

## At-a-Glance

- **Proposal to Clarify and Improve Variance Policies**
- **Affected/Proposed Policies:** 3.1 (Definitions), 3.4.7 – 3.4.10.5 (Application, Review, Dissolution, and Modification Processes for a Variance), 3.5.6.1 (Local Allocation), 3.6 (Allocation of Livers), and 3.7.1 (Exceptions)
- **Policy Oversight Committee (POC)**

The OPTN Contractor has initiated a plain language rewrite of the OPTN policies and bylaws. During the evaluation of the policies it was noted that significant changes to the variance policies were needed in order for members to better comply with the variance policies, create uniformity in how members apply for any type of variance, and promote reliability in the category of information provided with each variance application. As such, the following modifications are proposed:

- Elaboration of existing variance policies to provide clearer guidance to the community on how to apply for, modify, or dissolve a variance;
- Gathering all requirements into one policy category for the variance application, review, approval, modification, dissolution, and appeal processes;
- Eliminating redundancy in existing variance policies; and,
- Rewriting the variance policies using plain language.

*Note: The modifications do not impact the current operation of existing variances.*

- **Affected group**  
OPTN Members  
General Public, Candidates  
Recipients  
Donors
- **Number of Potential Candidates Affected**  
While variances do affect candidates, the proposed language changes do not impact candidates.
- **Compliance with OPTN Strategic Goals and Final Rule**  
Depending on the type of variance submitted by the member, current and proposed variance policies have the potential to impact the Program Goals of the Health and Human Services (HHS), and the OPTN Strategic Plan.
- **Specific Requests for Comment**  
Does the plain language rewrite and reorganization make the policies easier to understand while retaining the existing intent?

## **Proposal to Clarify and Improve Variance Policies**

**Affected/Proposed Policies:** 3.1 (Definitions), 3.4.7 – 3.4.10.5 (Application, Review, Dissolution, and Modification Processes for a Variance), 3.5.6.1 (Local Allocation), 3.6 (Allocation of Livers), and 3.7.1 (Exceptions)

### **Policy Oversight Committee**

#### **Summary and Goals of the Proposal:**

A variance is a policy experiment conducted by a member of the Organ Procurement and Transplantation Network (OPTN) to improve organ procurement and allocation. The OPTN Contractor manages the national organ procurement and organ allocation system and evaluates each variance for its use in national policy. Policies to create and evaluate variances exist; however, as currently written they are difficult to interpret. The proposed modifications make it easier for members to comply with the variance policies; enable the OPTN Contractor to evaluate a variance for national use; create uniformity in how members apply for any type of variance; and, promote reliability in the category of information provided with each variance application. As such, the POC is proposing the following policy modifications:

- Elaboration of existing variance policies to provide clearer guidance to the community on how to apply for, modify, or dissolve a variance;
- Gathering all requirements into one policy category for the variance application, review, approval, modification, dissolution, and appeal processes;
- Eliminating redundancy in existing variance policies; and
- Rewriting the variance policies using plain language.

#### **Background and Significance of the Proposal:**

In 2006 and 2008, UNOS surveyed OPTN members for feedback on a variety of issues as they relate to the efforts of the OPTN contractor. UNOS received over 2,000 individual responses for the 2006 survey, and over 1,500 individual responses for the 2008 survey. A significant number of the remarks alluded to confusing and complicated OPTN policies. Listed below are a few of the comments received:

- *“The regional variances are not well understood.”*
- *“Provide policy language in plain language. It's too legalistic to really derive meaning and application.”*
- *“Write in plain language that all members can understand.”*
- *“Sometimes the government language is a bit obscure, if things were explained in the manner they would be in a conversation it would be easier to understand.”*
- *“I think that the rules and regulations should be less complicated. They should be clear and easy to follow.”*

To address the concerns, UNOS initiated a “rewrite” project to rewrite OPTN bylaws and policies into plain language and to organize them logically. Following the plain language rewrite and reorganization, the plan is to send the changes out in their entirety during a special public comment period in 2012. However, if during the evaluation and rewrite of the policies there are areas identified that require

significant changes or change the intent of the policies, then the proposed changes will follow the standard policy development process.

### *Variance Policies*

Beginning in 2005, UNOS catalogued each existing variance and its status (e.g., approved by the Board, implemented in UNet<sup>SM</sup>, etc.). In 2008, as part of this effort, UNOS developed a variance application based on the content of the variance policies and the OPTN Final Rule. This application standardized the information required and the process for describing an existing variance or submitting an application for a new variance. UNOS requested all members with a variance to submit a completed application for each. In the application, members needed to indicate whether they intended on retaining, modifying, or dissolving the variance. The application has been modified based on the changes to policy and can be found in Appendix A. *Please note that the application is included for “informational purposes only.”*

The current policies that address variances<sup>1</sup> are repetitive and not well-organized in content. As indicated earlier, OPTN member surveys conducted by UNOS indicate that these policies, in general, are written in a style sometimes difficult to understand. As a result, it is possible that the organization and content of the current variance policies pose compliance challenges for the OPTN Contractor in evaluating a given variance for its use in national policy. Additionally, there are a significant number of variances and to date the OPTN Contractor has not incorporated these variances in national policy.

