a contrary interpretation exists. The Committee believes that it is appropriate to make this change in terminology. When the heart not working regardless of electrical activity, then circulation has ceased and death may still be declared according to state and hospital policies. It is consistent with the law to use this language but the Committee acknowledges that it does not answer all of the potential ethical questions as to when death occurs.

The second issue was about the terminology of withdrawal of medical treatment/support. The Committee offered no comments.

The third question involved the use of the term “disease” in the list of conditions that would permit valid first person consent. The Committee offered no comments about the use of the term “disease.”

The Committee discussed the issue of when donor families were contacted about the potential for DCD donation. Families have expressed concerns that they feel like they have little or no control of the end of life care decisions for their loved ones. One of the options available is organ donation. When first person consent is emphasized, the family role in donation is minimized. First person consent is similar to an advanced medical directive. It was noted that by being on a donor registry, it is not clear that a donor has any idea to what is involved in donation, and how that decision intersects with end of life care decisions.

With respect to the extent of authorization, what is the extent of the consent given when a donor is entered into a registry? The registry indicates an individual’s consent to donate organs, but not consent to all end of life care decisions. What does the public have in mind with respect to first person consent reflected in a donor registry? There was extensive discussion about donors who give first person consent to donation but not to all of the potential procedures that could be performed to maintain a potential donor after death has been declared.

Consent is appropriate for screening tests pre-mortem. While the patient is still alive, normal informed consent practices are still required. A potential donor would likely not want any of the screening tests to jeopardize the patient’s ability to become a DCD donor, and this would be an appropriate disclosure during the informed consent process.

It was asked when should DCD discussion be raised: before; during; or after discussion of withdrawal of care?

The Committee remains concerned that there is not clarity as to where the boundaries of first person authorization in terms of DCD practice recognizing that there is a legal component granting donation after death, and that there is a medical component of practice that must occur pre-mortem. The Ethics Committee does not agree with the OPO approaching the family prior to decision to withdraw treatment or support. The Committee has general concerns that there is a lack of clarity of the boundaries/scope of first person authorization. For example, there is a need to be clear which tests can be fairly included within the authorization given when a person is entered in a donor registry.

It was noted that it is ethically inappropriate to make the OPTN the arbiter on how to describe circulatory death. There is an absence of consensus about the appropriate time period of asystole.

The requirements are clear that the OPO staff have no role in the end of life care yet it was suggested that it is a common practice that it is not the patient’s physician who obtains consent for certain procedures performed to maintain the viability of the donor organs. The Committee agrees that the evaluation of the suitability for DCD may ethically occur pre-mortem.

Committee Response: The Committee has addressed most of the concerns from the Ethics Committee. Key issues addressed include first person authorization laws and consent for procedures. Because state first person authorization laws are different the Committee states in

the proposed language that "the timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy." Additionally, the proposed language states that "the OPO must confirm that consent has been obtained for any DCD related procedures or drug administration that occur prior to patient death."

Operations and Safety Committee:
The Committee did not review this proposal.

Pediatric Transplantation Committee:
After minimal discussion, the Committee unanimously voted to support the proposal as written (19 support, 0 oppose, 0 abstentions).

Thoracic Organ Transplantation Committee:
On May 8, 2012, the Committee reviewed a policy proposal sponsored by the OPO Committee. The Committee voted in favor of the proposal: 14-supported; 0-opposed; and, 0-abstained.

Transplant Administrators Committee:
No comment.

Transplant Coordinators Committee:
The Committee voted in full support of this proposal [For 14: Abstentions 0: Against 0]

5. Individual Public Comment Responses

Key Issues	Comment #	Committee Response
1. A group of individuals (i.e., individuals with disabilities on life support who are not necessarily terminally ill or near death) are being singled out for disadvantageous treatment, and further, can be evaluated without their knowledge or consent.	1, 5, 15[2], 19, 20, 21, 26, 28, 31, 36, 37, 39, 41	The Ethics Committee agrees that the evaluation of the suitability for DCD may ethically occur pre-mortem. The proposed language states that the timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy.
2. Comments not solicited from organizations representing patients with spinal cord disorders and neuromuscular disabilities.	4, 13/16/18, 14[3]	The Committee did not intentionally overlook these organizations. The OPTN has been committed to reaching out to as broad an audience as possible during the development of proposals. The Board has delayed a decision on this proposal which has allowed plenty of time for comments to be received from these organizations.

[2] National Catholic Partnership on Disability
[3] Not Dead Yet

Key Issues	Comment #	Committee Response
3. Failure to restore the ethical safeguard of separation between organ procurement and decision to withdraw life-sustaining treatment.	6, 13/16/18, 14, 28, 37	The Ethics Committee does not agree with the OPO approaching the family prior to decision to withdraw treatment or support. The proposed language states that the withdrawal of life sustaining medical treatment/support will be carried out in accordance with hospital policy.
4. Patients may be evaluated as a DCD candidate *prior* to a decision by family members and caregivers to withdraw life sustaining measures.	1, 2, 5, 6, 12, 15, 30, 38	The Committee agrees that the evaluation of the suitability for DCD may ethically occur pre-mortem.
5. A donor family may be approached about organ donation *before* the time at which a decision to withdraw life sustaining measures has been made.	1, 6, 21, 26, 36, 38, 41	The OPTN/UNOS Ethics Committee does not agree with the OPO approaching the family prior to decision to withdraw treatment or support. The current and proposed language does not address this issue and OPOs do not approach a donor family unless requested.
6. OPOs or transplant centers to provide DCD options to a conscious patient who is not necessarily near death. Failure to provide safeguards for conscious individuals.	1, 2[4], 21, 33, 36, 38, 41 6, 13/16/18, 14	Hospital practice does not fall under the OPTN. Safeguards for conscious individuals should be determined by hospital policy via hospital ethics committee and that language has been added to the proposed policy.
7. Omission of any requirement for psychosocial evaluation of a conscious patient who consents to be an organ donor constitutes gross negligence. Unethical for organ donation to be discussed as a factor in the decision to withdraw life support. The Requirements lack sufficient safeguards to ensure that any decision to donate organs is voluntary and not a product of depression or some other issue.	2, 4, 12	Safeguards for conscious individuals should be determined by hospital policy via hospital ethics committee and that language has been added to the proposed policy. However, the Committee has added language to require that OPOs confirm that a conscious patient has been assessed.

[4] National Catholic Bioethics Center

Key Issues	Comment #	Committee Response
8. Changes do not reflect "optional" nature of hospital participation in DCD. Changing model elements to requirements creates the potential that hospitals that are to have a donor recovery agreement with OPOs may have a conflict of interest as the primary care taker of the donor. Conflicts arise concerning adherence to Dead Donor Rule and Institute of Medicine standards that providers are obligated to secure the family's decision to withdraw life-support before any dialogue with the OPO. Removing the requirement that the health care provider must first determine that it is appropriate to withdraw life support creates a conflict of interest for the health care provider.	2, 5, 6, 12, 15, 21, 25, 30, 34, 38	Hospitals still have an option to have a DCD policy to "not participate in DCD donation" as allowed under the Joint Commission standards. The proposed language states that all decisions regarding medical care and withdrawal of life support be made by the healthcare team and next of kin in accordance with hospital policies.
9. Broadening of donor candidate criteria is dangerously expansive – adding "or disease" with placement of the comma indicating there are no limitations to what constitutes a disease. Hospitals are encouraged to solicit donations from people with any diseases that require ventilator support – authors did not list the diseases to avoid drawing attention from those groups.	2, 4, 13/16/18[5], 14, 15	The Committee has removed the word "disease" from the proposed language. The intent of the language has never been to encourage hospitals to encourage solicitation of organ donation from any particular population of patients.

[5] 200 identical letters, different signatures.

Key Issues	Comment #	Committee Response
10. Removing the requirement for a timeframe between removal of life support and declaration of death. The Institute of Medicine recommendation is 5 minutes.	2	Hospital practice does not fall under the OPTN. Time determined by hospital policy allows for the hospital ethics committee to determine appropriate time frame and to take into consideration the IOM report as one source for determining individual hospital policy.
11. Addition of the provision to allow drugs and procedures to maintain organs for transplant, without limitation by family "authorization." Use of authorization instead of consent contradicts UNOS definitions.	2	The policy language has been changed to clarify that consent must be obtained before administering drugs or performing any procedures.
12. Removal of provision to protect families from incurring donation related charges has been removed.	2	Similar language is not inclusive for brain dead donors, and payment for organ donor related charges are the responsibility of the OPO under CMS regulations.
13. National Disability Rights Network condemns third party decisions to withhold medical treatment from individuals without a terminal condition or permanent unconsciousness as a denial of basic constitutional and civil rights of individuals with disabilities.	4, 6, 13/16/18, 14, 27, 28, 39	The Committee clearly addresses what individuals are allowed to make medical decisions regarding the withdrawal of life sustaining medical treatment/support.
14. The challenge of changing the name and definition is not worth the risk of decreasing a hospital's support for DCD.	8	Nomenclature and policy changes are necessary to ensure clear communications between donor hospital, OPO and transplant center representatives involved in DCD.
15. Too much administrative work without clear benefit	9, 11	Same as 13.

Key Issues	Comment #	Committee Response
16. Section D should refer more to state and local laws for FPC that can vary regarding consent and the ability/need to required NOK consent. Use of circulatory should be interchangeable.	10	Same as 13.
17. Incorrect language suggesting that next of kin may overrule patient or designated agent.	14	The language has been modified to eliminate confusion regarding the next of kin.

Comments are provided in **Exhibit A**.

Post Public Comment Consideration:

There was a considerable amount of concern expressed during public comment and the Committee has work diligently to address the concerns.

Introduction – There were two primary changes made in the introduction section. The Committee added the following language to address concerns raised during public comment: "Any planned withdrawal of life sustaining medical treatment/support will be carried out in accordance with hospital policy" and "The timing of a potential DCD donor evaluation and donation discussion shall be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy."

Section A – Agreement – The Committee withdrew the language that specifically addresses what type of hospitals can participate in DCD recovery and stated that OPOs must have an agreement with ALL hospitals that participate.

Section C - Potential DCD Donor Evaluation – The Committee removed the word "local" in front of OPO in order to be consistent throughout the policy. The Committee also added "OPO's" in front of criteria to clarify ownership. Language listed under the fourth bullet point was removed because it was determined to be unnecessary and too prescriptive because it would fall under standard OPO practices.

The Committee created a new section that separates issues requiring consent (e.g. medical procedures, drug administration) from those that require authorization such as organ recovery.

Section D – Consent for DCD – A major concern raised during public comment dealt with conscious patients being able to make their own medical decisions. Since it is not the OPO's role to determine a potential donor's competency and capacity to make decisions, the Committee agreed that requiring OPOs to confirm that the healthcare team has made that assessment was sufficient.

Section E – Authorization for DCD Recovery - The Committee agreed to delete "if required by local law, an OPO must receive clearance from a medical examiner/coroner" because this is common practice in all OPOs.

Finally, there were other minor edits made to the language in order to be consistent throughout the proposed policy as well as other OPTN polices.

The Committee chairman noted that there were three organizations that had expressed concerns with the proposed changes to the policy and efforts will be made to reach out to them prior to the June Board of Directors meeting. The groups are the National Catholic Bioethics Center, the Catholic Partnership on Disability, and No Dead Yet.

Summary of Public Comments

9. Proposal to Update and Clarify Language in the DCD Model Elements (OPO Committee)

As of 6/25/2012, 86 responses have been submitted to UNOS regarding this policy proposal. Of these, 28 (32.56%) supported the proposal, 51 (59.30%) opposed the proposal, and 7 (8.14%) had no opinion. Of the 79 who responded with an opinion, 28 (35.44%) supported the proposal and 51 (64.56%) opposed the proposal. Comments on the proposal received to date are as follows:

I: Individuals Comments:

Comment 1:
vote: Oppose
Date Posted: 06/07/2012

First, as currently worded, it appears that a group of individuals (i.e., individuals with disabilities on life support who are not necessarily terminally ill or near death) are being singled out for disadvantageous treatment, and further, can be evaluated without their knowledge or consent. Second, the OPO Committee continues positions in the Requirements that were the subject of negative comments by the public without any explanation: It is like it doesn't matter what we say, the Requirements will go forward anyway and continue with these objectionable elements (1) that a patient may be evaluated as a DCD candidate prior to a decision by family members and caregivers to withdraw life sustaining measures, or (2) a donor family may be approached about organ donation before the time at which a decision to withdraw life sustaining measures has been made. On this last issue, it is better to keep the decision of life-sustaining support distinct from the consideration of organ donation, so as to avoid any conflict of interest that could violate the life and rights of the person receiving life support. Such conditions will likely create situations where families are pressured to weigh the value of organ donation in their decisions to continue or withdraw life support, where such life-support decisions should be based solely on the needs of the person receiving life-support. Thirdly, elements are included that allow an Organ Procurement Organization (OPO) or transplant center to provide DCD options to a conscious patient who is not necessarily near death! The Requirements lack sufficient safeguards to ensure that any decision to donate organs is voluntary and not a product of depression or some other issue. In fact, it looks like patients who might be in a depressed state might be encouraged to end their "sad" lives so that they can be remembered as someone who died to save the lives of others.

