

3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION. The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

- 3.4.1 Avoidance of Conflicts of Interest.** Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent's death may participate in the operative procedure for removing or transplanting an organ from the decedent. For purposes of this section, "organ" is defined as set forth in the OPTN Final Rule (42 C.F.R Part 121.2), and "decedent" is defined as a deceased individual whose body is or may become the source of a donated organ.
- 3.4.2 Time Limit For Acceptance.** A transplant center, or its designee, must access donor information within UNetSM within one hour of receiving the initial organ offer notification. If UNetSM is not accessed within one hour by the transplant center or its designee, the offer will be considered refused. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and ~~3.8.5.3.2.2~~, a transplant center shall be allowed one hour from the time of accessing the donor information, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and ~~3.8.1.6.1 (Time Limit)~~ 3.8.3.4 (organ Offer Limit), in which to communicate its acceptance or refusal of the organ. After one hour elapses, or shorter period as defined under Policies 3.3.5 and ~~3.8.1.6.1.3.8.3.4~~, without a response, the offer will be considered refused and the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority on the match list.

NOTE: The amendments to Policy 3.4.2 (Time Limit for Acceptance) shall be effective pending notice to the members and programming on UNet[®]. (Approved at the November 8-9, 2010 Board of Directors Meeting)

- 3.4.3 Multiple Organ Retrieval.** After a Member indicates its initial acceptance of an organ, the transplant centers or OPOs involved must agree upon the time that multiple organ procurement will begin. If the procurement time cannot be agreed upon, the Host OPO may withdraw the offer from the transplant center or OPO unable to agree upon a time for procurement to begin.
- 3.4.4 Department of Defense Directive.** Until such time as the OPTN and the Department of Defense (DOD) reach a mutual understanding on organ allocation policies, Members may cooperate with U.S. military facilities that are bound by DOD organ allocation directives which are in conflict with policies. However, the OPTN neither agrees with nor endorses present DOD directives.
- 3.4.5 Multiple Organs Offer.** If an OPO has permission to procure all organs from a particular donor, that OPO shall offer those organs through the Match System unless there is a contraindication to organ procurement.
- 3.4.6 National Distribution of Organs.** After an organ has been unsuccessfully offered to appropriate Members for allocation to local candidates or unsuccessfully offered to Members through an approved regional sharing arrangement, the Organ Center will allocate an abdominal organ first regionally, and then nationally, based upon the point system set forth in policies. The Organ Center will allocate thoracic organs according to Policy 3.7.
- 3.4.7 Receiving and Responding to Organ Offers.** Transplant centers must accept organ offer notifications in an electronic manner compatible with at least one of the options provided by UNetSM. Additionally, transplant centers must view organ offers and respond to these offers in an electronic data format (e.g., via Internet access) through UNetSM.

3.4.8 Variances

3.4.8.1 Acceptable Variances Permissible variances include, but are not limited to:

- Alternative allocation systems
- Alternative local units
- Sharing arrangements
- Alternative point assignment systems

The following principles apply to *all* variances:

- Variances must comply with the National Organ Transplant Act and the Final Rule.
- Members participating in a variance must follow all rules and requirements of the OPTN Policies and Bylaws.
- If the Board later amends a policy containing a variance, the policy amendment will not affect the existing variance.
- There must be a single waiting list for each organ within each local unit.
- Where the local unit is a subdivision of the OPO's Donation Service Area (DSA), the OPO will allocate organs to the remainder of the DSA after allocating organs to the local unit.
- If a Member's application to create, amend, or join a variance will require other Members to join the variance, the applicant must solicit their support.
- The Board of Directors may extend, amend, or terminate a variance at any time.

3.4.8.2 Application Members or Committees wishing to create or amend a variance must submit an application to the OPTN contractor. Completed applications will be considered through the policy development process described in *Article XI: Adoption of Policies* of the OPTN Bylaws. The application must address *all* of the following:

1. The purpose for which the variance is proposed and how the variance will further this purpose.
2. If a Member's application to create, amend, or join a variance will require other Members to join the variance, the applicant must solicit their support. Committees will not review a Member's variance application unless the applicant receives affirmative support from at least 75% of the Members required to join by the application.
3. A defined expiration date or period of time after which the variance will conclude, the participating Members will report results, and the sponsoring Committee will evaluate the impact of the variance.
4. An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.
5. Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.
6. Whether this is an open variance or closed variance and, if this is an open variance, any additional conditions for Members to join this variance.