The modifications proposed in this document do not change the intent of the variance policies, but do present new information and a reference to “other variances.” Please note that the modifications *do not* impact the current operation of existing variances. There exist, roughly, three different paths within the variance policies. The paths are similar but each one omits or contains extra components. The goal of this proposal is for all variances to follow the same path. The proposed policy modifications set clear expectations of the member and the OPTN Contractor on the variance application, review, and appeal processes. The proposed modifications retain some of the existing policy numbers, present policy written in plain language, and eliminate redundancy in the existing language. The intent of reorganizing the policies in Policy 3.1 (Definitions) is to provide a more logical presentation of content. The elimination of redundancy in Policy 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation) results in the clear guidance that a variance, regardless of its type (i.e., alternative allocation/alternative distribution system, alternative local unit, sharing arrangement and agreement, and alternative point assignment system), is a deviation from the current, national organ allocation system. As such, a member interested in applying for a new variance, regardless of type, needs to submit uniform categories of information to the OPTN Contractor. If the member wishes to modify its existing variance, it must submit a variance application to the respective committee.

### *Strengths of the Proposed Policy Modifications*

The proposed modifications consolidate variance language to eliminate redundancy, and clarify the variance application, review, and appeal process. The proposed modifications use the term “variance” to describe all deviations from the national allocation system. The emphasis on variance, rather than on

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<sup>1</sup>The current variance policies are: a) Alternative Allocation/Distribution System (Policy 3.1.7); b) Variances (Policy 3.1.8); c) Committee-Sponsored Alternative System (3.1.9); d) Local and Alternative Local Unit (3.1.10); e) Sharing Arrangement and Sharing Agreement (3.1.11); f) Alternative Point Assignment Systems (3.1.12); g) Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems (Policy 3.4.7); h) Application, Review, Dissolution and Modification Processes for Variances (Policy 3.4.8); and, i) Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems (Policy 3.4.9).

a type, has the potential to broaden the interpretation of what would constitute a variance. In other words, a member may apply for a variance type not currently cited as an example in policy. The OPTN Final Rule supports this interpretation of a variance.

#### *Weaknesses of the Proposed Policy Modifications*

Since the location of several policies has changed, a member could potentially get frustrated or have trouble finding the reorganized set of policies. Additionally, the sheer volume of language changes may make it difficult for members to compare the proposed version to the current version. To minimize confusion, there is a clean version of the new policies located at the end of the document. This version only contains the retained language and proposed new language.

#### *Intended Consequences of the Proposed Modifications*

The proposed policy modifications will:

- Improve the national organ allocation system through incorporation of these experimental policies that have use in this national system;
- Further encourage members to apply for variances that have the potential to improve the national organ allocation system;
- Promote reliability in the types of data submitted as evidence for continuing an existing variance or developing a new variance; and,
- Generate consistency in the application process and how the Board of Directors evaluates each variance for its use in the national system, as a result of reliability in what data members submit.

#### *Unintended Consequences of the Proposed Modifications*

The emphasis on research design may discourage members from submitting new applications, which may result in fewer opportunities to test allocation hypotheses on a local level that may benefit the national system.

#### **Supporting Evidence:**

The proposed modifications stem from three categories of evidence:

- OPTN Final Rule's statement that a variance is a policy experiment that has the goal of improving organ allocation;
- emphasis in the literature that public health documents be written in plain language;
- comments regarding plain language submitted in the UNOS member survey.

#### *Variance Section of the OPTN Final Rule*

The variance section of the OPTN Final Rule is cited again below:

[...] (g) Variances. The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time

limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4. [...]

The phrases, “...experimental policies that test methods of improving allocation” and “time limited” imply that the intent of a variance is to assess its utility in the national system. If a variance should continue past its time period, then it should be allowed to:

- collect additional, requisite data to determine its potential for use in national policy; or
- to satisfy a need for a given community that a national system cannot due to resource or other salient reasons.

Otherwise, the committee’s or Board of Directors’ evaluation of a variance should result in either its incorporation in the national system or its dissolution, because it has no potential for use in the national system.

### *Plain Language – A Brief Review of the Literature*

When discussing plain language, especially in public health, the concept of health literacy is at its core. Healthy People 2010<sup>2</sup> defines health literacy as “[t]he degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Stableford and Mettger (2007)<sup>3</sup> also emphasize the need for health care professionals to make use of existing literature and tools to translate or write health documents in plain language. Plain language “...is about writing for clarity and meaning.” Stableford and Mettger also challenge myths about documents written in plain language, and comment that developing documents that are written in plain language require professional skills.

Writing documents in plain language is not necessarily writing at a lower reading level, but rather, writing so that the reader understands clearly the intent of a given body of text, and understands what action, if any, she or he must perform (Rudd et al., 2004; Stableford & Mettger, 2007<sup>4</sup>). Writing documents in plain language should incorporate the principles of health communication, i.e., target the written text for the intended reader (U.S. Department of Health and Human Services, 2004<sup>5</sup>). OPTN policies require that its institutional members, who are comprised of individuals with formal training primarily at the college reading level or higher, not only read the text but act on them for organ allocation purposes. Their understanding of the policies is critical as the OPTN Contractor evaluates their compliance with these policies. Hence, these variance policies need to be written in plain language.

