

**OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
June 25-26, 2012
Richmond, Virginia**

Summary

I. Action Items for Board Consideration

- The Board is asked to consider extensive modifications to the policies to clarify and improve variance policies by making it easier for members to comply with variance policies; enable the OPTN to evaluate the variance for potential national policy; create uniformity; and promote reliability in the information provided with variance applications. (Item 1, Page 2)

II. Other Significant Items

- Review of 2012-2013 Committee Projects (Item 2, Page 17)
- Policy Rewrite Project Update (Item 3, Page 19)

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Stuart C. Sweet, MD, PhD, Chair

This report represents the deliberations and recommendations of the Policy Oversight Committee during its February 6, 2012 conference call and its April 9, 2012 meeting in Chicago, Illinois.

1. Proposal to Clarify and Improve Variance Policies The POC reviewed the comments received on this proposal that was distributed for public comment on September 16, 2011. The goals of the proposed modifications are to make it easier for members to comply with the variance policies; enable the OPTN 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. The proposed modifications include:

- 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.

The Committee considered all public comments received on the proposal at its April 9, 2012 meeting. Overall, there was strong public, regional, and other committee support for the proposal. Additional information about the proposal and responses to the comments can be found in **(Exhibit A)**.

The Resource Assessment and Impact Statement for this proposal is provided as **(Exhibit B)**.

The Committee recommends that the proposed policy language be considered by the Board. Committee vote: 11 in favor, 0 opposed, and 0 abstentions.

**** RESOLVED, that modifications to the following policies as set forth below, are hereby approved, effective pending notice to the members:**

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

3.4.8.3 Reporting Requirements

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

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

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

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

3.4.8.4 Final Evaluation

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

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

3.4.8.5 Terminating Variances

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

3.4.8.6 Appeals

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

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

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

3.4.9 Reserved

3.4.10 Reserved

~~3.4.8 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 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.~~

3.4.8.3 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~~

~~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.~~

~~**3.4.8.4 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 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.

3.4.9.2 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 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.

3.4.9.3 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 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.

~~3.4.9.5 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 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.~~

~~**3.4.10.2 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 UNetSM.~~

~~**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

- 2. Review of 2012-2013 Committee Projects.** The POC reviewed 41 proposed new committee projects and 74 ongoing committee projects. This process was created in November 2010 by the Board of Directors because OPTN leadership recognized the need to oversee the work of the committees, set

priorities, and establish work plans for each year. There were some modifications made to the process based on feedback from the initial review in 2011. This included changes to the new project form to better align with the POC scorecard as well as the creation of an ongoing project form and liaison profile form. Committee liaisons were instructed to work with their committee leadership to complete project forms for both new and ongoing committee projects in preparation for POC review.

Both new and ongoing projects were divided among three groups consisting of six POC members. New projects were scored using the modified scorecard (**Exhibit C**). Ongoing projects were simply scored yes or no to support continuing work on the project. Following review by the POC members, UNOS staff collated all the scores and comments in preparation for the meeting. Committee leadership reviewed the scores and comments and created a consent agenda and discussion agenda. The POC approved the consent agenda by a vote of 13 in favor, 0 opposed, and 0 abstentions. It was noted that the comments from the project reviewers will be forwarded to the liaison/committee. More information about the projects, scores, and comments can be found in (**Exhibit D**).

Following the review of the projects the POC discussed the current process and ways to improve it. Some of the recommendations include:

- Provide more information on the project forms about the frequency of the problem. It was noted that it might be difficult to estimate these numbers but whatever information could be provided would be very helpful during the review and prioritize the projects. It was noted that this information should be included in the scorecard as well.
- Provide committees with clear direction about what is within the purview of the OPTN. For example, if educational issues are needed then what organization is responsible for developing them. It was noted that there is an increased focus on education and the Professional Services Department is expanding to meet those needs.
- Items that have already been approved by the Board or are required by policy should not require review by the POC.
- Committees should prioritize their work for the upcoming year so the POC and Executive Committee can make an informed decision about the projects. This includes new and ongoing committee projects.

