

Proposal to Improve the Variance Appeal Process

Affected Policy: 3.4 (*Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation*)

Sponsored by the Policy Oversight Committee (POC)

- **Summary**

A variance¹ is a policy experiment conducted by a member of the Organ Procurement and Transplantation Network (OPTN) to improve organ allocation. For ease in reading, this proposal uses the term “variance” to describe it and its types. A review of variance policies revealed that most are silent on the process for appealing decisions of the committee or Board of Directors. This proposal attends to this deficiency. As such, the proposed modifications describe how an OPTN member may appeal a variance decision, and the role of the relevant committee and POC in the appeal process.

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

- **Affected groups**

OPTN Members and the Public

¹OPTN Final Rule: [...] (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. [...]

Proposal to Improve the Variance Appeal Process

Affected Policy: 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation))

Sponsored by the POC

Summary and Goals of the Proposal:

A variance is a policy experiment conducted by a member of the OPTN to improve organ procurement and allocation. For ease in reading, this proposal uses the term “variance” to describe it and its types. A review of variance policies revealed that most are silent on the process for appealing decisions of the committee or Board of Directors. This proposal attends to this deficiency. As such, the proposed modifications describe how an OPTN member may appeal a variance decision, and the role of the relevant committee and POC in the appeal process.

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

Problem Statement:

Currently, only Policy 3.4.8.3 (Appeal to Secretary) states that a member may appeal a variance decision. This appeal clause is only in Policy 3.4.8 (Application, Review, Dissolution and Modification Processes for Variances), and not in the other two sections of Policy 3.4 (Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation) that discuss variances: 3.4.7 (Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems) and 3.4.9 (Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems). Additionally, none of these variance policies address if or how a member may appeal a committee’s decision on a variance.

The lack of a committee appeal process in Policies 3.4.7, 3.4.8, and 3.4.9, and the lack of language about appealing to the Secretary of HHS in Policies 3.4.7 and 3.4.9 has the potential to prevent consistency in how members appeal a variance, regardless of its type, and disregards the role of OPTN/UNOS committees in the appeal process.

Significance of the Proposal:

The proposed policy modifications set clear expectations of the member and the OPTN Contractor on the variance appeal process. These modifications will lead to variance evaluations that may result in improvements to the national organ allocation system.

NOTE: This proposal *does not alter the current status of a variance already approved by the Board of Directors.*

Strengths of the Proposed Policy Modifications

The proposed modifications introduce the committee appeal process for all variance types (Policies 3.4.7, 3.4.8, and 3.4.9), and describes the process for appealing to the Secretary of the HHS for an alternative organ distribution or allocation system (Policy 3.4.7) and committee-sponsored alternative

system (Policy 3.7.9). The modified appeal process aims to allow for consistency in how OPTN members appeal a variance, regardless of its type.

Weaknesses of the Proposed Policy Modifications

The institution of the committee appeal process may increase the work load of committees.

Intended Consequences of the Proposed Modifications

The proposed policy modifications will generate consistency in the variance appeal process. The proposed policy modifications set clear expectations of the member and the OPTN Contractor on the variance appeal process.

Unintended Consequences of the Proposed Modifications

Due to political concerns surrounding a variance, access to transplantation, equity in allocation, and other such reasons, the the appeal process may need to be reviewed in the future if it appears to limit access to transplantation or result in inequities.

History of the Development of the Policy Proposal:

The Health Resources and Services Administration (HRSA) has a contract with UNOS to administer the OPTN. One component of this contract, Task 2.f., reads:

[...]

“2.f. *The Contractor shall submit a plan (including time frames) for how it will review each policy representing a deviation to national allocation policy (including but not limited to alternative allocation systems, paybacks, alternative local units) to determine whether each deviation meets the requirements of Section 121.8 of the OPTN Final Rule. The plan will include:*

- *a timeline for completing the review (to be approximately 18 months),*
- *a description of the evaluation method to be used,*
- *an opportunity for review and input from HRSA regarding whether Final Rule requirements are met, and*
- *presentation of the results to appropriate OPTN committees, the POC, and the Board of Directors.*

The Contractor shall submit the alternative allocation system report to the Project Officer for approval (See Delivery Item 31).” [...]