### **Expected Impact on Living Donors or Living Donation**

Not applicable

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<sup>2</sup> U.S. Department of Health and Human Services. (2000). *Healthy People 2010*. 2nd ed. Retrieved from <http://www.healthypeople.gov/>

<sup>3</sup> Stableford, S. & Mettger, W. (2007). Plain Language: A Strategic Response to the Health Literacy Challenge. *Journal of Public Health Policy*, 28, 71-93.

<sup>4</sup> Rudd, R.E., Kaphingst, K., Colton, T., Gregoire, J. & Hyde, J. (2004). Rewriting Public Health Information in Plain Language. *Journal of Health Communication*, 9, 195-206.

<sup>5</sup> U.S. Department of Health and Human Services. (2004). *Making Health Communication Programs Work*. Retrieved from <http://www.cancer.gov/pinkbook>

**Expected Impact on Specific Patient Population:**

No known impact on specific patient populations

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

The proposed policy modifications should make it easier for members to comply with the variance policies, enabling the OPTN Contractor to continue to meet its legislative requirement – the OPTN Final Rule – when its Board of Directors evaluates a variance for its use in the national organ allocation system.

Depending on the type of variance submitted by the member, current and proposed variance policies have the potential to impact the Program Goals of the Health and Human Services (HHS), and the OPTN Strategic Plan.

**Plan for Evaluating the Proposal:**

The OPTN Contractor and the POC, together with organ-specific committees, will evaluate the content of variance applications to assess how well the members understand proposed policy modifications. This evaluation will occur whenever members submit a new application to a committee, or whenever it is time for committees to review the outcome of existing variances. This includes:

- Do members demonstrate understanding of the revised policies by providing applications complete with the requisite information?
- Is the type of information provided sufficient to evaluate the impact of the proposed variance?

UNOS will continue to monitor the responses about policy language in the member survey. Based on this feedback as well as its own periodic review of the policy language, UNOS will recommend to the POC relevant modifications to the variance policies. UNOS will conduct this periodic review every three years.

**Additional Data Collection:**

The proposed modifications will not require additional data collection by OPTN members. Members that submit new variance applications will continue to be responsible for determining the data they need to collect to assess achievement of the variance's goals and objectives. Whenever possible, variance applicants should make use of existing data in UNet<sup>SM</sup> to achieve the variance's goals and objectives. If necessary, the OPTN Contractor will program approved variances in UNet<sup>SM</sup>. If the Board of Directors decides to incorporate a variance into the national allocation system, then the OPTN contractor will modify UNet<sup>SM</sup> as necessary.

**Expected Implementation Plan:**

The proposed policy revisions will be in effect upon approval by the Board of Directors and modifications to the UNet<sup>SM</sup> help documentation.

**Communication and Education Plan:**

If the Board of Directors approves the proposed modifications, standard communication methods will be used to inform members.

Communication Activities

Type of communication	Audience	Delivery method	Timeframe
Policy notice (informs community that the proposed policy was approved by the OPTN/UNOS Board of Directors)	OPTN Members	Email	Distributed 30 days after Board approval
UNet <sup>SM</sup> system notice (informs the community about an automated solution to an approved policy)	OPTN Members	Email	Four weeks before the update to the UNet <sup>SM</sup> help documentation, and on the date of the update

**Monitoring and Evaluation:**

This policy language modification will not require any changes in the monitoring efforts routinely conducted by the Department of Evaluation and Quality.

**Policy Proposal:**

In this section, proposed policy language is underlined (example) and deleted policy language is struck-through (~~example~~). Some of the deleted language was relocated.

Additionally, there is a reader friendly version of the policies at the end of this document that contains only retained and new language.

The following changes were made:

Amendments to 3.1.7 – 3.1.10, 3.1.11, 3.1.12, 3.5.6.1, 3.6, and 3.7.1

Strike 3.1.10.1 – 3.1.10.6 and 3.4.8 – 3.4.10.6

Add 3.4.8-3.4.10

**3.1.7 ~~Alternative Allocation/Distribution~~ System.** A type of variance that allows Members to allocate organs differently than the OPTN policies. The term “Alternative Allocation System” or “Alternative Distribution System” (AAD System) refers to any system, with the exception of “Variances” and “Committee-Sponsored Alternative Systems” as described in Policies 3.1.8 and 3.1.9, respectively below, used for local organ allocation or distribution, as applicable, that is different from the standard allocation or distribution system for that organ as defined by policy. Such systems are designed for the purpose

of increasing organ availability and/or organ quality, reducing or addressing an inequity in organ allocation/distribution unique to the local area, and/or examining a policy variation intended to benefit the allocation/distribution system overall. They exist in the forms of (i) alternative local units (ALUs), (ii) sharing arrangements and agreements, (iii) alternative point assignment systems, and (iv) systems that may include components of more than one of these AAD Systems. Liver payback provisions currently listed within existing Alternative Allocation/Distribution Systems will be eliminated.