It was noted that there needs to be some guidance about how much data and information gathering a committee should be allowed to do before an idea becomes a project proposal. The POC and Executive Committee need a certain level of information in order to make a decision so a recommendation was made to allow Policy Department leadership to approve this initial work and once it meets a certain threshold then it will need to be submitted as a project proposal.

It was noted that the project review process has improved greatly since the initial reviews in 2011. An important aspect being that incoming committee chairs have been actively involved in this process and see the importance of working with the liaisons to outline the committee work for the upcoming year. It was noted that one of the main things that has improved is the early recognition of overlap in work and the need to collaborate with other committees. The POC discussed the scorecard and whether additional changes need to be made, including changes to the scoring system. It was noted that while the scores are important, the questions outlined in the scorecard really direct the reviewers to think about the overarching goals of the organization and how the projects fit within those goals.

While the POC approved all the ongoing projects, it was noted by some members that it was difficult to review the ongoing projects and look at the details that were provided. A suggestion was made that

committees should simply provide a concise summary of the project and note if there have been any changes to the project scope, timeline, resource estimates, or if new barriers have been encountered. It was noted that review of ongoing projects might become more important if a project continues for several years because the resource allocation may have changed. Another question was raised about how to handle a project where the estimated liaison and research time is exceeded. A suggestion was made to include that in the screening process and determine if projects that have not exceeded their original resource estimates need to undergo POC review. Additionally, if projects have exceeded their resource estimate then a project update should be provided. Finally, projects that have not made any progress should probably be evaluated to determine if they really need to be done.

- 3. Policy Rewrite Project** The POC was provided with an update on the policy rewrite project. The project is still on schedule for a special public comment from July through August 2012. Following public comment and final review by the POC, the rewritten policies will be submitted to the Board of Directors for approval in November 2012 and if approved will be effective on February 1, 2013. It was noted that all the policies have been drafted and are undergoing final internal reviews. One exception being the multi-organ allocation policies because it was determined there is a need for a separate multi-organ allocation policy instead of having this information located throughout different policies. It was also noted that the thoracic policy is being divided into separate heart and lung policies. Lastly, the histocompatibility information is being consolidated into one policy since it currently exists within both the bylaws and several appendices of the policies.

The POC discussed the issue of items located in the “parking lot.” These items are policies that are vague and inconsistent, therefore potentially requiring substantive changes to policy and are outside the scope of this project. It was noted that there are currently over one-hundred items in the parking lot with most being the words should, verify, and review. An example given was if there is a requirement in policy to review something there should be an explanation about the standards, the reason for the review, and what will happen with the review. Some committees interpret “review” to mean approve whereas others interpret it to mean discuss or analyze. The plan is to send the parking lot items to the appropriate committees for review and consideration. It could be that something listed as a “should” in policy might become a guidance document or educational material or possibly a “must.”

The POC recommended that the list of parking lot items be distributed to the relevant committees along with any historical information and Department of Evaluation and Quality (DEQ) observation of program practices. This initial work can serve as a basis for the committee discussions and provide them with some options. It was noted that for the bylaws rewrite the MPSC got the entire draft and were given the opportunity to review it similar to the way the individual reviews were done. This was done as a final check to make sure none of the intent was changed and then a conference call was held for final discussion and changes. It was also noted that for the rewrite public comments a special website has been developed where the policies would be divided up in chapters so those interested in certain sections can more easily review them. There will also be one compiled document so people can see what the final document will look like.

- 4. Transplantation of Non-Resident Aliens** The POC reviewed the proposed revisions to Policy 6.0 (Transplantation of Non-Resident Aliens), which include changes to the non-resident alien transplant audit trigger policy and related definitions. The POC had previously reviewed this proposal prior to public comment and requested an update about the proposal. There were discussions about how the Ad Hoc International Relations Committee was going to review certain information and it was noted that the proposed policy language clearly outlines the process. The POC voted to support this proposal by a vote of 11 in favor, 0 opposed, and 0 abstentions.