Comment 2:
vote: Oppose
Date Posted: 06/14/2012

Read Comment - National Catholic Bioethics Center

Comment 3:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – Elizabeth Pieper

Comment 4:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – Anna Stubblefield

Comment 5:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – Betsy Fell

Comment 6:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – Bill Gaventa (same as comment #13 except first paragraph)

Comment 7:
vote: Oppose
Date Posted: 06/15/2012

Read Comment - Dohn Hoyle

Comment 8:
vote: Oppose
Date Posted: 06/05/2012

Read Comment – Medical University of South Carolina

Comment 9:
vote: Oppose
Date Posted: 06/05/2012

Read Comment - Vanderbilt University Medical Center

Comment 10:
vote: Oppose
Date Posted: 06/05/2012

Read Comment – Lifeshare of the Carolinas

Comment 11:
vote: Oppose
Date Posted: 06/05/2012

Committee Response:

Read Comment – Duke University

Comment 12:
vote: Oppose
Date Posted: 06/15/2012

Read Comment - Marna Ares

Comment 13:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – Ed Burke

Comment 14:
vote: Oppose
Date Posted: 06/15/2012

Read Comment - Not Dead Yet

Comment 15:
vote: Oppose
Date Posted: 06/15/2012

Read Comment – National Catholic Partnership on Disability

Comment 16:
vote: Oppose
Date Posted: 06/15/2012

Same letter as comment #13 (from 177 different individuals)

Comment 17:
vote: Oppose
Date Posted: 06/14/2012

Same letter as comment #13

Comment 18:
vote: Oppose
Date Posted: 06/18/2012

Same letter as comment #13 (from 7 more individuals)

Comment 19:
vote: Oppose
Date Posted: 06/07/2012

> As a pastoral visitor I believe this is an injustice Yet, making organ transplants more available is unquestionably a laudable objective. But it cannot justify singling out disabled people on life-support as donation candidates since it would unavoidably rest on the assumption that their lives are less valuable than those of other persons.

Comment 20:
vote: Oppose
Date Posted: 06/07/2012

> As someone deeply concerned about the dignity and worth of people with disabilites, who are among the most vulnerable members of society, I urge UNOS to reject the proposed changes to the Model Elements for organ donation. Simply put, the changes seek to expedite the process of organ donation and expand the organ pool at the expense of disabled persons on life support.

Comment 21:
vote: Oppose
Date Posted: 06/07/2012

As someone deeply concerned about the dignity and worth of people with disabilities, who are among the most vulnerable members of society, I urge UNOS to reject the proposed changes to the Model Elements for organ donation. Simply put, the changes seek to expedite the process of organ donation and expand the organ pool at the expense of disabled persons on life support. Three consequences of the proposed changes give me particular concern: First, the primary health care team and organ procurement organization staff may examine hospitalized patients on life-support to determine their suitability for organ donation without such patients or their families knowledge or consent, even though such patients are not necessarily terminal or near death; Second, if determined medically suitable, the hospital may initiate a request to the family for organ donation before the decision to withdraw such patients life-support is made; Third, an organ procurement organization is not required to condition eligibility for organ donation on assurances that a conscious patients decision to have life-support withdrawn is voluntary and not a product of clinical depression. Making organ transplants more available is unquestionably a laudable objective. But it cannot justify singling out disabled people on life-support as donation candidates since it would unavoidably rest on the assumption that their lives are less valuable than those of other persons. Thank you for your serious consideration.

Comment 22:
vote: Oppose
Date Posted: 06/07/2012

Repeat of comment #21

Comment 23:
vote: Oppose
Date Posted: 06/07/2012

Repeat of comment #21

Comment 24:
vote: Oppose
Date Posted: 06/13/2012

Repeat of comment #21

Comment 25:
vote: Oppose
Date Posted: 06/08/2012

Changes do not reflect the OPTIONAL nature of hospital participation in DCD. There are numerous problems with the changes (no firewall between decision by family to withdraw treatment and approach by the OPO, for example) but the biggest problem is at the level of participation at all. Dignity Health has identified ethical problems with DCD, including that pink dot organ donors have not signed up for THIS kind of organ donation and poor patients may mistrust motivations of the hospital to withdraw treatment when loved ones are seen as potential organ sources before they are dead. We have real concerns about potentially violating the dead donor rule, about treating dying patients as organ donors first and dying patients second,

and about the possibility of genuine informed consent, when the people giving the information are so highly motivated to secure the organs. In the Agreement, section A, it must be made clear that no hospital is obligated to directly participate in DCD. This means that in the Appendix, item II is completely unacceptable, because it would require that transplant hospitals facilitate the procurement of DCD donor organs, in spite of hospital policy prohibiting DCD participation. This is coercive and undermines (or attempts to trump) hospital policy.

Comment 26:
vote: Oppose
Date Posted: 06/09/2012

Each human person is unique and valuable in their own right, as a creation of God. This proposal appears to put persons on life support at risk by supplying information about organ donation to them at an inappropriately early point in time , and by evaluating their suitability for organ donation without their knowledge or consent. Besides this being an assault on human dignity, this would also put pressure on family members to consider the need for organ donation, when making treatment decisions for their Ill or compromised loved one when the decisions should instead be based soley on the best interests of the patient.

Comment 27:
vote: Oppose
Date Posted: 06/07/2012

Human rights must be applied in all cases of health care ... End of life is a personal choice and not an issue to be decided by whole or in part those who may benefit from the death ... This is not a decision that should be influenced br a sales pitch (no matter how delicately presented) ...

Comment 28:
vote: Oppose
Date Posted: 06/09/2012

I am an RN and I fully oppose this proposed legislation. It would target a whole class of people who are dependent on life support treatments to determine their eligibility for organ donation WITHOUT their knowledge or consent. Also, this could be done in cases before any decision has been made regarding the withdrawal of life support. This proposal is a violation of human rights and dignity. The decision of life-sustaining support must be kept separate from the consideration of organ donation in order to avoid any conflicts of interest that could violate the life and rights of the person receiving life support.

Comment 29:

vote: Oppose
Date Posted: 06/14/2012

I am the parent of a child who has autism and a concerned citizen. Human life is sacred and we must honor its sacredness even if a person's life appears "hopelessly impaired." People matter because of who they are, created in the image and likeness of God, not because of what they have. It would appear from this proposal that only lives of a certain quality should be preserved.

Comment 30:
vote: Oppose
Date Posted: 06/07/2012

I strongly oppose the assessment of an individual for potential organ donation viability before the individual themselves or those relatives responsible for their care are at the point of life or death decisions. The potential or perceived potential conflict of interest/pressure related to organ donation is too radical a line to cross. If this process moves forward it will bode very badly for the administration of any entity involved with only one conflict ever occuring and the organ donation program. Additionally, this has the extreme potential to cause life and death hard to individuals with non-life threatening conditions such as the developmentally disabled. This is an unacceptable proposal that crosses into a radical arena of potential harm.

Comment 31:
vote: Oppose
Date Posted: 06/14/2012

I think what we owe patients with a.l.s. or spinal cord injuries is good patient education to get across to them that it is possible to achieve a high quality of life on mechanical ventilation or noninvasive ventilation. They need to know that with the help of computer-assisted communication, they can enjoy many meaningful activities. We need to give them and their families good laws and good support that make it possible for them to obtain the assistance that they need without undue restrictions. It is a real step down the slippery slope to approach these people with the goal of procuring their organs.

Comment 32:
vote: Oppose
Date Posted: 06/08/2012

My Comments have been sent in letter form as an attachment to: publiccomment@unos.org.

Comment 33:
vote: Oppose
Date Posted: 06/15/2012

On behalf of the CMDA Ethics Committee, I share the stated goal of the proposed Requirements that each patient be treated with the dignity, respect and compassion appropriate to end-of-life care. Accordingly, the specific policies of the Requirements ought consistently to reflect that goal. We thank the OPO Committee for considering our letter from November 2011. Having reviewed and considered the Committee's response, we understand the Committee's reasoning on some points while we hold fully to our initial concerns. There is one particular point in the current draft to which we would draw the OPO Committee's attention and on which we urge reconsideration. The proposed Requirements, as we read them, would press for OPO evaluations even of a conscious patient, for example, with ALS or spinal cord injury, prior to or in the absence of that patient's consent to such evaluation. The hospital or hospice patient who is conscious and competent and who has not requested DCD for organ donation should not have to be confronted unexpectedly by an OPO team arriving at the bedside to evaluate that patient for organ donation candidacy. We believe that such practice would breach the crucial ethical boundary between patient care and donation solicitation and would be tantamount to coercion. We recommend, at a minimum, the reasonable precaution of permitting OPO evaluations to be initiated only upon the authorization of the patient's attending physician and not before.

Comment 34:
vote: Oppose
Date Posted: 06/08/2012

Our overarching comment is that it is ethically indefensible to require hospitals to participate in DCD and therefore the revisions to the DCD Model Elements should make explicit that participation is voluntary. Many hospitals and ethicists continue to have the following significant concerns about DCD: concerns that DCD violates the dead donor rule, concerns about DCDs impact on end of life care and the dying process, concerns about the adequacy of informed consent, and concerns about treating living patients as a mere means to the end of organ procurement, particularly since DCD protocols sanction performing procedures and administering medications on living patients that serve only to maximize the success of procurement efforts and have no therapeutic intent/effect. In light of the legitimate debate that remains about DCD, it is essential that any guidelines preserve the option for hospitals to opt in or out of participation. We agree that all hospitals should have policies that address whether they offer DCD, and that non-participating hospitals establish procedures for transferring patients to DCD participating hospitals at the patient or familys request. More detailed comments are offered below: p. 6 We want to register our strong support for the comment the OPO reviewed and rejected under the Explicitly endorse in the Proposal paragraph on page 6 that stressed the importance of maintaining the longstanding and ethically significant firewall that has always existed between discussions and decisions to withdraw life support and discussions and decisions to pursue organ donation. We understand that CMS regulations require hospitals to notify OPOs of imminent death and agree that there should be nothing to stop the OPO from doing appropriate clinical evaluations of donor eligibility, or checking to determine whether referred patients are registered organ donors. But approaching patients/families with any discussion about organ donation before they have made a decision to withdraw life sustaining treatment remains ethically problematic. p. 11 Attachment III A. AgreementIt should be explicitly added and clarified that no hospital is obligated to participate in DCD recovery, even those that have ventilators and functional operating rooms. p. 12 D Authorization for DCD Recovery For those hospitals who participate in DCD recovery, there should be a requirement to receive explicit consent from the patient or legally authorized decision maker (which in some states like California may not be next-of-kin) for any procedures or drug administration not only to prepare the patient for DCD recovery as stated, but also both to

evaluate the patients eligibility as a donor and to maintain the patient while they are undergoing evaluation. p. 13/14 Pronouncement of Death: This points to the lack of consensus and arbitrary nature of protocols around the determination of death in a DCD context which needs to be more fully acknowledged and addressed. p. 14 Appendix B to Bylaws--Since many hospitals and ethicists find DCD ethically controversial and problematic, we are troubled by the suggestion that transplant hospitals would be required to participate in the recovery of organs from DCD donors. p. 16 For those hospitals who participate in DCD, the operating room should not be mandated as the only venue for the withdrawal of life support.

Comment 35:
vote: Oppose
Date Posted: 05/15/2012

Comment 36:
vote: Oppose
Date Posted: 06/15/2012

The Archdiocese of Washington's Department of Special Needs Ministries believes it is better to keep the decision of life-sustaining support distinct from the consideration of organ donation so as to avoid any conflict of interest that could violate the life and rights of the person receiving life support. Such conditions will likely create situations where families are pressured to weigh the value of organ donation in their decisions to continue or withdraw life support, where such life-support decisions should be based solely on the needs of the person receiving life-support. As an organization tasked to recognize the dignity and worth of all persons, including people with disabilities, (who are among the most vulnerable members of society,) I urge UNOS to reject the proposed changes to the Model Elements for organ donation. Simply put, the changes seek to expedite the process of organ donation and expand the organ pool at the expense of disabled persons on life support. Three consequences of the proposed changes give me particular concern: First, the primary health care team and organ procurement organization staff may examine hospitalized patients on life-support to determine their suitability for organ donation without such patients or their families knowledge or consent, even though such patients are not necessarily terminal or near death; Second, if determined medically suitable, the hospital may initiate a request to the family for organ donation before the decision to withdraw such patients life-support is made; Third, an organ procurement organization is not required to condition eligibility for organ donation on assurances that a conscious patients decision to have life-support withdrawn is voluntary and not a product of clinical depression. Making organ transplants more available is unquestionably a laudable objective. But it cannot justify singling out disabled people on life-support as donation candidates since it would unavoidably rest on the assumption that their lives are less valuable than those of other persons. Thank you for your serious consideration. Regards, Margaret L. Kolm Coordinator Department of Special Needs Ministries Archdiocese of Washington 7202 Buchanan Street Hyattsville, MD 20784

Comment 37:
vote: Oppose
Date Posted: 06/13/2012

The proposed policy is dangerous because a class of individuals is being singled out for disadvantageous treatment and can be evaluated without their knowledge or consent. It is better to keep the decision of life-sustaining support distinct from the consideration of organ donation so as to avoid any conflict of interest that could violate the life and rights of the person receiving life support. The requirements lack sufficient safeguards to ensure that any decision to donate organs is voluntary and not a product of depression.

Comment 38:
vote: Oppose
Date Posted: 06/07/2012

Three consequences of the proposed changes give me particular concern: First, the primary health care team and organ procurement organization staff may examine hospitalized patients on life-support to determine their suitability for organ donation without such patients or their families knowledge or consent, even though such patients are not necessarily terminal or near death; Second, if determined medically suitable, the hospital may initiate a request to the family for organ donation before the decision to withdraw such patients life-support is made; Third, an organ procurement organization is not required to condition eligibility for organ donation on assurances that a conscious patients decision to have life-support withdrawn is voluntary and not a product of clinical depression or other mental health symptom.

Comment 39:
vote: Oppose
Date Posted: 06/15/2012

We wish to express our opposition to the proposed model elements. Simply put, the proposed changes subject a class of disabled people to discriminatory treatment, while offering justifications that are inapposite, unconvincing, and clearly violative of patient's rights. We will submit our full set of comments outlining our specific concerns via email, which will be sent by Robert Quinlan (bquinlan@ncpd.org).