Members wishing to join an existing open variance must submit an application as dictated by the specific variance. If a Member's application will require other Members to join the variance, the applicant must solicit support from them. When an open variance is created, it may set conditions for the OPTN contractor to approve certain applications. The OPTN contractor may approve an application to join an open variance

when all Members required to join the variance support the application. When all Members do not support the application, only the sponsoring Committee may approve the application.

3.4.8.3 Reporting Requirements Members participating in a variance must submit relevant data and status reports to the sponsoring Committee at least annually, that:

1. Evaluate whether the variance is achieving its stated purpose
2. Provide data for the performance measures in the variance application
3. Address any organ allocation problems caused by the variance.

Participating Members must also submit a final report to the sponsoring Committee at least six months before the variance's expiration date.

The sponsoring Committee must actively monitor and evaluate these reports to review the variance's achievements toward its stated purpose.

3.4.8.4 Final Evaluation Prior to the variance's expiration date, the sponsoring Committee must evaluate whether the variance achieved its stated purpose and make a final recommendation to the Board of Directors. The Board of Directors may take *any* combination of the following actions:

- Direct the sponsoring Committee to develop a policy proposal based on the results of the variance
- Amend the variance
- Extend the variance for a set period of time
- Terminate the variance.

3.4.8.5 Terminating Variances Members participating in a variance may apply to the sponsoring Committee to withdraw from or terminate a variance. The applicant must solicit feedback from all other Members participating in the variance. The sponsoring Committee must recommend to the Board of Directors whether to approve or deny the request. The Board of Directors may approve, modify, or deny the request.

3.4.8.6 Appeals Members participating in a variance or seeking to join an open variance may appeal a Committee or Board of Directors' decision on an existing variance. To appeal a decision of a Committee, the Member must submit a written appeal to the sponsoring Committee within thirty days of notice of the decision and submit any new evidence not previously provided. The sponsoring Committee may request additional information from the Member. The sponsoring Committee will meet to consider the appeal. The Member submitting the appeal may participate in this meeting of the sponsoring Committee. The sponsoring Committee will recommend action on the variance to the Board of Directors.

Once the sponsoring Committee recommends action on the variance to the Board of Directors, a Member cannot request another appeal until the Policy Oversight Committee (POC) *and* Board of Directors decide on the variance. While evaluating the variance, the POC may request additional information from the Member. The sponsoring Committee must submit any information received from the Member to the POC. The POC will recommend action on the variance to the Board of Directors.

The Board of Directors will consider the variance including the recommendations of the sponsoring Committee and the POC. The Member may participate in this meeting of the Board of Directors.

3.4.9 Reserved

3.4.10 Reserved

3.4.11 Allocation of Organs During Regional/National Emergency Situations. In the event of a regional or national emergency situation that compromises telecommunications, transportation, or the function of / access to the waiting list and UNetSM, a notice and instructions will be distributed, if possible, to all transplant centers and organ procurement organizations advising them of the impact of the situation on the system and how members should proceed with organ allocation, distribution and transplantation. Members should reference Policies 3.4.11.1; 3.4.11.2; and 3.4.11.3 in cases of regional/national emergency.

3.4.11.1 Regional/National Transportation Disruption. In these situations, the OPTN contractor and members are able to communicate and the waitlist and matching systems are accessible, but transportation of organs is either not possible or severely impaired. Members are required to contact the OPTN contractor to determine proper operating procedures.

3.4.11.2 Regional/National Communications Disruption. In these situations, the OPTN contractor and members are unable to communicate through one or more of the available communications methods (internet and phones) and the waitlist and matching system are operational.

Internet Outage. Members are required to contact the OPTN contractor and determine the proper operating procedures.

Telecommunications (Land and Mobile Phone) Outage. Internet contact with the OPTN contractor should be made via e-mail to determine operation procedures and to obtain assistance. Members will continue to use the waitlist and matching system for organ allocation and distribution. Organ procurement organizations must document any variations in allocation or distribution due to telecommunications problems for submission to the OPTN contractor.

Combined Outage. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not accessible. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN contractor.

3.4.11.3 Operational Disruption. In these situations, the OPTN contractor and members are unable to communicate through any communications method and the waitlist and matching system are not operational. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN contractor.