**3.1.8 Variances.** An experimental policy that tests methods of improving allocation. The term “Variance” refers to any system for organ allocation and/or distribution that meets the criteria for a “Variance” as described in the Final Rule for operation of the Organ Procurement and Transplantation Network, 42 C.F.R. §121.8(g). Such systems may be designed pursuant to policy-making processes and the Final Rule, §121.4, as potentially temporary policies for the purpose of previewing methods for improving organ allocation or distribution. They must include a plan for data collection and analysis and have a defined time limit for the policy variation.

**3.1.9 Open and Closed Variances.** An open variance is a variance that allows other Members to join it. A closed variance is a variance that is not open for other Members to join it. ~~**Committee Sponsored Alternative System.**~~ The term “Committee Sponsored Alternative System” refers to an Alternative Allocation System or Alternative Distribution System developed by the relevant Committee(s) and approved by the Board of Directors to address issues in organ allocation/distribution applicable to multiple local areas but not nationally, or for which consensus to modify standard policy for the nation as a whole has not been achieved.

**3.1.10 Local and Alternative Local Unit (ALU).** A local unit is the geographic area for organ procurement and distribution. An alternative local unit is a type of variance that creates a distinct geographic area for organ procurement and distribution. The Local Unit will be the OPO in most cases. Alternative Local Units (Alternative Local Units or ALUs) such as subdivisions of the OPO which function as distinct areas for organ procurement and distribution, entire states, Regions or other appropriate units are acceptable if they can be demonstrated to the satisfaction of the Board of Directors to fulfill the principles below and ALU application requirements, as well as adhere to applicable laws and regulations.

The principles for defining local, all of which should be addressed and appropriately balanced in each instance, are as follows:

**3.1.10.1** There should be a single waiting list for each organ within each Local Unit. Any deviation from this principle must be submitted for approval.

**3.1.10.2** There should be Local Unit review. The OPO or OPOs involved shall collect and review data on organ procurement, organ distribution, organ quality, and organ function for the Local Unit.



~~3.1.10.3~~ There should be a demonstrated inequity in organ distribution within the OPO or OPOs involved that is addressed by the ALU and corrected or at least improved within a specified period of years as shown through objective criteria. The purpose of the ALU should be to provide a system of equitable organ distribution. Equitable organ distribution should attempt to balance justice and medical utility.

~~3.1.10.4~~ There should be monitorable organ distribution. Data collection and review are necessary to be certain that the distribution system is being followed and that it is achieving its goals.

~~3.1.10.5~~ There should be no organ distribution predicated on the procuring transplant center or individual.

~~3.1.10.6~~ There should be effective organ procurement throughout the Local Unit. Enhancement of the organ supply should be a primary goal of any organ distribution system.

~~In cases where a subdivision of an OPO is the Local Unit, organs recovered, but not used within that segment of the OPO will be used in the remainder of the OPO before regional or national distribution. Cooperative working relationships within and among OPOs are encouraged to serve the best interests of transplant candidates, in a manner that is consistent with the principles set forth in the Policy 3.1.10.~~

~~Once an ALU is approved, Members participating in the ALU are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.~~

**3.1.11 Sharing Arrangement and Sharing Agreement.** A type of variance that permits two or more OPOs to share organs. The term sharing arrangement refers to an arrangement entered into by two or more OPOs to share organs, interregionally or intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement after fulfilling the Sharing Arrangement/Sharing Agreement application requirements and obtaining approval by the Board of Directors. Organs must be distributed within the sharing area on the basis of a common Waiting List unless an appropriate Alternative Local Unit for the area is approved by the Board of Directors. Unless specifically required for examining the effectiveness of the Sharing Agreement, as required by its evaluation plan, OPOs participating in a sharing arrangement must have geographically contiguous service areas. The term sharing agreement refers to the written document that defines the sharing arrangement.

~~Once a Sharing Arrangement is approved, Members participating in the Sharing Arrangement are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.~~

**3.1.12 Alternative Point Assignment Systems.** ~~A type of variance that permits Members to assign points differently than the OPTN policies. An OPO, Members participating in an approved Alternative Local Unit or Members participating in an approved sharing arrangement may assign to each of the point system criteria set forth in Policies 3.5 through 3.11 a number of points other than the number of points set forth in such policies for allocation of local organs after fulfilling the alternative point assignment system application requirements and obtaining approval by the Board of Directors. Members participating in an approved alternative point assignment system shall be obligated to: (a) stay aware of all applicable provisions of the organ allocation policies and any amendments thereto ("policy requirements") (as well as all other Bylaws and Policies), (b) evaluate the continued benefit of the system in light of the policy requirements and (c) request Committee and Board of Director approval for any adjustment to the alternative point assignment system deemed appropriate and desirable by the Member(s) following such evaluation. No approved alternative point assignment system will automatically be modified in light of or to incorporate in any way any policy requirement adopted by the Board of Directors following approval of the system unless otherwise specifically provided by the Board of Directors. Any modification of an approved alternative point assignment system shall require application by the applicable Member(s) in accordance with Policy 3.4.6.4.~~

~~Once an alternative point assignment protocol is approved, Members participating in the protocol are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.6.~~