Comment 40:
vote: Support
Date Posted: 06/15/2012

Read Comment (AOPO)

Comment 41:
vote: Support
Date Posted: 06/07/2012

As someone deeply concerned about the dignity and worth of people with disabilities, who are among the most vulnerable members of society, I urge UNOS to reject the proposed changes to the Model Elements for organ donation. Simply put, the changes seek to expedite the process of organ donation and expand the organ pool at the expense of disabled persons on life support. Three consequences of the proposed changes give me particular concern: First, the primary health care team and organ procurement organization staff may examine hospitalized patients on life-support to determine their suitability for organ donation without such patients or their families knowledge or consent, even though such patients are not necessarily terminal or near death; Second, if determined medically suitable, the hospital may initiate a request to the family for organ donation before the decision to withdraw such patients life-support is made; Third, an organ procurement organization is not required to condition eligibility for organ donation on assurances that a conscious patients decision to have life-support withdrawn is voluntary and not a product of clinical depression. Making organ transplants more available is unquestionably a laudable objective. But it cannot justify singling out disabled people on life-support as donation candidates since it would unavoidably rest on the assumption that their lives are less valuable than those of other persons. Thank you for your serious consideration. Julia Tracey

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Comment 42:
vote: Support
Date Posted: 06/08/2012

I support this proposal, but as a board certified chaplain who works with physicians, OPOs, and families considering organ donation - as well as a donor mom. My 17 year old daughter was a donor following her death in 2003 caused by a speeding red light runner. This proposal serves to update and clarify language in order to continue to allow the option of DCD. There are many families who want to honor the wishes of their loved one not to remain alive through artifical means despite not meeting brain death criteria - and who want to honor their loved one's wishes to give the gift of life through donation. I urge you to approve this proposal and not bow to the misinterpretation by religious and other groups who oppose it. In my experience as a professional clinician, these groups are responding out of a personal anti-donation agenda and/or theology that they wish to impose upon others, not in the desire to honor personal beliefs and values. Thank you for your consideration.

Comment 43:
vote: Support
Date Posted: 06/15/2012

NATCO supports this proposal as written.

Comment 44:
vote: Support
Date Posted: 06/08/2012

Please note the email below that is being circulated. You may wish to contact Rev. Gaventa to address his fears because he is working hard to reverse this proposal as you'll see. From: california-collaborative@googlegroups.com On Behalf Of Risley, Carol@SCDD Sent: 6/7/12 To: CA Collaborative Subject: CA Collaborative Proposed Modifications to the Requirements for Organ Donation Could Adversely Impact People with Disabilities From the newsletter of the National Catholic Partnership with Disability

Action Alert Proposed Modifications to the Requirements for Organ Donation Could Adversely Impact People with Disabilities - Send Comments Today The National Catholic Partnership on Disability (NCPD) urges you to express your concerns directly by computer submission to stop serious threats to hospitalized persons with disabilities on life support. Such threats are due to occur if current proposals are put into effect that would increase pressure on individuals and families to decline further treatment in order for the patient's organs to be donated. The organization we are asking you to contact is the UNOS/OPTN. OPTN's Proposed Amendment on Organ Donation after Cardiac Death (DCD) Model Elements would target a class of persons with disabilities who are dependent on life-support treatments (such as ventilators, dialysis, and certain medications) to determine their eligibility for organ donation without their knowledge or consent, and in many cases before any decision has been made regarding withdrawal of life support. After analysis by NCPD's Ethics and Public Policy Committee, there are essentially three points in the proposed Model Elements (which are now stated as Requirements) which raise serious threats to hospitalized persons with disabilities who are singled out for organ donation. They are: (1) The proposed Requirements broaden donor criteria to include patients without cognitive neurological injury. Patients with chronic illnesses such as spinal cord injury or amyotrophic lateral sclerosis (ALS) would be vulnerable to real or perceived pressure to decline further treatment in order to donate their organs, especially since the Requirements would permit evaluation of their eligibility for organ donation without their knowledge or consent. It is important to note that such patients, while dependent on life-support, are not required to be terminally ill or near death; neither do they have to previously agree to donate their organs. NCPD is concerned that a class of individuals (i.e., individuals with disabilities on life support who are not necessarily terminally ill or near death) are being singled out for disadvantageous treatment, and further, can be evaluated without their knowledge or consent. (2) The OPO Committee continues the positions in the Requirements, despite public comments to the contrary, (1) that a patient may be evaluated as a DCD candidate prior to a decision by family members and caregivers to withdraw life sustaining measures, or (2) a donor family may be approached about organ donation before the time at which a decision to withdraw life sustaining measures has been made. NCPD believes it is better to keep the decision of life-sustaining support distinct from the consideration of organ donation so as to avoid any conflict of interest that could violate the life and rights of the person receiving life support. NCPD contends that such conditions will likely create situations where families are pressured to weigh the value of organ donation in their decisions to continue or withdraw life support, where such life-support decisions should be based solely on the needs of the person receiving life-support. (3) Provisions are included that allow an OPO or transplant center to provide DCD options to a conscious patient who is not necessarily near death. The Requirements lack sufficient safeguards to ensure that any decision to donate organs is voluntary and not a product of depression. This seems to encourage the choice to end one's life for the sake of others who would benefit from the person's organs. Comments are due by June 15, 2012. Please ACT NOW. To submit comments, click here [http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/proposals.asp] Bill Gaventa, M.Div. Associate Professor, Pediatrics Coordinator, Community and Congregational Supports The Elizabeth M. Boggs Center on Developmental Disabilities UMDNJ-Robert Wood Johnson Medical School 335 George St., P.O. Box 2688 New Brunswick, New Jersey 08903 (732) 235-9304. Fax: (732) 235-9330 email: bill.gaventa@umdnj.edu website: http://rwjms.umdnj.edu/boggscenter

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Comment 45:
vote: Support
Date Posted: 06/15/2012

Read Comment - AST

Comment 46:
vote: Support
Date Posted: 06/25/2012

Read Comment - ASTS

THE NATIONAL CATHOLIC BIOETHICS CENTER
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June 8, 2012

John R. Lake, MD
President, Board of Directors
Organ Procurement and Transplantation Network/United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

Dear Dr. Lake:

I am writing as Director of Bioethics and Public Policy of The National Catholic Bioethics Center (NCBC) to provide comment to the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Board of Directors, and to encourage rejection of many of the provisions of the *Proposal to Update and Clarify Language in the Controlled Donation after Circulatory Death (DCD) Model Elements*.[1] We understand that UNOS/OPTN is currently in the process of revising what since 2007 have been "Model Elements" (i.e., guidelines) to what will soon be binding "Requirements" for OPTN members. We welcome this opportunity to provide comment on this proposal and to make suggestions for revisions.

The NCBC is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The Center serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.

As you undoubtedly know, the Catholic Church encourages organ donation as providing the gift of life to those in need. Our Center has often reflected on and written about the

[1] *Organ Procurement Organization (OPO) & Organ Availability (OAC) Committees, United Network for Organ Sharing, Proposal to Update and Clarify Language in the DCD Model Elements* (2012), http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_309.pdf. [hereinafter Proposal]. DCD refers to organ donation after cardiac death.

moral challenges associated with organ donation. The United States Conference of Catholic Bishops encourages organ donation for ethically legitimate purposes. Specifically their document entitled *Ethical and Religious Directives for Catholic Health Care Services* states:

> 63. Catholic health care institutions should encourage and provide the means whereby those who wish to do so may arrange for the donation of their organs and bodily tissue, for ethically legitimate purposes, so that they may be used for donation and research after death.[2]

Thus, the NCBC welcomes the opportunity to address the OPTN/UNOS regarding this DCD proposal, and it is grateful that the OPTN is attempting to provide greater transparency to the procedures by having extended the period for public comment.

I will outline our concerns related to the Proposal as follows:

- **The Proposal represents a "Requirement," not "Model Elements."** All transplant centers and Organ Procurement Organizations (OPO) must adhere to policies of UNOS, which are binding for participation in OPTN. If the UNOS disagrees with these policies it will seek remediation with the OPOs and transplant centers. The Proposal contains new language, stated as follows:

  1) 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.
  2) 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.[3]

  There is the potential that hospitals that are to have a donor recovery agreement with the OPO, which now has to implement the new "Requirements" pursuant to participation with UNOS, may have a conflict of interest as the primary care taker of the donor. Conflicts may arise concerning adherence to the Dead Donor Rule[4] and the standards advised by the Institute of Medicine regarding the obligations of the provider to first have secured the family's decision to remove life-sustaining medical treatment or ventilator support before any dialogue occurs with the OPO, as referenced below. This is particularly true since the

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[2] U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, D.C.: USCCB, 2009), n. 63.

8 The blood serum test is an even more

[3] Ibid, p. 1.

[4] Committee on Non-Heart-Beating Transplantation II-The Scientific and Ethical Basis for Practice and Protocols-Division of Health Care Services-Institute of Medicine: *Non-Heart-Beating Organ Transplantation: Practice and Protocols.* Edition 2000 edition. Edited by Medicine I. Washington, DC , National Academy Press; 2000:156.

Proposal description describes the mandatory nature of the proposed "Requirements:"

> DEQ [UNOS Department of Evaluation and Quality] 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.[5]

At the same time, the proposal states:

> The requirement is designed to provide for flexibility depending on the state and local laws and regulations and the hospital specific policies and procedures.[6]

This appears to be a contradiction. The proposal appears to be flexible only in the areas where it should not be, i.e., areas that involve donor safety and informed consent: the breadth of who can be a potential donor; the lack of a definition of "irreversibility;" the omission of the obligation of the provider to first have secured the family's decision to remove life-sustaining medical treatment or ventilator support before any dialogue occurs with the OPO; the lack of specification of a timeframe between withdrawal of life support and declaring of death;[7] omitting the obligation to obtain informed consent for the use of drugs and procedures to maintain organ suitability for transplant; the use of ECMO and EISOR;[8] and not requiring psychological evaluation before a conscious patient can consent to be a donor.[9]

- **The broadening of donor candidate criteria is dangerously expansive**. Donor criteria which include patients with permanent and irreversible neurological injury (current language) have been broadened to include patients with "a permanent and irreversible neurological injury, or disease [note placement of comma, indicating that there are no limitations on what constitutes a disease] which may allow for a planned withdrawal of life-sustaining medical treatment *or* ventilated support."[10] [emphasis added] Thus, such a non-terminally ill patient with an upper spinal cord injury, or emphysema, or amyotrophic lateral sclerosis, who may or may not be on a ventilator, who may be alert and also may be depressed, could be a donor. Such a patient could be sedated, removed from the ventilator, declared dead in a non-specified period (up to each hospital), and become an organ donor. In fact, the Proposal removes the requirement that the person has to be experiencing an "end-stage" pathology to be a donor. There is no recognition of the fact that depression plays a key role in the wish to terminate one's life; and depressed persons,[11] especially those with disabilities (and perhaps even through their exhausted

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[5] Proposal, p. 10.
[6] Ibid, p. 5
[7] Ibid, pp. 4, 12.
[8] Ibid, p. 6.
[9] Ibid, pp. 5-6.
[10] Proposal, pp. 11-12.
[11] A study published in the *British Medical Journal* followed 58 patients in Oregon who requested aid in dying. Most were terminally ill with cancer or Lou Gehrig's disease. Of the 58, twenty-six percent were independently diagnosed with depression. See: Linda Ganzini, Elizabeth R Goy, Steven K Dobscha, "Prevalence of depression and anxiety in patients requesting physicians' aid in dying: cross sectional survey," *British Medical Journal* (2 August 2008), Abstract.

family caregivers), can be discriminated against as they erroneously are presented with options that may provide what is perceived to be an "heroic end." The very categories of persons identified as potential donors are persons with significant disabilities, who should not be presented with premature options as if their lives are not as valued as those without disabilities. Furthermore, this represents a direct contradiction by UNOS that it is relying on CMS Standards for the revisions in the Proposal.[12] CMS standards indicate that hospitals are obligated to notify OPOs about "individuals whose death is *imminent* [emphasis added], or who have died" (CFR 42, Volume 3, Revised October 1, 2004, Chapter IV, Part 482: Sec. 482.45).

- **The absence of a definition of "irreversibility**," compounds the aforementioned scenario and the dangers inherent in the changes in the donor candidate criteria. Thus, arbitrary criteria can be used to determine if life-sustaining medical treatment or ventilator support is to be withdrawn. This is compounded by the absence of specifications for a determination of the permanent absence of circulation. Furthermore, the Proposal states:

  > 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).[13]

  Obviously, it is critical that before acceptance of this Proposal, the public have a clear understanding of who are to be included under these expanded criteria.

- **Removing the requirement that family and primary health care provider must 1st determine that it is appropriate to withdraw life-sustaining medical treatment or ventilator support creates a conflict of interest for the primary care physician**.[14] It is proposed that even before this decision has been made by the family to withdraw life-sustaining medical treatment or ventilator support, the local OPO and the primary health team are to make a determination if donor candidate criteria have been met. This is a significant breach of medical non-maleficence. Thus, a person with a neurological disease, who is on a ventilator and even awake, can be evaluated by his provider and the local OPO for consideration to be a donor candidate,[15] and ***then*** be approached with the possibility of sedation and removal of ventilation for the purpose of being a donor. Furthermore, in 2000, the Institute of Medicine explicitly recommended that "the decision to withdraw life-sustaining treatment should be made independently of and *prior to* any staff-initiated discussion of organ and tissues donation."[16] [emphasis added] This commitment was reaffirmed by the IOM in its 2006 report.[17] The Proposal justifies such a procedural omission in the Proposal by citing the 2006 version of the UAGA[18] which allows for an OPO

[12] Proposal, pp. 1, 3-6, 8.
[13] Ibid, p. 9.
[14] Proposal, pp. 6, 7, 11, 12.
[15] Ibid, pp. 11-12.
[16] COMMITTEE ON NON-HEART BEATING TRANSPLANTATION II, INSTITUTE OF MEDICINE, NON-HEART-BEATING ORGAN TRANSPLANTATION: PRACTICE AND PROTOCOLS 16 (National Academy Press 2000) (emphasis added).
[17] COMMITTEE ON INCREASING RATES OF ORGAN DONATION, INSTITUTE OF MEDICINE, ORGAN DONATION: OPPORTUNITIES FOR ACTION 136 (James F. Childress & Catharyn T. Liverman, eds., National Academies Press 2006).
[18] www.nccusl.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006).

to "conduct any reasonable examination necessary to ensure the medical suitability." However, the UAGA specifically indicates that he potential donor must be "at or near death."[19] Such a requirement is missing from the Proposal. Furthermore, the Proposal incompletely cites that the UAGA has been enacted in 44 of 50 states and legislation pending in three states.[20] However, the National Conference of Commissioners on Uniform State Laws acknowledges that:

> Many states have related laws that should not be repealed but should remain in effect, such as: donor registry provisions; donor awareness programs; Transplant Councils; and licensing provisions for procurement organizations and health care providers. The state may also have regulatory and other law that applies to the subject matter of this [act] that should remain in place. However, it is highly desirable that the core provisions of the [act] be uniform among states as there is very little time available to timely prepare, possibly transport across state lines, and transplant life-saving organs, let alone assess and comply with significant variations of state law.[21]

Thus, adoption of the UAGA does not constitute the legal adoption of the parameters referenced herein.