As part of Task 2.f., beginning in 2005, UNOS catalogued each existing variance and its status (e.g., approved by the Board, implemented in UNetSM, 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 Kidney Transplantation Committee did not take part in this review as it was engaged in reviewing possible new national allocation systems that would

eliminate all kidney variances.) The effort in 2008 resulted in members voluntarily dissolving six variances.

As of March, 2009, the organ-specific committees had reviewed 80% of the liver, intestine, thoracic, and pancreas variances that were in existence (over 60). These committees reviewed these applications, submitted their decision on each application to the POC, which submitted its decision on each variance application to the Board of Directors. The Board of Directors' decision on each variance is in its meeting summaries², beginning in November, 2008. The Board voted in favor of dissolving two variances, and continuing eight variances. Four other variances require additional committee discussion.

To continue to enable a deliberate evaluation of each existing variance as well as a new variance, the logical, and contractually obligated, next step is the review of the variance policy language. This review took place in 2009.

The modifications proposed in this document do not change the intent of the variance policies, but do present new information, such as the committee appeal process.

Discussions in October, 2009 resulted in these modifications that included only the variance appeal process. UNOS staff incorporated the appeal modifications to enable consistency in how the OPTN/UNOS Committees and the Board of Directors evaluate each variance. UNOS staff and the POC will continue to evaluate the variance policies for improvement, and if there are modifications, submit them for public comment in the future.

The majority of the POC members voted in favor of the following resolution:

****RESOLVED**, that the proposed variance appeal modifications in Policy 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation) will be circulated for public comment.

Supporting Evidence:

The Board of Directors' assessment of existing variances for continuation in 2008 and 2009 identified the lack of the appeal process language in Policies 3.4.7 and 3.4.9, as well as the lack of language in all three policies (3.4.7, 3.4.8, and 3.4.9) that would enable the member to appeal to an OPTN/UNOS Committee – in addition to the Secretary of Health and Human Services (HHS).

The proposed modifications insert language about the appeal process wherever it is absent. The intent of these modifications is to instill parity in how each member appeals a variance.

Expected Adherence to OPTN Final Rule:

Depending on the type of variance continued or approved by the Board of Directors, current and proposed variances have the potential to achieve goals that include:

- Improving equity in the distribution of donor organs;
- Reducing geographic disparities in the allocation of donor organs;

²Click on the following link to read summaries of Board of Directors' meetings:
<http://optn.transplant.hrsa.gov/members/executiveSummary.asp>

- Reducing geographic disparities in the availability of donor organs;
- Improving candidate access to transplantation;
- Promoting equity in the organ allocation system; or,
- Studying methodology, for which there is no national consensus, e.g., organ availability, organ utilization, access to transplantation, listing practices, standardizing medical care of candidates, improve donor management, etc.

Plan for Evaluating the Proposal:

To monitor the effectiveness of the proposed modifications, the OPTN Contractor and the POC will review how members appeal variances, and will compare how this was done prior to the modifications and since. This evaluation will occur whenever members appeal a variance decision of the committee or Board of Directors.

Additional Data Collection:

The proposed modifications do not warrant additional data collection.

Expected Implementation Plan:

The proposed policy revisions will be in effect upon approval by the Board of Directors and modifications to the UNetSM help documentation.

Communication and Education Plan:

If the Board of Directors approves the proposed modifications, Table 1 lists related communication efforts.

Table 1

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

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 underlined and struck-through (~~example~~). Some of the deleted language was relocated.

- 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.

[There are no changes to Policies 3.4.1 through 3.4.6.]

- 3.4.7 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.

- 3.4.7.1 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.

3.4.7.2 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 UNetSM) 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.

3.4.7.3 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 UNetSM. 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.

3.4.7.4 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.

3.4.7.5 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

3.4.7.6 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).

3.4.8 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.

3.4.8.1 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 UNetSM 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.

3.4.8.2 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 UNetSM) 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.

3.4.8.3 ~~Appealing A Variance Decision to Secretary.~~ 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).

3.4.8.4 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 UNetSM. 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.

3.4.8.5 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.

3.4.9 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.

3.4.9.1 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 UNetSM. 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 UNetSM. 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.

3.4.9.2 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.

3.4.9.3 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 UNetSM.

3.4.9.4 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.

3.4.9.5 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.

3.4.9.6 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).

[There are no further changes to Policy 3.4.]