5. **Policy Conflicts** The POC discussed the issue of committees being asked to make decisions about conflicting or ambiguous policies. The POC discussed setting up a framework for addressing those decisions in the short term and long term. It was noted that it is important to distinguish between policies that are unclear and policies that are in conflict. An example of this occurred when the Thoracic Organ Transplantation Committee received a request to reinstate waiting time for a second transplant following graft failure. The thoracic policy clearly restricts this however the policy addressing waiting time modifications does not specifically address thoracic candidates which led to some confusion. The Thoracic Organ Transplantation Committee recommended clarifying the policy so they would not have to review a similar case in the future, however before that could be done another request was submitted. It is noted that waiting time modifications are allowed under certain circumstances for kidney, pancreas, and liver candidates. This raised the question about whether there should be consistency across all organs unless there is a biological reason that prevents it. Because there are different rules for the various organs, the rewrite project has put them together so the differences are clearly displayed in the policy. The POC should take the opportunity to look at these issues across the board and determine if there is a broader principle that should apply to all organs.

It was noted that it is impossible to write policies that cover every situation; therefore, there needs to be a process in place to deal with situations as they come up. The POC can help provide some guidance to the committees based on the best assessment of historical perspectives and broad representation. Additionally, the POC could consider issues where there are ambiguities or conflict and develop interpretive guidance and the Executive Committee and Board of Directors can use the information to recommend particular actions to the committees such as policy changes. Additionally, once a precedent has been set that decision can guide the committees if similar issues come up in the future. The question was raised about how to handle situations where a committee has resolved the issue on its own. It was noted that it is important for the POC to be aware of these in case they apply to other organs and to provide the POC with the opportunity to review the committee decision.

It was determined that the POC's role would be to help facilitate the initial review of the issue, gather information, and provide recommendations to the Executive Committee. The Executive Committee could serve as the second level of oversight in the process and provide some authority to the recommendation to the committee to take action within a recommended timeline. The role of the POC is addressed in the bylaws and a recommendation was made to review the language and consider changes based on the new direction of the POC.

6. **Update from the PSR Consensus Conference** The POC was provided with an update from this consensus conference that was held in February 2012. A summary of the meeting is included in **(Exhibit E)**. The SRTR noted that they are proceeding with the recommendations that came out of the conference. The SRTR Technical Advisory Group (STAC) has met and reviewed many of the technical issues and has created a list of priorities. The SRTR is interested in getting the POC involved as those goals and objectives move forward once they are approved by HRSA. The STAC did suggest the idea of looking at the PSR models less frequently but more thoroughly. For example, every three years a thorough review can be done where there is interaction with the committees and get their input on whether the variables still make sense. It was noted that just because a particular covariate statistically correlates with the outcome does not necessarily mean it is the best covariate to have in the model. So the plan is to work closely with the committees to answer those questions, especially on variables that are borderline as far as being included in the models. The SRTR would schedule the reviews so they are not being done at the same time and they would like to work with HRSA, the OPTN, and the POC on how to structure the reviews and develop a timeline.

Other recommendations include determining what to collect and what not to collect, especially for the purpose of risk prediction in the PSR models. There was agreement that this is important but no

determination has been made about how to manage this operationally but the POC should be included in those discussions. Other items that were discussed include:

- *Accurate and consistent data* – There needs to be a determination about whether certain data elements are informative or need to be removed or modified. This discussion will happen with each iteration of the PSR but would benefit from a global review of data that are collected on all forms, not just the organ-specific components. Another aspect of this is data collection and entry and the need to get feedback from coordinators and data entry staff about the difficulties of gathering data. While defining definitions and source documentation may happen independently of the other processes, there may be value in understanding the issues.
- *Adding additional data elements* – There should be a process in place to determine when additional data elements should be added. There should be an evidence-based process to ensure the data are informative and provide improved risk stratification. This is an issue where the POC can provide assistance to the SRTR and STAC.
- *Unknowns* – There is continued concern about the number of unknowns being submitted on the data forms. It was noted that one part of the review process could be to look at the frequency of unknowns for each data element and if they meet a certain threshold then more investigation can occur about why this is happening, potential solutions which could include no longer collecting that data element.