### **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 Appendix C 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. However, if the application to join an existing open variance does not receive affirmative support from all of the Members required to join by the application, the OPTN contractor may not approve the application and 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**

~~**3.4.8 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified AAD System, review of such systems and withdrawal from such systems by any one or more of the participants.~~

~~**3.4.8.1 Application.** Applications to allocate organs locally using alternative point assignment systems may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved sharing arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the alternative point assignment system whether or not the institution supports the system. Applications to distribute organs according to sharing arrangements or ALUs may be submitted by OPOs; any such application must indicate for each applicant OPO whether or not the OPO's Board of Directors supports the sharing arrangement or ALU, as applicable. In cases where unanimity cannot be achieved at the local level, applications to allocate organs using either an alternative point assignment system, sharing agreement or ALU must have approval of 75% of the Member OPOs and or transplant centers.~~

~~Applications to allocate organs using alternative point assignment systems or to distribute organs using sharing arrangements or ALUs are submitted to the appropriate organ specific committees for consideration before being issued for public comment according to processes for public comment. Such applications are then reconsidered by the relevant Committee in light of public comment. Final applications to allocate organs locally using alternative point assignments or to distribute organs using sharing arrangements or ALUs must be presented to and approved by the Board of Directors before they can be implemented or used in organ allocation/distribution. An application to allocate organs locally using an AAD System must specify the purpose for which it is proposed, how the system is intended to accomplish this purpose, and an evaluation plan by which the participating Members will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the AAD System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by recipient populations), and (c) organ availability and/or organ quality. Applicants are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the AAD system that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a system intended to adjust priority for pediatric candidates. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by~~

~~the Members for the Members to address in assessing the ongoing operations of the AAD System.~~

~~Applications shall comply with other application requirements as may be established by the appropriate committees and Board of Directors. Once approved, notice of the AAD System will be included in the policies. Initial approval by the Board of Directors of any AAD System shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable Members must have demonstrated through objective criteria that the purpose for which the system was approved has been achieved or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the AAD System be: (a) finally approved, (b) approved on a continued provisional basis for a specific period of time, or (c) terminated.~~

~~When an alternative point assignment system, sharing arrangement or ALU is proposed to permit participation of a distribution unit in a scientific study to test a stated hypothesis with defined parameters under controlled conditions, such an alternative point assignment system, sharing arrangement or ALU may be approved by the Board of Directors for implementation if it (a) is of scientific merit (The Board may consider prior approval of such national agencies as the National Institutes of Health, Veterans Administration or national voluntary health agencies in making this determination); (b) extends for a defined, limited time period not greater than the initial 3-year provisional period, plus 2 years; and, (c) will have no net effect on the number of organs available for transplant within the applicable distribution unit, or potentially affected larger distribution units which include the applicable distribution unit. Such proposals will be considered in accordance with the standard process for consideration of alternative point assignment systems, sharing arrangements or ALUs, as applicable.~~

~~**3.4.8.2 Data Submission Requirements.** Members receiving permission of the Board of Directors for evaluating alternative point assignment systems, sharing arrangements and ALUs, including those denied with conditions and those approved on a provisional basis, shall submit, at one year intervals, or more frequently upon request, relevant data and status reports that assess the impact of the AAD System, relative to the system's stated objectives and using the performance measures proposed in the participating Members' application, address any organ allocation problems that may have arisen as a result of the system and, in the case of ALUs, demonstrate adherence to the principles for defining local (Policy 3.1.9) and progress toward correcting or at least reducing the inequity that the ALU is intended to address. From time to time, these Members may be provided with data reports (from UNet<sup>SM</sup>) showing the experience of the alternative organ distribution\allocation~~

~~system as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. Members receiving approval by the Board of Directors to participate in an alternative point assignment system, sharing arrangement or ALU as part of a limited duration scientific study shall be subject to the data submission requirements stipulated above in addition to submission of a final report within six months following completion of the study.~~

~~The appropriate committee(s) shall actively monitor these data and status reports to provide consistency to efforts to assist the participating OPOs and transplant centers in dealing with each of their special circumstances; to make recommendations to the Board of Directors for continuation, modification or termination of the AAD Systems; and, in the case of alternative point assignment systems to review the alternative system in light of standard organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any AAD System as deemed appropriate by the Board of Directors.~~

~~**3.4.8.3 Dissolution of Alternative Assignment Systems** Sharing Arrangements and ALUs. Members operating with an approved (a) alternative point assignment system who unanimously elect to withdraw from that system and use the standard point system criteria pursuant to Policies 3.5 through 3.11, (b) sharing arrangement who unanimously elect to withdraw from that arrangement and define the OPOs as the Local Units for purposes of organ distribution or (c) ALU who unanimously elect to withdraw from that ALU and use the OPO, or larger sharing area under a Board approved sharing arrangement, as the Local Unit pursuant to Policy 3.1.7, shall provide timely written notification of such withdrawal and resulting dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, to the relevant Region, appropriate committees and the Board of Directors. Dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, shall be effective after appropriate re-programming on UNet<sup>SM</sup>. A request to withdraw from an alternative point assignment system, sharing arrangement or ALU that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.6.4 below.~~

~~**3.4.8.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs.** Any proposed modification of an approved alternative point assignment system, sharing arrangement or ALU, other than a proposal to dissolve the system agreed to unanimously by the parties, shall require application by the participating Member(s) in the case of an alternative point assignment system, or participating OPOs in the case of a sharing arrangement or ALU, and approval by the Board in~~

accordance with the application process described in Policy 3.4.6.1 above.