- **The Proposal removes the requirement of a standard for assessment that death is likely to occur after withdrawal of life sustaining medical treatment or ventilator support within a timeframe necessary for organ donation, allowing each hospital to establish its own timeframe for organ suitability**.[22] This is dangerous to the wellbeing and consent of the donor. The Proposal inaccurately justifies the lack of standard on this issue by stating that "there is no industry standard,"[23] when, in fact, the Institute of Medicine recommendation is five (5) minutes between the withdrawal of life support and declaration of DCD.[24] This arbitrary policy is not consistent with the rights of the donor and the Dead Donor Rule[25] and clearly violates the principle of medical non-maleficence.

- **This danger is potentiated by the addition of the provision of allowing drugs and procedures to maintain organs for transplant, with no limitation but family "authorization**."[26] Crossed out in the Proposal is the current provision, E.5, which requires that, "If applicable, placement of femoral cannulas and administration of pharmacological agents (e.g. regitine, heparin) for the sole purpose of donor organ function must be detailed

[19] Ibid, Sec. 14 (c).
[20] Proposal, p. 7.
[21] National Conference of Commissioners on Uniform State Laws, *Uniform Anatomical Gift Act, with Prefatory Note and Comments* (July 2006). http://www.law.upenn.edu/bll/archives/ulc/uaga/2009final.pdf.
[22] Proposal, pp. 4, 12.
[23] Ibid, 4.
[24] Committee on Non-Heart-Beating Transplantation II-The Scientific and Ethical Basis for Practice and Protocols-Division of Health Care Services-Institute of Medicine.
[25] S. J. Youngner and R. M. Arnold, "Ethical, Psychological, and Public Policy Implications of Procuring Organs from Non-Heart-Beating Cadaver Donors," *JAMA* 269 (1993): 2769-74.
[26] Proposal, p. 12.

in the *consent* process."[27] [emphasis added] "Authorization" clearly does not constitute "informed consent," by UNOS' own definition:

> Currently, UNOS policy uses the term "consent" to describe the act of making an anatomical gift. However, the public associates "consent" with the medico-legal concept of "informed consent" through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.[28]

The procedures and drugs should never be the cause of the acceleration of donor death; and families need to know of the risks and side effects through "informed consent" before giving their "authorization."

- **Changing terminology of "Cardiac Death" to "Circulatory Death" is not an issue if the protocol precludes the use of the extracorporeal membrane oxygenation (ECMO) and EISOR**. ECMO bypasses the heart and lungs while artificially profusing all body organs of the non-heart beating donors. Its use in such cases has been described as designed "to resuscitate the donor after a formal declaration of cardiac death."[29] The ECMO is oxygenating all organs, including the brain. But a person who is not dead but on ECMO support erroneously could be considered dead for the purpose of organ donation. This is facilitated by the fact that the Proposal omits criteria for determining the permanent absence of circulation. Furthermore the protocol specifies that it will not preclude the use of ECMO or EISOR (extracorporeal interval support for organ retrieval),[30] which involves placing an occlusion balloon in the thoracic aorta to prevent the oxygenated blood from reaching the heart and the brain, thus avoiding reanimation,[31] effectively *causing* brain death. This is of increased concern because no longer will "informed consent "be required for the use of ECMO, just "authorization" by the legally competent party. Thus, by UNOS' own definition of informed consent, there is no requirement to provide to "patients [or surrogate decision-makers] all the information they need to understand the risks, benefits, and costs of a particular medical treatment."[32]

- **The omission of any requirement for a psychological evaluation of a conscious patient who consents to be an organ donor constitutes gross negligence**. States that have legalized physician assisted suicide have gathered years of data concerning why

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[27] Ibid, p.13.
[28] *Organ Procurement Organization (OPO) Committee, United Network for Organ Sharing, Proposal to Change the Term "Consent" to "Authorization" throughout Policy When Used in Reference to Organ Donation* (2011), p. 3. http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_297.pdf.
[29] Steven M. Rudich et al., "Extracorporeal Support of the Non-Heart-Beating Organ Donor (Letters to the Editor)," *TRANSPLANTATION* 73:158 (2002), 158.
[30] Proposal, pp. 6, 12.
[31] Mark T. Gravel, et al., "Kidney Transplantation from Organ Donors Following Cardiopulmonary Death Using Extracorporeal Membrane Oxygenation Support," *ANNALS OF TRANSPLANTATION* 9:57, 57-58. See also Carla DeJohn & Joseph B. Zwischenberger, "Ethical Implications of Extracorporeal Interval Support for Organ Retrieval (EISOR)," *ASAIO* JOURNAL 52:119 (2006), 119-122.
[32] *Organ Procurement Organization (OPO) Committee, United Network for Organ Sharing, Proposal to Change the Term "Consent" to "Authorization" throughout Policy When Used in Reference to Organ Donation* (2011), p. 3. http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_297.pdf.

persons request assisted suicide. The lowest frequencies for such a request are pain and finances; but one of the most frequent stated reasons for wishing to die is fear of a loss of dignity (82.7%).[33] This is a terrible reason to end one's life. It reflects a sense of hopelessness about the future that is not about physical suffering, but fear of being a burden and being rejected. Hopelessness breeds depression, which can dictate choices that do not truly reflect the will of the patient, but a choice between the lesser of evils. Furthermore, when the law is permissive rather than mandatory[34] pertaining to requiring a psychological evaluation of candidates, data support that the evaluation does not occur. Out of the 596 having died by physician assisted suicide in Oregon over a fourteen year period, only 40 received a psychological evaluation. For truly informed consent, such a requirement should be mandatory.

- **The provision to protect families from incurring donation related charges has been removed.[35] Also, the provision for the developmental of protocols for International Organ Exchange raises significant safety and informed consent concerns**. We hope that both of these areas that concern justice for the donor and donors' families will be thoroughly explored for further comment.

Statement of Request:

We strongly encourage a rejection of this Proposal, or at a minimum a revision of the Proposal, as follows:

1. Require that the potential donor be suffering from an end-stage terminal and irreversible condition from which death is inevitable and imminent (consistent with the UAGA[36] and CMS standards[37] cited earlier).
2. Define irreversibility consistent with the understanding that the condition is causally leading to inevitable death with no possibility of restoration of physiological integrity disrupted by the condition.
3. Require that the provider first has secured the family's decision to remove life-sustaining medical treatment or ventilator support before any dialogue occurs with the OPO.
4. Prohibit OPO from physically evaluating the patient without the knowledge or consent of the decision-maker.
5. Require the use of the Institute of Medicine standard for the timeframe between withdrawal of life support and declaration of death.[38]
6. Require the securing of true informed consent for the use of drugs and procedures to maintain organ suitability for transplant; also, prohibiting the use of any organ maintaining procedures or drug doses that will hasten death.

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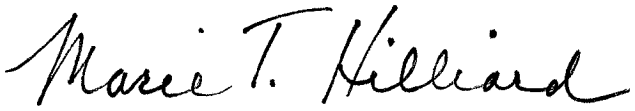
[33] Oregon Public Health Division, " Table 1. Characteristics and end-of-life care of 596 DWDA patients who have died from ingesting a lethal dose of medication as of February 29, 2012, by year, Oregon, 1998-2011" (on-line: http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/ar-index.aspx.)
[34] Oregon Revised Statute 127.800-127.995. Available at http://egov.oregon.gov/DHS/ph/pas/ors.shtml.
[35] Proposal, p. 14.
[36] www.nccusl.org/Act.aspx?title=Anatomical%20Gift%20Act%20(2006).
[37] CFR 42, Volume 3, Revised October 1, 2004, Chapter IV, Part 482: Sec. 482.45.
[38] Proposal, pp. 4, 12.

7. Prohibit the use of ECMO that allows organs to be removed from a patient by DCD who is not totally brain dead, but because of ECMO the patient has no beating heart (but does have adequate circulation, and thus is alive by the 'circulatory" death standards); prohibit the use of EISOR[39] to cause brain death.
8. Require a psychological evaluation before a conscious patient can consent to be a donor.[40]

Thank you for this opportunity to respond to the Proposal. If you have any questions concerning these comments do not hesitate to contact me.

Sincerely yours,



Marie T. Hilliard, JCL, PhD., RN
Director of Bioethics and Public Policy

[39] Ibid, p. 6.
[40] Ibid, pp. 5-6.

Exhibit E

From: bettypieper@aol.com
To: Publiccomment
Subject: Rule 9...A Parent Perspective on a Public Disgrace
Date: Thursday, June 14, 2012 6:50:47 PM

Elizabeth Pieper
569 Ridge Road
Scotia, NY 12302-6721

June 14, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

I want to comment on what you call a the Proposal to Update and Clarify Language in the DCD (Donation after Cardiac Death) Model Elements.

Dr. Wolfensberger called it "language perversion and madness" when words are consciously chosen to clothe the downright dirty and unacceptable with nicities that mean just the opposite. Thus, life giving and life saving - and a chance to live on - with what is really proposed: death making.

The rule change proposed in #9 is disgraceful! I never thought I would live to see the day that this could happen in the USA.

Your goal is to secure more organs at all costs. To 'save' one person, supposedly more worthy, at the cost of the life of another. The fact that you do not even think to list the "donor" of his or her life among those affected was I'm sure a PR oversight...but it is revealing of your purposes in building your own empire of supposed do-gooderism.

Now it is not only life sustaining, extraordinary care but even treatment that can be withheld for the big payoff. It is not only people who are terminally ill but it is people most in the need of treatment and carethemselves.

This goes well beyond the inevitable rationing of care we all saw coming. It is a perversion of the goals of health care. And, the very idea of allowing people with heavy agendas in reaping organs into the room and into the conversations under the guise of 'education' and 'offering families opportunities"is disgusting. As is doing any of this ghoulish planning without people's knowledge and without giving every opportunity for prior thought and independently, intimately, and quietly discerned consent.

We should all remember that the slippery slope of Nazism was not recognized as such. Even a 3 month commentary period here.....unknown to many activists in the human rights field...is insufficient. To say the least.

Hannah Arendt thought that we can't have morals worth having without great thought and dialogue....including a rich internal dialogue. If you dare

to think this through you will be ashamed at first, then frightened. Very, very frightened.

Sincerely,

Elizabeth Pieper
5183729488

Exhibit E

From:	chat4anna@gmail.com
To:	Publiccomment
Subject:	DCD proposals should be revised
Date:	Thursday, June 14, 2012 8:35:42 PM

Anna Stubblefield
5 Beechwood Terrace
West Orange, NJ 07052-2001

June 14, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

The DCD proposal that is currently being considered is discriminatory to people with disabilities.

1. Eligible donors include people with spinal cord injuries and neuromuscular disabilities, but comments were not solicited from organizations representing members of these groups.

2. Hospitals are encouraged to solicit donations from people with any diseases that cause the patient to need to use a ventilator, yet most such diseases were not specifically named, which suggests that the authors of the proposal were trying to avoid drawing attention to the relevance of the proposal to people with the diseases not named.

3. It is unethical for organ donation to be discussed as a factor in a decision to withdraw a ventilator or other life-sustaining treatment. The decision to withdraw treatment should be made entirely on its own merits, regardless of the possibility of organ donation.

4. Policies regarding organ donation should fully support efforts to make sure that conscious individuals do not decide to refuse treatment (and donate organs) based on erroneous beliefs about their future quality of life. Every effort must be made to provide psychological counseling and accurate information about options for community living.

5. On May 24, 2012, the National Disability Rights Network (NDRN) issued a groundbreaking report condemning third party decisions to withhold medical treatment including hydration and nutrition from individuals with disabilities without a terminal condition or permanent unconsciousness as a denial of the basic constitutional and civil rights of individuals with disabilities.

I was a member of the expert panel that reviewed that report, and I agree with the report's conclusions. The DCD proposal should incorporate the recommendations of that report. Any policy that assumes or insinuates that life with a disability is less worth living than life without is oppressive to disabled people and a violation of their civil rights.

Sincerely,

Anna Stubblefield

Exhibit E

From: bafell@comcast.net
To: Publiccomment
Subject: Nothing About Us Without Us
Date: Friday, June 15, 2012 7:00:44 AM

Betsy Fell
21 Patten Lane
Carlisle, MA 01741-1852

June 15, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

The purpose of this letter is to provide comments on the Proposal to Update and Clarify Language in the DCD (Donation after Cardiac Death) Model Elements.

I value the huge public service that organ donation programs provide. However, safeguards must be in place to protect the potential donors.

Disabled people should not be examined or considered for organ donation without their knowledge and consent. If they are cognitively disabled and have a guardian, then the guardian should be informed and give consent prior to any examination of a person for possible organ donation.

Disabled people, such as those living on ventilator support, should not be considered or examined for organ donation unless they are near death and the above notification and consent has been given.

Disabled people -- even those who are nonverbal or using ventilator assistance -- are still living human beings and their lives must be respected.

Just because someone has severe disabilities, one must not assume they do not value and enjoy their lives.

Please ensure that any proposed policy respects the lives and the dignity of all disabled people.

Sincerely,

Betsy Fell

Exhibit E

From:	wcg47@comcast.net
To:	Publiccomment
Subject:	Don"t target neuromuscular disabilities for organ harvesting
Date:	Friday, June 15, 2012 8:45:41 AM

Bill Gaventa
32 Dead Tree Run Road
Belle Meade, NJ 08502-5901

June 15, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

Dr. Lake and Mr. Shepherd.

I am adding my voice to the concerns raised by the Cener for Disability Rights about the new guidelines for organ procurement and donation. I have long been a card-carrying member of the "Organ Donor" pool and I have done a little work with the NJ statewide system to encourage others to do so. But I have also worked for 35 years with people with intellectual, developmental and other disabilities. To shorten some of the issues below, I am very concerned about the ways that quality of life assumptins get made by others in relation to people with disabilities without full knowledge and concent. I do a quite a bit of training for provider staff on grief, loss, and end of life issues related to the people they serve, and unfortunately I have heard enough stories to have to make the point that "typical hospital care for others can become an end of life issue for some people with intellectual and developmental disabilities" because of the asusmptions made by hospital staff who do not know the person behind the labels and disabilities. Very often, that person may not have a family network, or, on the other hand, a huge network of people who have been deeply committed to them and their care.

And, as recent situations have shown, if people with severe disabilities are to be organ donors, with the proper safeguards, then there should be other safeguards that allow them to be eligible receivers.

I know a number of ethicists and theologians interested in these issues and would be glad to obtain further input or assist in rewriting if appropriate.

Rev. Bill Gaventa
Associate Professor, Pediatrics
Director, Community and Congregational Supports
The Elizabeth M. Boggs Center on Developmental Disabilities
UMDNJ- Robert Wood Johnson Medical School
Former Editor, Journal of Religion, Disability, and Health.

The purpose of this letter is to provide comments on the Proposal to Update and Clarify Language in the DCD (Donation after Cardiac Death) Model Elements.

Failure to Acknowledge and Outreach to Affected Groups

Failure to Restore the Ethical Safeguard of Separation Between Organ Procurement and Decision to Withdraw Life-Sustaining Treatment

A 2007 NEJM article discussed ethical concerns about Donation After Cardiac Death (DCD) as follows:

"[S]ome physicians and nurses at the bedside 'continue to have concerns about the ethical propriety of the practice' that 'are numerous, complex and related to the specific roles they play.' …They may be uncomfortable recommending the withdrawal of life-sustaining treatment for one patient and hoping to obtain an organ for another." (Steinbrook, R, Organ Donation After Cardiac Death, N Engl J Med 357;3, p. 212, July 19, 2007 pp. 210-211.)

The public comment notice acknowledges that preliminary comments urged revisions to: "[e]xplicitly endorse in the Proposal the longstanding ethical safeguard that the donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures has been agreed to by the patient's next of kin, … Gone is the crucial wall separating patient care from donation solicitations. Such undue influence on difficult decisions at a heart-wrenching time is ethically unacceptable."

In response to this entreaty, the public comment notice states that "the OPO Committee disagrees with the position that a donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures have been agreed to."

The implication that the ethical principle of separation between health care treatment decisions and organ procurement has never existed is an effort to rewrite history. In 2000, the Institute of Medicine recommended that "the decision to withdraw life-sustaining treatment should be made independently of and prior to any staff initiated discussion of organ and tissues donation." Committee on Non-Heart Beating Transplantation Ii, Institute Of Medicine, Non-Heart-Beating Organ Transplantation: Practice and Protocols 16 (National Academy Press 2000).

People with disabilities who would not die but for the removal of life support should not have the presence of OPO personnel or the prospect of organ donation suggested in any way as a potential factor in the decision to withdraw a ventilator or other life sustaining treatment. Any implication that a person's organs are valued more than their life is unacceptable. The separation between health care decisions and organ procurement must be restored and carefully observed in policy and practice.

Failure to Provide Safeguards for Conscious Individuals

The separation between health care decisions and organ procurement is perhaps most essential for individuals who are considering ending their lives through withdrawing a ventilator or other form of life sustaining treatment. People with disabilities know that the decision to refuse life sustaining treatment can be very complex, and many of the factors are psychological, social and even economic in terms of the residential and home care options available.

In contrast, the public comment notice sounds like an insensitive bureaucrat wrote it:

"The OPO Committee noted that there have been cases when the OPO is contacted by the hospital when patients have irrecoverable, ventilator dependant, devastating neurologic injuries or illness and the patient is making the decision to withdraw the ventilator or cardiopulmonary assist device. This level of autonomy is consistent with the Federal Patient Self

Determination Act of 1990...."

Back in the 1980's, several court cases involving young men on ventilators established the right to refuse treatment, using a similarly superficial approach. Men like Larry McAfee and David Rivlin did not want to be stuck in a nursing facility and, in essence, said "give me liberty or give me death." (See Applebome, P, An angry man fights to die, then tests life, New York Times, Feb. 7, 1990, http://www.nytimes.com/1990/02/07/us/an-angry-man-fights-to-die-then-tests-life.html?pagewanted=all&src=pm.)
The courts uniformly ignored the demand for freedom from confinement in a nursing facility and the need for home care, and uniformly found a "right to die." Years later, one of the bioethicists involved in the Rivlin case issued an apology to the disability rights activists who criticized these rulings:

"I am now embarrassed to realize how limited was the basis on which I made my decisions about David Rivlin. In hindsight, it has been very well documented that there was no medical need for Rivlin to be effectively incarcerated in a nursing home. If Rivlin had been given access to a reasonable amount of community resources, …he could have been moved out of the nursing home and probably could have had his own apartment. He could have been much more able to see friends, get outside a bit, and generally have a much more interesting and stimulating life. The reasons he gave for wanting to die were precisely how boring and meaningless life was for him.

"This is the key lesson that disabilities advocates are trying to teach the rest of us." Brody, H, A bioethicist offers an apology, Health, Oct 6 2004, http://www.lansingcitypulse.com/lansing/archives/041006/features/health.asp

OPTN/UNOS has made similar mistakes, which should be corrected rather than being again codified into public policy. While the organ procurement community is not solely responsible to develop safeguards to ensure that an individual's decision to withdraw life sustaining treatment is truly informed and voluntary, that community can certainly call for appropriate safeguards, help ensure that the disability community's leadership in developing safeguards is respected and followed, and draw a firm line between organ procurement efforts and health care decisions.

Violations of Civil and Constitutional Rights of People With Disabilities

On May 24, 2012, the National Disability Rights Network (NDRN) issued a groundbreaking report condemning third party decisions to withhold medical treatment including hydration and nutrition from individuals with disabilities without a terminal condition or permanent unconsciousness as a denial of the basic constitutional and civil rights of individuals with disabilities. The NDRN Report states:

"[T]here are times, as this report will describe where physicians recommend and family or other surrogate decision makers decide to not provide a needed transplant, to withhold medical treatment including hydration and nutrition of individuals without a terminal condition, or to sterilize people all on the basis of their disabilities. Applied in these ways, medical decision making and procedures are discriminatory and deny basic constitutional rights to individuals with disabilities including the rights to liberty, privacy, and other statutory and common law rights." Devaluing People with Disabilities: Medical Procedures that Violate Civil Rights, at pp. 10-11.
http://www.ndrn.org/images/Documents/Resources/Publications/Reports/Devaluing_People_with_Disabilities.pdf

The procedures outlined in the DCD proposal appear to treat people who depend on a ventilator or other form of life support, but are not otherwise terminally ill (e.g. from end stage cancer), as though they are expendable commodities rather than people. These individuals are singled out for discriminatory treatment by those who pursue what would otherwise be a laudable and noble goal. What has already transpired and what is proposed as policy must be revisited and revised to give full weight to the civil and constitutional rights of individuals with the most significant disabilities. And that process cannot take place without the substantial involvement of people who themselves depend on ventilators and other forms of life-sustaining treatment as well as those who advocate on their behalf.

Sincerely,

Bill Gaventa
732-718-5875

Exhibit E

From: dhoyle@arcmi.org
To: Publiccomment
Subject: DCD proposals need extensive revision
Date: Friday, June 15, 2012 9:40:41 AM

Dohn Hoyle
1325 S. Washington Ave.
Lansing, MI 48910-1652

June 15, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

One more time, one more place, persons with disabilities are not perceived as equal citizens. This is far too close to harvesting organs. Not only is the referral process and determination of eligibility frightening, they would not be acceptable to persons without disabilities. Further, it pushes the euthanasia of persons with disabilities, by medical professionals to a new level, for other person's benefit.

Dohn Hoyle, Executive Director
The Arc Michigan
1325 S. Washington Ave.
Lansing, MI 48910

Just unacceptable!

Dohn Hoyle
517-487-5426

Exhibit E

UNOS REGIONAL RESPONSE FORM (Non-Voting Rep)
March 16, 2012 Public Comment
Region 11 Meeting, May 18, 2012
*******Please turn in at registration table following the meeting*******

(Name) Kim Phillips

(Organization Name) Medical Univ of South Carolina (SCDHHS)

Support	Oppose	No Opinion	Proposal Name
X			***Kidney Transplantation Committee***: Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant
X			***Kidney Transplantation Committee***: Proposal to Establish Kidney Paired Donation (KPD) Policy
X (1)			***Kidney Transplantation Committee***: Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program
X			***Liver and Intestine Transplantation Committee***: Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score
X			***Organ Procurement Organization Committee***: Proposal to Require Documentation of Second Unique Identifier
(2)	X		***Organ Procurement Organization Committee***: Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements
(4)	X		***Operations and Safety Committee***: Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal
X			***Living Donor Committee:*** Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors
(3)	X		***Policy Oversight Committee:*** Proposal to Update Data Release Policies
X			***Thoracic Transplantation Committee:*** Proposal to Revise the Lung Allocation Score System

PLEASE PRINT COMMENTS
(I can't report them if I can't read them ☺)

(1) Bridge donors - need a bit more detail to understand the ideal time to require a B donor to wait

(2) The challenge of changing the name + definition is not worth the risk of decreasing a hospital's support for DCD -

(3) Need more discussion about how to protect misuse of data. i.e. competing center data used for negative marketing

Data requests for back up from Non-Tx centers may overwhelm systems and further delay time it takes to receive critical Tx center specific data utilized for QAPI — currently takes 4-6 weeks to get a full data export from UNOS Data Center ~~editing~~ if this policy increases requests for data could significantly reduce UNOS' ability to generate data centers need to improve care for recipients

(4) 5 days to strict - in often times Vessel Use is separate from main transplant + so tracking by coordinator is difficult to assure notification is completed - make Time from > 14 days or 30 days.

Use technology to help - make UNET Vessel disposition a mandatory field when delisting patient ~~If~~ currently Center can enter Unknown a center should always know by 24hr if a vessel was used.

If a vessel is Not used for original recipient can UNET generate an auto notification reminder if no usage reported before day 14.

Exhibit E

UNOS REGIONAL RESPONSE FORM (Non-Voting Rep)
March 16, 2012 Public Comment
Region 11 Meeting, May 18, 2012
*******Please turn in at registration table following the meeting*******

(Name)

David Shaffer

(Organization Name)

Vanderbilt

Support	Oppose	No Opinion	Proposal Name
✓			***Kidney Transplantation Committee***: **Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant**
✓			***Kidney Transplantation Committee***: **Proposal to Establish Kidney Paired Donation (KPD) Policy**
✓			***Kidney Transplantation Committee***: **Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program**
✓			***Liver and Intestine Transplantation Committee***: **Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score**
✓			***Organ Procurement Organization Committee***: **Proposal to Require Documentation of Second Unique Identifier**
	✓		***Organ Procurement Organization Committee***: **Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements**
			Operations and Safety Committee: **Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal**
✓			***Living Donor Committee:*** **Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors**
	✓		***Policy Oversight Committee:*** **Proposal to Update Data Release Policies**
			Thoracic Transplantation Committee: **Proposal to Revise the Lung Allocation Score System**

PLEASE PRINT COMMENTS
(I can't report them if I can't read them ☺)

2nd unique identifier – specify where in donor information and where in DonorNet this identifier will be documented.
Changes in DCD – too much administrative work without clear benefit
POC – potentially not validated data; what additional need for data outside of existing, validated SRTR

Exhibit E

UNOS REGIONAL RESPONSE FORM (Non-Voting Rep)
March 16, 2012 Public Comment
Region 11 Meeting, May 18, 2012
*******Please turn in at registration table following the meeting*******

(Name)

CYNTHIA WILLIS

(Organization Name)

OPO COMMITTEE / LIFE SHARE OF THE CAROLINAS

Support	Oppose	No Opinion	Proposal Name
✓			***Kidney Transplantation Committee*: Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant**
✓			***Kidney Transplantation Committee*: Proposal to Establish Kidney Paired Donation (KPD) Policy**
✓			***Kidney Transplantation Committee*: Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program**
✓			***Liver and Intestine Transplantation Committee*: Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score**
✓			***Organ Procurement Organization Committee*: Proposal to Require Documentation of Second Unique Identifier**
	✓		***Organ Procurement Organization Committee*: Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements**
✓			***Operations and Safety Committee*: Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal**
✓			***Living Donor Committee:* Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors**
	✓		***Policy Oversight Committee:* Proposal to Update Data Release Policies**
✓			***Thoracic Transplantation Committee:* Proposal to Revise the Lung Allocation Score System**

PLEASE PRINT COMMENTS
(I can't report them if I can't read them ☺)

OPO - DCD - Section D should refer more to state & local laws for FPC that can vary regarding consent & the ability/need to require LNOK consent.
Use of circulatory should be interchangable

Exhibit E

UNOS REGIONAL RESPONSE FORM (Non-Voting Rep)
March 16, 2012 Public Comment
Region 11 Meeting, May 18, 2012
*******Please turn in at registration table following the meeting*******

(Name) Kimberly Nicoll

(Organization Name) Duke Univ

Support	Oppose	No Opinion	Proposal Name
X			***Kidney Transplantation Committee***: Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant
X			***Kidney Transplantation Committee***: Proposal to Establish Kidney Paired Donation (KPD) Policy
	X		***Kidney Transplantation Committee***: Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program
			Liver and Intestine Transplantation Committee: Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score
X			***Organ Procurement Organization Committee:*** Proposal to Require Documentation of Second Unique Identifier
	X		***Organ Procurement Organization Committee:*** Proposed Changes to the Donation after Cardiac Death (DCD) Model Elements The labor to change name in policy creates greater burden than potential benefit
	X		***Operations and Safety Committee:*** Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal 5 days is too short
X			***Living Donor Committee:*** Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors
	X		***Policy Oversight Committee:*** Proposal to Update Data Release Policies Suggest ~~either~~ a 12mon collection of data request to be reviewed to identify data elements that are commonly requested + delete them into proposal.
			Thoracic Transplantation Committee: Proposal to Revise the Lung Allocation Score System

PLEASE PRINT COMMENTS
(I can't report them if I can't read them ☺)

Exhibit E

From:	marna.ares@state.co.us
To:	Publiccomment
Subject:	Restore ethics in organ procurement
Date:	Thursday, June 14, 2012 5:00:51 PM

Marna Ares
1120 Lincoln, Suite 706
DENVER, CO 80203-2117

June 14, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

There are several problems with the proposed requirements. I'm concerned that even though a person may be neither terminal nor near death, and a decision to withdraw life support has not been made; the hospital may refer that person to the local organ procurement organization.