**~~3.4.8.5 AAD Systems Approved Prior to March 15, 2005.~~** Members using an approved AAD System as of March 15, 2005, that meets the criteria for such system in effect prior to that date, shall be permitted to continue the system for 3 years from March 2005, at which time they will be required to re-apply to continue their systems under the requirements and criteria of applicable policies for AAD Systems then in effect.

**~~3.4.8.6 Appealing A Decision on An Alternative Organ Distribution or Allocation System.~~** A participating Member can appeal a committee's or a Board of Directors' decision on an alternative organ distribution or allocation system. To appeal a decision on an alternative organ distribution or allocation system, the participating Member must follow the process described below.

*a. Appealing A Committee's Decision*

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the alternative organ distribution or allocation system.

To express its intent to appeal a committee's decision on an alternative organ distribution or allocation system, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would the application (see Policy 3.4.7.1 – Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the alternative organ distribution or allocation system, the participating Member *cannot request another appeal* until the POC *and* the Board of Directors decide on the alternative organ distribution or allocation system.

In its evaluation of the alternative organ distribution or allocation system, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the alternative organ distribution or allocation system and submit its recommendation to the Board of Directors. The Board of



~~Directors will consider the alternative organ distribution or allocation system, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.~~

~~If the Board of Directors decides in favor of the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is approved for the trial period requested by the participating Member. If the Board of Directors decides against the alternative organ distribution or allocation system, then the alternative organ distribution or allocation system is not approved.~~

~~*b. Appealing a Board of Directors' Decision*~~

~~To appeal the decision of the Board of Directors on an alternative organ distribution or allocation system, the participating Member of the alternative organ distribution or allocation system may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).~~

~~**NOTE: Policy 3.4.8.6 (Appealing A Decision on An Alternative Organ Distribution or Allocation System) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)**~~

~~**3.4.9 Application, Review, Dissolution and Modification Processes for Variances.**~~

~~The following policies define the processes for applying for a new or modified Variance, review of such systems by, and withdrawal from such systems by any one or more participants.~~

~~**3.4.9.1 Application.** Applications to allocate or distribute organs using a Variance may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved Sharing Arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the Variance whether or not the institution supports the system. Unanimity among participants is encouraged but not required. In cases where unanimity cannot be achieved, Variance applications must include statements of support or opposition on behalf of each potential participant explaining their position. Variance applications are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Variance applications are then reconsidered by the relevant Committee in light of public comment. Final Variance applications must be presented to and approved by the Board of Directors before they can be implemented on UNet<sup>SM</sup> or used in organ allocation/distribution. Once approved, notice of the Variance will be included in the policies.~~

~~A Variance must comply with application requirements as may be established by the appropriate committees and Board of Directors and specify the purpose for which it is proposed, incorporating a review of the method for improving organ allocation or distribution; how the system is intended to accomplish this purpose; and a plan for data collection and analysis for assessment of the system's success in achieving its stated purpose. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by the Members for the Members to address in assessing the ongoing operations of the policy variance. The plan must include a defined end point by which the Variance will be completed and results reported.~~

~~Once a Variance is approved, Members participating in the variance are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.7.2. Participants in an approved Variance are further required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.~~

~~**3.4.9.2 Data Requirements.** Members receiving permission of the Board of Directors for evaluating Variances shall submit, at one-year intervals, or more frequently upon request, relevant data and status reports that: (i) assess the impact of the Variance relative to the system's proposed effect and in accordance with the plan for data collection and analysis defined in the participating Members' application, and (ii) address any organ allocation problems that may have arisen as a result of the system. From time to time, these Members may be provided with data reports (from UNet<sup>SM</sup>) showing the experience of the variance as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. In addition to the periodic reports stipulated above, Variance participants must submit a final report within six months following completion of the plan.~~

~~The appropriate committee(s) shall actively monitor these data and status reports to review the Variance and any potential for improving standard national organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any Variance as deemed appropriate by the Board of Directors.~~

~~**3.4.9.3 Appeal to Secretary.** Decisions of the Board of Directors to approve a Variance may be appealed to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR § 121.4.~~

~~**3.4.9.3 Appealing A Variance Decision.** The participating Member can appeal a committee's or Board of Directors' decision on a variance. To appeal a~~

decision on a variance, the participating Member must follow the process described below.

*a. — Appealing a Committee's Decision*

The committee will notify the participating Member in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.

To express its intent to appeal, the participating Member must do so in writing and within 30 days, inclusive, of the committee's communication of its decision. The participating Member must appeal a committee's decision *before* the Policy Oversight Committee (POC) reviews this recommendation. The participating member should contact the OPTN Contractor for the POC meeting schedule.