The organ procurement organization may examine people who are on life-support to determine whether they are eligible for organ donation. This can be done without their knowledge or consent, even though they are neither terminal nor near death.

The organ procurement organization can declare a person eligible for organ donation on assumptions that a conscious patient's decision to have life-support withdrawn is informed and voluntary and not a product of clinical depression. Consideration must be made for other factors that affect a person's perception of quality of life, such as the need for adequate attendant services and to be free to live in a place of their choosing, rather than in a nursing home.

Sincerely,

Marna Ares
3038613005

Exhibit E

From: epbconsult@gmail.com
To: Publiccomment
Subject: Problems in the Proposal to Update & Clarify Language
Date: Thursday, June 14, 2012 5:25:42 PM

Ed Burke
11744 Remington Road
Remington, VA 22734-9436

June 14, 2012

John R. Lake M.D.
President, Board of Directors, OPTN/UNOS
700 N. 4th Street
Richmond, VA 23218

Dear Dr. Lake:

I am writing to alert you to some major problems I see in the Proposal to Clarify Language in the DCD (Donation after Cardiac Death) Model Elements. The issues are as follows:

1. A Failure to Acknowledge and Engage in Outreach to Affected Groups

The listing of "Affected Groups" at page 1 and 2 of the public comment notice includes "Donor Family Members" but not Prospective Donors. Since eligible organ donors include people with spinal cord injuries and neuromuscular disabilities who may choose to donate their organs following withdrawal of life-sustaining treatment, OPTN/UNOS should solicit comments from organizations representing people with these conditions. The basic democratic principle of "Nothing about us without us," should be brought to bear here.

2. The Addition of the Term "Disease" Is Handled in a Misleading Manner

According to the public comment notice:

"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."

The notice refers to "a disease that renders them ventilator dependent (i.e. amyotrophic lateral sclerosis)." The use of "i.e." rather than "e.g." suggests that ALS is the only disease that may render someone ventilator dependent. Obviously, this is not the case, as other neuromuscular disabilities, such as muscular dystrophy and spinal muscular atrophy, as well as post-polio syndrome are among the "diseases" that can require the use of a ventilator to sustain life.

It appears that the 2012 proposal language has been manipulated to avoid flagging disability groups that represent people who are now classified as potential DCD candidates. At the same time, the language encourages hospitals to tap into "currently unrealized donor potential" by notifying them of the eligibility of these same groups.

3. A Failure to Restore the Ethical Safeguard of Separation Between Organ Procurement and Decision to Withdraw Life-Sustaining Treatment

A 2007 NEJM article discussed ethical concerns about Donation After Cardiac Death (DCD) as follows:

"[S]ome physicians and nurses at the bedside 'continue to have concerns about the ethical propriety of the practice' that 'are numerous, complex and related to the specific roles they play.' …They may be uncomfortable recommending the withdrawal of life-sustaining treatment for one patient and hoping to obtain an organ for another." (Steinbrook, R, Organ Donation After Cardiac Death, N Engl J Med 357;3, p. 212, July 19, 2007 pp. 210-211.)

The public comment notice acknowledges that preliminary comments urged revisions to: "[e]xplicitly endorse in the Proposal the longstanding ethical safeguard that the donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures has been agreed to by the patient's next of kin, … Gone is the crucial wall separating patient care from donation solicitations. Such undue influence on difficult decisions at a heart-wrenching time is ethically unacceptable."

In response to this entreaty, the public comment notice states that "the OPO Committee disagrees with the position that a donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures have been agreed to."

The implication that the ethical principle of separation between health care treatment decisions and organ procurement has never existed is false. In 2000, the Institute of Medicine recommended that "the decision to withdraw life-sustaining treatment should be made independently of and prior to any staff initiated discussion of organ and tissues donation." Committee on Non-Heart Beating Transplantation II, Institute Of Medicine, Non-Heart-Beating Organ Transplantation: Practice and Protocols 16 (National Academy Press 2000).

People with disabilities who would not die but for the removal of life support should not have the presence of OPO personnel or the prospect of organ donation suggested in any way as a potential factor in the decision to withdraw a ventilator or other life sustaining treatment. Any implication that a person's organs are valued more than their life is unacceptable, and may even be construed as pre-meditated manslaughter or murder.

4. A Failure to Provide Safeguards for Conscious Individuals

The separation between health care decisions and organ procurement is perhaps most essential for individuals who are considering ending their lives through withdrawing a ventilator or other form of life sustaining treatment. People with disabilities know that the decision to refuse life sustaining treatment is very complex, and many of the factors are psychological, social and even economic in terms of the community residential and home care options available.

In contrast, the public comment notice sounds virtually mechanical:

"The OPO Committee noted that there have been cases when the OPO is contacted by the hospital when patients have irrecoverable, ventilator dependant, devastating neurologic injuries or illness and the patient is making the decision to withdraw the ventilator or cardiopulmonary assist device. This level of autonomy is consistent with the Federal Patient Self Determination Act of 1990...."

In the 1980s, several court cases involving young men on ventilators established the right to refuse treatment, using a similarly superficial

approach. Men like Larry McAfee and David Rivlin did not want to be stuck in a nursing facility and, in essence, said "give me liberty or give me death." (See Applebome, P, An angry man fights to die, then tests life, New York Times, Feb. 7, 1990.) The courts uniformly ignored the demand for freedom from confinement in a nursing facility and the need for home care, and uniformly found a "right to die." Years later, one of the bioethicists involved in the Rivlin case issued an apology to the disability rights activists who criticized these rulings:

"I am now embarrassed to realize how limited was the basis on which I made my decisions about David Rivlin. In hindsight, it has been very well documented that there was no medical need for Rivlin to be effectively incarcerated in a nursing home. If Rivlin had been given access to a reasonable amount of community resources, …he could have been moved out of the nursing home and probably could have had his own apartment. He could have been much more able to see friends, get outside a bit, and generally have a much more interesting and stimulating life. The reasons he gave for wanting to die were precisely how boring and meaningless life was for him.

"This is the key lesson that disabilities advocates are trying to teach the rest of us." Brody, H, A bioethicist offers an apology, Health, Oct 6 2004,
http://www.lansingcitypulse.com/lansing/archives/041006/features/health.asp

OPTN/UNOS has made similar mistakes, which should be corrected rather than being again codified into public policy. While the organ procurement community is not solely responsible to develop safeguards to ensure that an individual's decision to withdraw life sustaining treatment is truly informed and voluntary, that community can certainly call for appropriate safeguards, help ensure that the disability community's leadership in developing safeguards is respected and followed, and draw a firm line between organ procurement efforts and health care decisions.

5. Violations of Civil and Constitutional Rights of People With Disabilities

On May 24, 2012, the National Disability Rights Network (NDRN) issued a groundbreaking report condemning third party decisions to withhold medical treatment including hydration and nutrition from individuals with disabilities without a terminal condition or permanent unconsciousness as a denial of the basic constitutional and civil rights of individuals with disabilities. The NDRN Report states:

"[T]here are times, as this report will describe where physicians recommend and family or other surrogate decision makers decide to not provide a needed transplant, to withhold medical treatment including hydration and nutrition of individuals without a terminal condition, or to sterilize people all on the basis of their disabilities. Applied in these ways, medical decision making and procedures are discriminatory and deny basic constitutional rights to individuals with disabilities including the rights to liberty, privacy, and other statutory and common law rights." Devaluing People with Disabilities: Medical Procedures that Violate Civil Rights, at pp. 10-11.
http://www.ndrn.org/images/Documents/Resources/Publications/Reports/Devaluing_People_with_Disabilities.pdf

The procedures outlined in the DCD proposal appear to treat people who depend on a ventilator or other form of life support, but are not otherwise terminally ill (e.g. from end stage cancer), as though they are expendable commodities rather than people. These individuals are singled out for discriminatory treatment by those who pursue what would otherwise

be a laudable and noble goal. What has already transpired and what is proposed as policy must be revisited and revised to give full weight to the civil and constitutional rights of individuals with the most significant disabilities. And that process cannot take place without the substantial involvement of people who themselves depend on ventilators and other forms of life-sustaining treatment as well as those who advocate on their behalf.

The five issues described above are quite serious and need to be addressed before the proposed changes go forward. This is truly a matter of life and death, and we would do well to follow the first proviso on medical intervention in the Hippocratic Oath, "First, do no harm..."

Sincerely,

Ed Burke

The Resistance

June 14, 2012

John R. Lake, M.D.
President
Board of Directors
Organ Procurement and Transplantation Network/United Network on Organ Sharing
700 North 4th Street
Richmond, VA 23218

Dear Dr. Lake:

I am writing as President and CEO of Not Dead Yet, a national disability rights organization. Not Dead Yet's primary goals are to oppose legalization of assisted suicide from a secular disability rights perspective and to oppose various forms of nonconsensual withholding of life-sustaining treatment from people with disabilities. The purpose of this letter is to provide comments on the Proposal to Update and Clarify Language in the DCD (Donation after Cardiac Death) Model Elements.

Failure to Acknowledge and Outreach to Affected Groups

At the outset, I note that the listing of "Affected Groups" at page 1 and 2 of the public comment notice includes "Donor Family Members" but not Prospective Donors. Since the protocol explicitly contemplates conscious donors who may choose to donate their organs following withdrawal of life-sustaining treatment, this appears to be a significantly affected group. This raises the question, raised in our preliminary comments, about whether OPTN/UNOS has again failed to solicit comments from organizations representing the affected groups who qualify as prospective donors.

Addition of the Term "Disease" Handled in a Misleading Manner

The public comment notice states, "Please comment on what impact the following changes in terminology might have on your institution: … The addition of the term "disease" which is included in the suitable candidate evaluation section."

According to the public comment notice:

> *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*.

The notice refers to "a disease that renders them ventilator dependent (i.e. amyotrophic lateral sclerosis)." The use of "i.e." rather than "e.g." suggests that ALS is the only disease that may render someone ventilator dependent. Obviously, this is not the case, as other neuromuscular disabilities, such as muscular dystrophy and spinal muscular atrophy, as well as post-polio syndrome are among the "diseases" that can require the use of a ventilator to sustain life. In fact, I myself have a progressive neuromuscular disease which is likely to make me ventilator dependent in the future. If people with all of the relevant conditions were indicated, rather than the one condition which the public has been conditioned to view as invariably and rapidly terminal (i.e. ALS), OPTN/UNOS might anticipate a broader and more concerned reaction to the proposed revisions.

Furthermore, it must be noted that the previous, and withdrawn, proposal specifically mentioned people with "upper spinal cord injury" as DCD eligible. Among the national organizations that contacted OPTN/UNOS expressing concern about the previous proposal was United Spinal. The new proposal no longer mentions spinal cord injury separately, but subsumes this under the category of "neurological injury."

It should also be noted that the DCD Model Elements that went into effect in July 2007, when these issues were not on the disability community's "radar screen", specifically provided that "A patient . . . who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for donation after cardiac death. Other conditions [may] include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury." (See Steinbrook, R, Organ Donation After Cardiac Death, N Engl J Med 357;3, p. 212, July 19, 2007.)

It's difficult to escape the conclusion that the 2012 proposal language has been manipulated to avoid flagging disability groups that represent people who are now classified as potential DCD candidates. At the same time, the language encourages institutions to tap into "currently unrealized donor potential" by notifying them of the eligibility of these same groups.

<u>Failure to Restore the Ethical Safeguard of Separation Between Organ Procurement and Decision to Withdraw Life-Sustaining Treatment</u>

The 2007 NEJM article cited above discussed ethical concerns about DCD as follows:

> *[S]ome physicians and nurses at the bedside "continue to have concerns about the ethical propriety of the practice" that "are numerous, complex and related to the specific roles they play." Some feel uncomfortable about participation in medical practices that may be required during the transition from end-of-life care to organ donation. For example, in multidisciplinary ICUs, doctors and nurses who care for both potential organ donors and organ recipients may have conflicting interests. They may be uncomfortable recommending the withdrawal of life-sustaining treatment for one patient and hoping to obtain an organ for another. (Steinbrook, pp. 210-211.)*

The public comment notice acknowledges that the previous proposal in 2011 generated comments urging revisions to:

> *Explicitly endorse in the Proposal the longstanding ethical safeguard that the donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures has been agreed to by the patient's next of kin, as recommended by the Institute of Medicine. The proposed Requirements remove the important stipulation separating patient care from donation solicitations. Whereas previously the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate, under the proposed policy a patient may be evaluated as a DCD candidate prior to a decision by family members and caregivers, which ought to be free from external pressure. Gone is the crucial wall separating patient care from donation solicitations. Such undue influence on difficult decisions at a heart-wrenching time is ethically unacceptable.*

In response to this entreaty, the public comment notice states:

- The OPO [Organ Procurement Organization] Committee disagrees with the position that a patient may not be evaluated as a DCD candidate prior to a decision by family members and caregivers to withdraw life sustaining measures.
- The OPO Committee disagrees with the position that a donor family not be approached about organ donation until the time at which a decision to withdraw life sustaining measures have been agreed to.
- The OPO Committee noted that the deleted language "the hospital's primary healthcare team and the legal next of kin must have decided to withdraw ventilated support or other life-sustaining treatment before the patient is evaluated as a DCD candidate" in the original proposal was included then deleted during the drafting of the original proposed changes.
- That language has never been included in any version of the bylaws.