In considering the appeal, the committee will *only review evidence not considered previously*. The committee will evaluate the appeal as it would a variance application (see Policy 3.4.8.1 — Application). The participating Member may choose to take part in this appeal discussion. The committee may request additional information from the participating Member. Once the committee makes its final decision on the variance, the participating Member *cannot request another appeal* until the POC and the Board of Directors decide on the variance.

In its evaluation of the variance, the POC may request additional information from the committee, who will communicate this query to the participating Member. The committee will submit any information received from the participating Member to the POC. The POC will then decide on the variance and submit its recommendation to the Board of Directors. The Board of Directors will consider the variance, including the decisions of the committee and POC. The participating Member may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the variance, then the variance is approved for the trial period requested by the participant. If the Board of Directors decides against the variance, then the variance is not approved.

*b. — Appealing a Board of Directors' Decision*

To appeal the decision of the Board of Directors, the variance applicant may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).

***NOTE: Policy 3.4.9.3 (Appealing A Variance Decision) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)***

~~**3.4.9.4 Termination of Member Participation in Variance.** Members operating with an approved Variance who unanimously elect to withdraw from the variance and use the standard allocation and distribution system criteria pursuant to applicable policies shall provide timely written notification of such withdrawal and resulting termination of Variance to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Variance shall be effective after appropriate re-programming on UNet<sup>SM</sup>. A request to withdraw from a Variance that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.7.5 below.~~

~~**3.4.9.5 Modification of Variance.** Any proposed modification of an approved Variance, other than a proposal to dissolve the variance agreed to unanimously by the parties, shall require application by the participating Member(s), and approval by Board of Directors in accordance with the application process described in Policy 3.4.7.1 above.~~

~~**3.4.10 Development, Application, Review, Dissolution and Modification Processes for Committee Sponsored Alternative Systems.** The following policies define the processes for developing a new or modified Committee Sponsored Alternative System, application to participate in such systems, review of such systems, and withdrawal from such systems by any one or more participants.~~

~~**3.4.10.1 Development and Application.** Committee-Sponsored Alternative Systems are developed by the applicable reviewing Committee(s), submitted for public comment according to processes for public comment, and reconsidered by the sponsoring Committee in light of public comment. Final proposals for Committee-Sponsored Alternative Systems must be presented to and approved by the Board of Directors prior to implementation on UNet<sup>SM</sup>. Once approved, notice of the Committee-Sponsored Alternative System will be included in the policies. A Committee-Sponsored Alternative System must specify the purpose for which it is proposed, how the system is intended to accomplish this purpose, and an evaluation plan by which the sponsoring Committee will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the Committee-Sponsored Alternative System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by candidate populations), and (c) organ availability and/or organ quality. Committees are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the Committee-Sponsored Alternative System that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a~~

~~system intended to adjust priority for pediatric candidates. The system must be established for a defined period of time, during which the sponsoring Committee must collect and evaluate relevant data to assess whether the system is achieving its objectives and should be continued, modified, or terminated. By the end of this period, the sponsoring Committee must have demonstrated through objective criteria that the purpose for which the system was approved has been accomplished or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been attained. Based upon this assessment, the sponsoring Committee shall recommend to the Board of Directors whether the Committee-Sponsored Alternative System should be continued without change, modified, or terminated.~~

~~OPOs and their affiliated transplant centers may apply to participate in an approved Committee-Sponsored Alternative System by demonstrating unanimous agreement to such participation among the OPO(s) and their transplant centers with programs for transplantation of the applicable organ(s). For those OPOs with multiple units (ALUs), signatures must be obtained from each transplant center within the OPO (with programs for transplantation of the applicable organ(s)) indicating that they agree to participate in the system. Applicants also must provide Member contact and other information as may be determined by the appropriate Committees and Board of Directors. Once the Board of Directors has approved a Committee-Sponsored Alternative System, individual participant applications do not require Committee or Region review or Board approval prior to implementation on UNet<sup>SM</sup>. Participants in Committee-Sponsored Alternative Systems are required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.~~

~~**3.4.10.2 Data Requirements.** Members participating in a Board-approved Committee-Sponsored Alternative System are not required to submit alternative system data other than any specific data submission requirements of the system.~~

~~**3.4.10.3 Termination of Member Participation in Committee-Sponsored Alternative System.** An OPO and its affiliated transplant centers participating in an approved Committee-Sponsored Alternative System may unanimously elect to withdraw from the alternative system and use the standard allocation and distribution system criteria pursuant to applicable policies upon providing timely written notification of such withdrawal and resulting termination of participation in the alternative system to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Members' participation in the alternative system shall be effective after appropriate re-programming in UNet<sup>SM</sup>.~~

~~**3.4.10.4 Modification of Committee Sponsored Alternative System.** Any proposed modification of an approved Committee-Sponsored Alternative System, other than withdrawal by individual participant(s), shall require application by the sponsoring Committee, and approval by Board of Directors in accordance with the application process described in Policy 3.4.8.1 above.~~

~~**3.4.10.5 Committee Sponsored Alternative Systems Approved Prior to March 15, 2005.** Committee-Sponsored Alternative Systems approved by the Board of Directors as of March 15, 2005, shall be permitted to continue to operate for 3 years from March 2005, at which time the applicable sponsoring Committees will be required to re-apply to continue the systems under the requirements and criteria of applicable policies for Committee-Sponsored Alternative Systems then in effect.~~