The implication that the ethical principle of separation between health care treatment decisions and organ procurement has never existed is an effort to rewrite history. In 2000, the Institute of Medicine recommended that "the decision to withdraw life-sustaining treatment should be made independently of and prior to any staff initiated discussion of organ and tissues donation." Committee on Non-Heart Beating Transplantation Ii, Institute Of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols* 16 (National Academy Press 2000).

More recently, Arthur Caplan, a leading bioethicist based at the University of Pennsylvania Medical Center, noted:

> *From its early days, transplant policy in the United States and in nearly every other nation with a donation system made a clear division between those health professionals with responsibility for the best interests of very sick patients with healthy organs and those responsible for very sick patients who needed healthy organs. . . . Increasingly, those who request organs and tissues are attempting to approach families before their loved ones are dead. Some organ procurement teams are subtly shifting the criteria by*

> *which death is pronounced in order to maximize the odds of obtaining a transplantable vital organ. (A Caplan, Going Too Extreme, pp. 30-31, Bioethica Forum / 2010 / Volume 3 / No. 2)*

The public comment notice continues its attempt to justify abandonment of the ethical principle of separation by citing a federal regulation that "hospitals are obligated to notify OPOs about 'individuals whose death is imminent, or who have died'." (CFR 42, Volume 3, Revised October 1, 2004, Chapter IV, Part 482: Sec.482.45). Thus, the referral to an OPO could occur prior to the family being aware of donation options. The public comment notice also states that "the evaluation of a patient as a potential organ donor can be facilitated without OPO communication with the family" and that this evaluation could occur prior to a decision to withdraw treatment.

This proposed justification raises several questions. If the use of a ventilator would enable an individual to live for an extended period of time, and the decision to withdraw the ventilator has not been made, then how could that individual be identified as someone "whose death is imminent" for purposes of referring the individual to the OPO under the federal regulation? What would an evaluation of a live potential donor consist of that does not require patient or health care proxy consent? Would the true purpose of the evaluation procedure be disclosed or hidden from the patient or family if and when consent is secured?

In short, the justification fails to make sense, much less provide an ethical basis for allowing OPO involvement with individuals for whom a decision to withdraw treatment has not been made. People who would not die but for the removal of life support should not have the presence of OPO personnel or the prospect of organ donation suggested in any way as a potential factor in the decision to withdraw a ventilator or other life sustaining treatment. Any implication that a person's organs are valued more than their life is unacceptable. The separation between health care decisions and organ procurement must be restored and carefully observed in policy and practice.

<u>Failure to Provide Safeguards for Conscious Individuals</u>

As noted above, the proposed changes affecting people who depend on ventilators "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." The separation between health care decisions and organ procurement is perhaps most essential for individuals who are considering ending their lives through withdrawing a ventilator or other form of life sustaining treatment.

About 15 years ago, a disabled friend wrote a public letter to Jack Kevorkian about her father who had ALS. She opposed Kevorkian's activities, telling of how she had convinced her father to try living on a ventilator when he progressed to the point of needing one. He went home from a Denver rehabilitation facility using a ventilator and enjoyed two more years with his family. On the day he was discharged, the nurses told the family how much they wished more doctors and families would support this option, saying that he was only the second person in many years to go home on a vent.

People with disabilities know that the decision to refuse life sustaining treatment can be very complex, and many of the factors are psychological, social and even economic in terms of the residential and home care options available.

In contrast, the public comment notice sounds like an insensitive bureaucrat wrote it:

> *The OPO Committee noted that there have been cases when the OPO is contacted by the hospital when patients have irrecoverable, ventilator dependant, devastating neurologic injuries or illness and the patient is making the decision to withdraw the ventilator or cardiopulmonary assist device. This level of autonomy is consistent with the Federal Patient Self Determination Act of 19901. In these cases, the OPO and hospital have a legal obligation to honor the patients advance directive which may include organ donation. Good end-of-life care would dictate that if the patient has questions or requests information regarding the donation process, then both the OPO and the hospital should cooperate to ensure that the patient receives the information required to make an informed decision.*

Back in the 1980's, several court cases involving young men on ventilators established the right to refuse treatment, using a similarly superficial approach. Men like Larry McAfee and David Rivlin did not want to be stuck in a nursing facility and, in essence, said "give me liberty or give me death." (Applebome, P, An angry man fights to die, then tests life, New York Times, Feb. 7, 1990, http://www.nytimes.com/1990/02/07/us/an-angry-man-fights-to-die-then-tests-life.html?pagewanted=all&src=pm.) The courts uniformly ignored the demand for freedom from confinement in a nursing facility and the need for home care, and uniformly found a "right to die." Years later, one of the bioethicists involved in the Rivlin case issued an apology to the disability rights activists who criticized these rulings:

> *I am now embarrassed to realize how limited was the basis on which I made my decisions about David Rivlin. In hindsight, it has been very well documented that there was no medical need for Rivlin to be effectively incarcerated in a nursing home. If Rivlin had been given access to a reasonable amount of community resources, of the sort that other persons with disabilities were making use of at the time, he could have been moved out of the nursing home and probably could have had his own apartment. He could have been much more able to see friends, get outside a bit, and generally have a much more interesting and stimulating life. The reasons he gave for wanting to die were precisely how boring and meaningless life was for him.*
>
> *This is the key lesson that disabilities advocates are trying to teach the rest of us. If we look at a case one way, it seems that the problem is the person's physical disability. If we shift our view, we realize that the problem is not the disability, but rather the refusal of society to make reasonable and not terribly expensive accommodations to it.*
>
> *There's every reason to believe in hindsight that David Rivlin died unnecessarily, and that we who claimed to care about his "rights" should have been demanding that services be made available for him rather than that he be allowed to die. As one who argued the wrong thing back then, I apologize for my shortsightedness. Brody, H, A*

bioethicist offers an apology, Health, Oct 6 2004,
http://www.lansingcitypulse.com/lansing/archives/041006/features/health.asp

OPTN/UNOS has made similar mistakes, which should be corrected rather than being again codified into public policy. While the organ procurement community is not solely responsible to develop safeguards to ensure that an individual's decision to withdraw life sustaining treatment is truly informed and voluntary, that community can certainly call for appropriate safeguards, help ensure that the disability community's leadership in developing safeguards is respected and followed, and draw a firm line between organ procurement efforts and health care decisions.

Incorrect Language Suggesting That Next of Kin May Overrule Patient or Designated Agent

The public comment notice states:

> *For the purpose of obtaining 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*
> *3. the designated health care agent*

As worded, this could be taken to imply that any of the above could authorize DCD in a specific case. In each specific case, only one of the three can authorize DCD, depending on patient capacity and state surrogacy law. In general, the designated health care agent trumps the next of kin, and the patient trumps both. The language should be clarified to avoid the potential for misunderstanding.

Violations of Civil and Constitutional Rights of People With Disabilities

On May 24, 2012, the National Disability Rights Network (NDRN) issued a groundbreaking report condemning third party decisions to withhold medical treatment including hydration and nutrition from individuals with disabilities without a terminal condition or permanent unconsciousness as a denial of the basic constitutional and civil rights of individuals with disabilities. NDRN is the national association of the federally funded protection and advocacy agencies in all 50 states, charged to protect the civil rights of people with disabilities. (These should not be confused with adult protective services.) The NDRN Report states:

> *In recent years, new types of assistive and medical technology and procedures have emerged that allow people with disabilities, even those with the most significant disabilities, to live longer lives and improve their quality of life to live outside of institutions in their own homes in the community. The legacy of eugenics however, and the basic discriminatory structures that underlie it, are still powerful factors in medical decision making by some doctors and surrogate decision makers for people with disabilities. These technologies and procedures have not only been used to enhance quality of life, but they have also been used, at times, to reinforce social policies that devalue people with disabilities and keep them separate from community life. In fact, there are times, as this report will describe where physicians recommend and family or other surrogate decision makers decide to not provide a needed transplant, to withhold*

> *medical treatment including hydration and nutrition of individuals without a terminal condition, or to sterilize people all on the basis of their disabilities. Applied in these ways, medical decision making and procedures are discriminatory and deny basic constitutional rights to individuals with disabilities including the rights to liberty, privacy, and other statutory and common law rights*. Devaluing People with Disabilities: Medical Procedures that Violate Civil Rights, at pp. 10-11. http://www.ndrn.org/images/Documents/Resources/Publications/Reports/Devaluing_People_with_Disabilities.pdf

The NDRN report states that reliance on ethics committees and consultations are insufficient protections of a patient's legal rights and that hospitals and other providers must "establish and implement due process protections to ensure the civil rights of a person with a disability are protected . . . ." Too many in the health care system have given virtual "carte blanche" powers to surrogates so long as they decide to deny life-sustaining care. This is not acceptable.

The procedures outlined in the DCD proposal, and the existing practices on which they are said to be based, appear to treat people who depend on a ventilator or other form of life support, but are not otherwise terminally ill (e.g. from end stage cancer), as though they are expendable commodities rather than people. These individuals are singled out for discriminatory treatment by those who pursue what would otherwise be a laudable and noble goal. What has already transpired and what is proposed as policy must be revisited and revised to give full weight to the civil and constitutional rights of individuals with the most significant disabilities. And that process cannot take place without the substantial involvement of people who themselves depend on ventilators and other forms of life-sustaining treatment as well as those who advocate on their behalf.

If there are any questions concerning these comments, please don't hesitate to contact me at ndycoleman@aol.com or 708-420-0539.

Sincerely,

Diane Coleman, J.D.
President/CEO
Not Dead Yet
497 State Street
Rochester, NY 14608
(585) 697-1640
www.notdeadyet.org
ndycoleman@aol.com

Exhibit E

From: Bob Quinlan
To: Publiccomment
Subject: Proposal to Update and Clarify Language in the DCD Model Elements (OPO Committee)
Date: Friday, June 15, 2012 1:53:58 PM

Below are the detailed comments referenced in the online submission of Janice Benton.

I am the Executive Director of the National Catholic Partnership on Disability (NCPD). NCPD was established thirty years ago to implement the *Pastoral Statement on People with Disabilities* of the U.S. Catholic bishops. On behalf of NCPD and the fourteen million Catholics with disabilities it serves, I urge UNOS to reject the proposal for changing the DCD Model Elements.

The proposed changes aim "to maximize the number of donors and transplants by identifying … currently unrealized donor potential [.]" As laudable as that objective is, it cannot justify singling out a class of disabled people, those dependent on life-support, for adverse treatment. Under the proposal, for example, the hospital and local OPO may examine patients on life-support to determine their eligibility for organ donation without their knowledge or consent, even though they are neither terminal nor near death. Further, the hospital may initiate a request for donation of such patient's organs before the decision to withdraw life-support is made. Finally, the OPO is not required to condition eligibility for organ donation on assurances that a conscious patient's decision to have life-support withdrawn is voluntary and not a product of clinical depression. Simply put, the proposed changes subject a class of disabled people to discriminatory treatment, while offering justifications that are inapposite, unconvincing, and clearly violative of patients' rights.

The proposal imposes specific rules that OPOs and transplant centers must follow. If approved by the Secretary of HHS, such rules become conditions of participation in the OPTN and, in effect, revisions of existing law. *See* 42 C.F.R. §§ 482.45(b)(1).

The proposed changes expand "potential DCD donor" beyond patients with permanent and irreversible neurological injury to include those whose "disease" renders them dependent on life-sustaining medical treatment or ventilated support. "Disease" was added to allow "patients that do not have a neurological injury, but a disease that render[ed] them ventilator dependent … to grant first person consent for donation [.]" Given the ease in which patients on life-support can already donate their organs, *see Revised Uniform Anatomical Gift Act*, §5 (2008), one may ask why an admittedly "rare" occurrence should occasion a major expansion of donor criteria. In any event, the text is ambiguous on whether "permanent and irreversible" qualifies only neurological injury or applies to disease as well. And contrary to the proposal's explanation, the language is not in fact limited to conscious patients or those on ventilated support.

The proposed changes require participating hospitals to be Medicare and Medicaid certified. Under CMS regulations, such hospitals "must notify, in a timely manner, the OPO … of individuals whose death is imminent or who have died in the hospital." 42 C.F.R. §482.45(a)(1). The proposal expands this duty to include patients on life-support, regardless of whether their death is imminent or whether they have offered to donate their organs.

Under existing law, "The OPO determines medical suitability for organ donation [.]" *Id.* Given the expanded donor class, the proposal further provides that "The primary healthcare team and the local OPO must evaluate potential DCD donors to determine if … [they have] a permanent and

irreversible neurological injury, or disease which may allow for a planned withdrawal of life-sustaining medical treatment or ventilated support." This language is sufficiently broad to authorize a physical examination, as well as a record review, without requiring that patients' or their families' know or consent. In the absence of some offer to donate, the provision would most certainly violate patients' rights to be free from unwanted medical procedures.

The proposed changes erroneously rely on CMS regulations and the UAGA for support. As the proposal itself recognizes, CMS regulations require hospitals to report only those patients "whose death is imminent, or who have died [.]" *Id.* Likewise, UAGA's authorization for physical examination of potential donors is limited to patients, referred to procurement organizations, who are "at or near death [.]" *Revised Uniform Anatomical Gift Act,* §14(a-c).

Conceding that referral for evaluation may occur "prior to family knowledge of donation options," the proposed changes offer two primary justifications: First, "the evaluation of a patient as a potential organ donor can be facilitated without OPO communication with the family [;]" second, "the patient may have already been registered as an organ donor, which requires no further authorization by a surviving family or caregiver." It should go without saying that, if patients have the right to be free from unwanted medical procedures, they or their families also have the right to know when such procedures take place. Further, even if staff can examine registered donors without further authorization, that provides no support for such examination where an offer to donate has never been made.

The proposal contends that, "by not allowing for an OPO's evaluation for donor candidacy prior to a decision to withdrawal (sic)," the health care system will in some way mislead families into believing that "their loved one is not a donor candidate, when in fact they (sic) might be" or that "they are authorized to make donation decisions for the individual at or near death, while in fact they may not be." Of course, it is hardly misleading to say nothing unless one has a duty to speak. But there can be no duty to inform families that their loved ones are donor candidates if that entails violating patients' rights not to be examined without knowledge and consent. And whether the OPO is obliged to inform families that they are not authorized to make donation decisions, because, for example, a refusal record was found during a search of a patient near death, *see Revised Uniform Anatomical Gift Act*, §12(a), that says nothing about OPO's obligation when death is not imminent. Finally, examinations to determine donor eligibility without family knowledge and consent may well expedite "withdrawal procedures as agreed to by … [such] family [;]" but this would simply justify violation of patients' rights by reference to the benefit it may produce.

Though agreeing that "ethical concerns and safeguards are paramount in the organ donation process [,]" the proposal nonetheless rejects the IM recommendation that "the decision to withdraw life-sustaining treatment should be made independently of and prior to any staff initiated discussion of organ and tissues donation." Committee on Non-Heart Beating Transplantation Ii, Institute Of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols* 16 (National Academy Press 2000). It claims instead that patient protection will increase by ensuring that "hospitals and caregivers have a policy and … that OPOs and Transplant Centers abide by the policies developed." Of course, requiring "a policy" without specifying what that policy contains is an empty gesture. And the two safeguards the proposed changes actually require, that "no member of the Organ Recovery team or OPO staff may guide or administer palliative care, or declare death" and that "no member of the Transplant Center surgical team may be present for the withdrawal of life-sustaining medical treatment or ventilated support [,]" provide scarcely more protection from pressure for families considering withdrawal. The former applies after the

decision to withdraw life-support is made; the latter, besides inexplicably omitting OPO staff, comes at a time when family may not even be present rather than the time they are most susceptible to pressure, when they are wrestling with whether to withdraw life-support.
The proposal acknowledges that patients with chronic illnesses are "vulnerable to real or perceived pressure to decline further treatment in order to donate their organs, especially since the Requirements would permit evaluation of their eligibility for organ donation in advance of a decision whether to withdraw ventilatory or other life-sustaining support." Nevertheless, it rejects psychiatric evaluations, waiting periods before withdrawal occurs, and other safeguards to ensure valid consent, claiming that these are policies for the hospital to prescribe, "[i]ndependent of the option for organ donation[.]" Given the likely impact the proposed changes will have on the decision to withdraw life-support, the claim that procedures overseeing donation and withdrawal are independent and that "[t]he separation of the OPO and Hospital responsibilities related to these assessments further safeguards patient autonomy and decision-making" is plainly facetious. Without effective safeguards, like the rule the IM recommends, to ensure that patients or families make the withdrawal decision voluntarily, the proposal's assurance of patient protection is merely "a promise to the ear to be broken to the hope."

The proposed changes no longer expressly list those with specific disabling conditions, "end-stage musculoskeletal disease, pulmonary disease … [and] upper spinal cord injury" as potential DCD donors. Even so, patients dependent on life-support certainly have "a physical or mental impairment that substantially limits one or more major life activities," 45 C.F.R. §§ 85.3, and thus are "handicapped" for purposes of federal civil rights law. Under regulations implementing the 1978 Amendments to the Rehabilitation Act, HHS "may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would [s]ubject qualified individuals with handicaps to discrimination on the basis of handicap[.]"/§85.21(b)(3)(i).

Clearly, the proposal identifies patients on life-support as "the currently unrealized donor potential [.]" It "would maximize the number of donors and transplants" by permitting staff to examine such patients without their consent. It would permit staff to approach patients or families, before they decide to withdraw life-support, to inform them that the patient's condition allows "for a planned withdrawal of life-sustaining medical treatment or ventilated support" and discuss the options for organ donation once the patient is dead. Further, it would not require assurances, as a condition for donor eligibility, that a conscious patient's decision to withdraw life-support is voluntary and not a product of clinical depression. It is hard to avoid the conclusion that the proposed changes target patients on life-support because they are considered more valuable when dead.

In our November 9, 2011 letter, we cautioned that adoption of the then proposed changes "would cause many within and outside the disability community to question UNOS' continued oversight role under its contractual arrangements with HHS." Regrettably, the present proposal gives us no

reason to alter that belief.
Respectfully submitted,

Janice L. Benton
Executive Director
National Catholic Partnership on Disability

Exhibit E

aopo
association of
organ procurement organizations

June 15, 2012

Re: Comments on the Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record; and the Proposal to Update and Clarify Language in the DCD Model Elements

To Whom It May Concern:

The Association of Organ Procurement Organizations (AOPO) is the national not-for-profit organization comprised of all fifty-eight organ procurement organizations (OPOs) located within the United States and its territories which seeks to maximize the availability of organs and tissues for transplantation and enhance the quality, effectiveness and integrity of the donation process so that those in need of a transplant receive donated organs or tissues in a timely manner in order to end deaths on the transplant waiting list. For more information about the Association, please visit www.aopo.org.

AOPO is commenting on two revisions to the bylaws. First, the OPTN is proposing to modify requirements that OPOs and living donor recovery centers document all locally assigned unique identifiers in the donor record. We agree that the recording of donor data will assist our tracking activities and those of the transplant centers. Second, the OPTN has proposed modifying the language in the DCD model elements. Specifically, you sought comment on the proposal to change the "C" in DCD to "Circulatory" rather than "Cardiac" to conform to the Uniform Determination of Death Act's definition of death.

The reference to circulatory death is consistent with how OPOs identify and describe donors, and we believe it is beneficial to the public's understanding of donor characteristics to amend the definition as proposed. However, if there are any inconsistencies in reporting, we urge the OPTN to be mindful of the affect this change would have on the future description of OPO demographic characteristics and limiting researchers' ability to engage in trend analysis.

In addition, the document proposes several other changes to make the bylaws conform to revised CMS requirements, changes in the language used by our community, and added flexibility within the guidelines in anticipation of ongoing advances in pharmaceuticals and other clinical technologies. Again, we believe these modifications are consistent with our current practices. The inclusion of the term "disease" in the language describing suitable candidate conditions is a helpful clarification to ensure that patients can grant first person authorization for donation when DCD donation is anticipated in patients that do not have a neurologic injury, but rather a disease that renders them ventilator dependent.

Thank you for the opportunity to provide feedback on this proposal. If you have any questions or need any additional information, please contact our Executive Director, Elling Eidbo at (703) 556-4242 ext. 204.

Sincerely,

Tim Brown
President

Exhibit E

AST
AMERICAN SOCIETY OF TRANSPLANTATION

Improving Human Life by Advancing the Field of Transplantation

To: OPTN/UNOS

From: American Society of Transplantation

Re: Policy Proposal Comments

Date: June 15, 2012

Thank you for inviting the American Society of Transplantation (AST) to comment on the ten proposals currently out for public comment. Our specific comments for each proposal are enclosed.

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AMERICAN TRANSPLANT CONGRESS 2012

June 2-6, 2012
Boston, MA

9. Proposal to Update and Clarify Language in the DCD Model Elements (OPO Committee)

Summary:
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 do not change any current level of oversight by the donor hospital to ensure that appropriate practices are following for a patient's end of life care, and that hospital approved practitioners follow hospital palliative care policies and guidelines involving the withdrawal of life sustaining medical treatment/support. These Model Elements identify specific requirements that OPOs and transplant centers must include in the 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 be modified for consistency. These proposed changes will help provide a common understanding of DCD protocols for the transplant community and the public.

AST Comments:
The AST finds this proposal to be explicit in what substantive changes were made and the rationale behind making them. It is clearly labeled as a policy change and not a plain language re-write. The AST is supportive of this proposed change.

ASTS
American Society of Transplant Surgeons

June 15, 2012

John Lake, MD
President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear. Dr. Lake,

The American Society of Transplant Surgeons (ASTS) has reviewed and considered the following ten proposals out for public comment. Below is the Society's position on each proposal.

Proposal 1: Kidney Transplantation Committee: Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant.

ASTS **supports** this proposal that will clarify the allocation priority assigned to prior living organ donors (kidney, partial pancreas, and liver lung or small bowel segment) who later require a kidney transplant. This policy proposal will clearly state that priority is available for not only the first kidney transplant but any subsequent transplants, if needed.

Proposal 2: Kidney Transplantation Committee: Proposal to Establish Kidney Paired Donation (KPD) Policy.

ASTS is concerned that it is premature to formulate policy on this magnitude, including MPSC punitive action, given the limited history of this program. We suggest that any final decisions regarding OPTN KPD policy should be postponed until the consensus document from the March 29-30, 2012 KPD conference held in Herndon, VA is released. Additionally, ASTS would support a full formal assessment of the program to date.

OPTN specifically asked for comments to the following questions regarding this proposal:

Is it clear what the policy requirements are for transplant hospitals?

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While the policy requirements are reasonably clear, it is critical that these are aligned with CMS requirements and every effort should be made to eliminate duplicative processes between the two regulatory bodies.

Is it clear how the OPTN contractor will audit these requirements?

Again, the audit requirements are reasonably clear within the proposal. However, we maintain that it is critical that these are aligned with CMS requirements and every effort should be made to eliminate duplicative processes between the two regulatory bodies.

Is the process for matching participants in the OPTN KPD Program transparent?

There is a table delineating the prioritization points but the policy proposal fails to provide rationale for the variables considered and the point valuation for each characteristic.

Are the informed consent elements that are specific to KPD appropriate and complete?

ASTS believes that informed consent elements specific to KPD should be vetted through the Joint Societies Work Group (JSWG) as part of its work to develop consensus from the medical societies on areas with the potential to direct or prescribe medical care. Since these elements were not vetted through the JSWG, ASTS opposes their inclusion in the KPD policy.

Proposal 3: Kidney Transplantation Committee: Proposal to Include Bridge Donors in the OPTN Kidney Paired Donation (KPD) Program.

ASTS **supports** this proposal and recognizes that the inclusion of bridge donors in the OPTN KPD program is designed to maximize matching opportunities by extending the chains to achieve more transplants and is likely to increase transplant center participation in the program.

The proposal asks for specific feedback on the following question:

Should there be a limit on how long a bridge donor will be asked to wait in the OPTN KDP program as his/her candidate receives a transplant?

ASTS believes it is difficult to set a time limit for how long a donor will be asked to wait in the OPTN KPD program and would oppose artificial limits that do not support the overall goal of maximizing matching opportunities.

Proposal 4: Liver and Intestinal Transplantation Committee: Proposal to Allow Transplant Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated Exception Score.

ASTS **supports** this proposal that allows transplant centers to place candidates with an HCC exception on "HCC Hold" without loss of accumulated exception points. This policy proposal will facilitate more appropriate timing of liver transplantation for candidates with HCC, increase access to transplantation for more urgent cases and allow for greater efficiency in organ placement.

Proposal 5: Thoracic Organ Transplantation Committees: Proposal to Revise the Lung Allocation Score (LAS) System.

ASTS **supports** this proposal which proposes revisions to the 2005 policy to better reflect waitlist urgency and post-transplant survival and designed to increase efficient placement of available lungs.

Proposal 6: Living Donor Committee: Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors.

ASTS **supports** the overarching goals of this proposal that expands current policy to address the reporting of unexpected potential and proven disease transmission involving living donors but has several concerns. First, the proposal acknowledges that the existing guidance document is not sufficient. Instead of presenting a revised guidance document in tandem with the policy proposal, the committee plans to collaborate with the DTAC committee in the coming months to update the document. In order to fully evaluate the policy, the revised guidance document should have been presented with the policy proposal. Second, this policy proposal will impact informed consent as the donor must agree to the dissemination of personal information for two years post-donation. Third, this proposal could negatively impact a transplant center's ability to achieve living donor follow-up thresholds as some donors may avoid follow-up care as a mechanism to avoid disclosure of certain infections to the public health authorities and the recipient transplant center. Finally, it may be preferable to wait until the PHS Guideline for Reducing HIV, HBV, and HCV Transmission through Solid Organ Transplantation is finalized to ensure that OPTN policy and the guideline are properly aligned.

Proposal 7: Operations and Safety Committee (OSC): Proposal to Require Extra Vessel(s) Disposition to be Reported to the OPTN within Five Days of Transplant or Disposal.

ASTS **opposes** this proposal. As written, this proposal adds a reporting burden to the transplant center and fails to provide further protection to patient health. In fact, the two cases of disease transmission through the use of vessels cited within the policy proposal would not have been avoided even if this proposal was in place (one was used prior to identification of rabies and the second was properly labeled but not recognized by the surgical team).

Proposal 8: OPO Committee: Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record.

ASTS **supports** this proposal that will require OPOs and living donor recovery centers to document all unique identifiers that are used to label any tissue typing specimen in the donor record. This will allow transplant centers to validate second the unique identifier information.

Proposal 9: OPO Committee: Proposal to Update and Clarify Language in the DCD Model Elements.

ASTS **supports** this proposal which identifies specific requirements the OPOs and transplant centers must include in their DCD policies and redefines DCD as Donation after Circulatory Death. This policy proposal is consistent with ASTS recommended guidelines and mirrors CMS requirements.

Proposal 10: Policy Oversight Committee: Proposal to Update Data Release Policies.

ASTS **opposes** this proposal. Transplantation already boasts a huge amount of publicly available information at the national, state and center-specific level. While we recognize that final rule requires the OPTN to respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that resources permit, or as directed by the Secretary, we question the need to "allow OPTN to release more data than is currently released." At the April 2012 SRTR Consensus Conference there was significant debate about the currently available data and the manner in which it is used by payers, other transplant centers and the media. Instead of creating new policy to allow for the release of more data, we urge the committee to focus on the directive that requested data must be needed for bona fide research/analysis and to consider amending the "Specific Projects" criteria to better define what constitutes such research/analysis.

Thank you for the opportunity to comment on these proposals. Please do not hesitate to contact me or Kim Gifford, ASTS Executive Director, if you have any questions or require additional information.

Sincerely yours,

Kim M. Olthoff, MD
President