~~**3.4.10.6 Appealing A Decision on A Committee Sponsored Alternative System.**~~

~~The committee sponsoring a Committee-Sponsored Alternative System may appeal the decision of the Policy Oversight Committee (POC), but cannot appeal a decision of the Board of Directors.~~

~~*a. Appealing the POC's Decision*~~

~~The POC will notify the sponsoring committee in writing of its decision within 10 business days, inclusive, of the meeting in which it determined the outcome of the variance.~~

~~To express its intent to appeal, the sponsoring committee must do so in writing and within 30 days, inclusive, of the POC's communication of its decision. The sponsoring committee must appeal the POC's decision *before* the Board of Directors reviews the POC's recommendation.~~

~~In considering the appeal, the POC will *only review evidence not considered previously*. The POC will evaluate the appeal as it would an application for a Committee-Sponsored Alternative System (see Policy 3.4.9.1 – Development and Application). The sponsoring committee may choose to take part in this appeal discussion. The POC may request additional information from the sponsoring committee. Once the POC makes its final decision on the variance, the sponsoring committee *cannot request another appeal* until the Board of Directors decide on the Committee-Sponsored Alternative System.~~

~~In its evaluation of the Committee-Sponsored Alternative System, the POC may request additional information from the sponsoring committee. Once the sponsoring committee submits any information requested by the POC, the POC will then decide on the Committee-Sponsored Alternative System and submit its recommendation to the Board of Directors. The Board of Directors will consider the Committee-Sponsored Alternative System. The~~

sponsoring committee may choose to take part in this meeting of the Board of Directors.

If the Board of Directors decides in favor of the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is approved for the trial period requested by the committee. If the Board of Directors decides against the Committee-Sponsored Alternative System, then the Committee-Sponsored Alternative System is not approved.

*b. ~~Appealing the Board of Directors' Decision~~*

~~Only a member participating in an existing Committee-Sponsored Alternative System can appeal the Board of Directors' decision on a Committee-Sponsored Alternative System.~~

~~To appeal the decision of the Board of Directors on a Committee-Sponsored Alternative System, the member participating in an approved Committee-Sponsored Alternative System may appeal directly to the Secretary of the Health and Human Services (HHS), in accordance with the OPTN Final Rule, 42 CFR § 121.4 (OPTN policies: Secretarial review and appeals).~~

**~~NOTE: Policy 3.4.10.6 (Appealing A Decision on A Committee Sponsored Alternative System) shall be effective following notice to the membership. (Approved at the June 21-22, 2010 Board of Directors Meeting.)~~**

*No further changes to this policy*

**3.5.6.1** Local Allocation. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to local candidates within the local unit as defined in Policy 3.1.7 ~~the locale where the kidneys are procured.~~

*No further changes to this policy*

### **3.6 ALLOCATION OF LIVERS.**

Unless otherwise approved according to ~~Policy 3.8 (Variances)~~ Policies ~~3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances), Policy 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates),~~ the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgment for the benefit of liver transplant candidates as a group, each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease

(PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Candidates will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

*No further changes to Policy 3.6.*

### **3.7.1 Exceptions.**

Unless otherwise approved according to Policy 3.8 (Variances) ~~Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments (Variances)), and 3.4.6 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems)~~, or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

*No further changes to Policy 3.7.1*

## **Reader friendly version of proposed policy changes:**

*Please note that this version contains only the retained language and new language (underlined). Please refer to the earlier version to see the deleted language displayed with strikethroughs.*

- 3.1.7 Alternative Allocation System.** A type of variance that allows Members to allocate organs differently than the OPTN policies.
- 3.1.8 Variances.** An experimental policy that tests methods of improving allocation.
- 3.1.9 Open and Closed Variances.** An open variance is a variance that allows other Members to join it. A closed variance is a variance that is not open for other Members to join it.
- 3.1.10 Local and Alternative Local Unit (ALU).** A local unit is the geographic area for organ procurement and distribution. An alternative local unit is a type of variance that creates a distinct geographic area for organ procurement and distribution
- 3.1.11 Sharing Arrangement.** A type of variance that permits two or more OPOs to share organs.
- 3.1.12 Alternative Point Assignment Systems.** A type of variance that permits Members to assign points differently than the OPTN policies.

*No further changes to 3.1 (Definitions)*

### **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 Appendix C 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. However, if the application to join an existing open variance does not receive affirmative support from all of the Members required to join by the application,

the OPTN contractor may not approve the application and 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

**3.4.10.1.1** Reserved

*No further changes to this policy*

**3.5.6.1 Local Allocation.** With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to ~~local~~ candidates within the local unit as defined in Policy 3.1.7 the locale where the kidneys are procured.

*No further changes to this policy*

### **3.6 ALLOCATION OF LIVERS.**

Unless otherwise approved according to Policy 3.8 (Variances), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgment for the benefit of liver transplant candidates as a group, each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Candidates will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

*No further changes to Policy 3.6.*

### **3.7.1 Exceptions.**

Unless otherwise approved according to Policy 3.8 (Variances), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

*No further changes to Policy 3.7.1*