The POC will be actively involved in this process as it moves forward. It was suggested that it might be beneficial to form a subgroup of the POC to provide oversight to move the process along. It was noted that it might also be helpful to seek advice from experts in other systems as we work through the data elements to make evidence-based decisions.

7. **Multi-Organ Allocation Policies** The POC has been working on this issue for a year and has recently sent a memo (**Exhibit F**) to the organ-specific committee requesting feedback. It was noted that the Liver and Intestinal Organ Transplantation Committee has reviewed the memo and formed a subcommittee. There has been an increase in the number of combined liver-heart candidates/transplants. Additionally, there have been two consensus conferences about liver-kidney transplants with recommendations but no formal policies. This is an important ongoing project that not only has allocation implications but also procurement and waitlist management implications. The Histocompatibility Committee discussed the issue and noted that it is important to consider the histocompatibility issues in multi-organ transplants because it involves more than one organ that is at risk for rejection instead of just one. An example is that for liver transplantation most programs do not perform HLA testing because the liver is usually resistant to antibody-mediated damage. However, when you involve the liver and another organ there can be rejection and graft loss when there are HLA antibodies and this can sometimes be overlooked in the transplant setting.
8. **Data Release Proposal** The POC reviewed the regional slides in preparation for the upcoming regional meetings. There is still some concern about the implications of this proposal when it comes to releasing more data to any requestor. Currently you can get the number of transplants for any center by organ, size of the waiting list, outcome data from the SRTR and other information. There was some concern about certain information like turn down data, acceptance of marginal kidneys, and import data. It was noted that there is a separate process that requires the requester to go through a patient-identified process which includes signing a data use agreement, however it would not prohibit the requestor from then releasing an analysis by institution. The question was raised about whether there are potential HIPAA¹ concerns. It was noted that the data use agreement contains a HIPAA

¹ The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

disclosure. The SRTR noted that they have been releasing center-specific data for a long time and the policy has always been to protect patients not centers. They have strict rules about the cell size in an effort to reduce the potential for identifying individual patients. It was noted that if more detailed data is released there is the potential to identify patients, especially in small volume centers.

There was a suggestion made to expand the data use agreement to include any data that could potentially identify patients. UNOS Research staff noted that it has been discussed but would be difficult to do operationally with data on the website. Requiring a data use agreement for every transaction might present a barrier which is different than requiring a research plan for every transaction. There was concern about finding a balance between transparency and providing as much information as possible without hindering what people want to know. It was suggested that the OPTN consider requiring a basic agreement so there is some expectation about how individuals are going to use the information. This could be done with a simple electronic acknowledgement that is part of the requesting process. The POC will continue to monitor the public comments being received on this proposal and will review and respond to all comments following the close of the public comment period.

9. **Review of Public Comment Proposals** During its February 6, 2012 conference call, the POC reviewed draft policy proposals that will be distributed for public comment on March 16, 2012.

- **Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Donor** (*Living Donor Committee*)

The POC supported this proposal but expressed a few concerns about what type of events would be reportable and within what timeframe. It was noted that the intent of this proposal is to encourage the reporting of potential disease transmissions. It was also noted that this proposal is to address “unexpected or proven disease transmissions” and the most recent version of the proposal has an appendix that lists some examples. Additionally, this proposal is intended to enhance patient safety and generate some data for future policy development. The POC agreed that the requirements should be clearer about what is expected and what is unexpected in order to monitor them. As currently written it creates a level of ambiguity for DEQ. The POC recommended moving this forward and allowing the dialogue to continue through public comment.

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.6
Proposed Solution	1.8
Target Population Impact	0.6
Project Plan/Collaboration	2.0
Cost/Benefit	1.6

Weight: 1.8 (13.68 total score)

- **Improvements to Vessel Disposition Reporting** (*Operations and Safety Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.6
Proposed Solution	1.4
Target Population Impact	1.2
Project Plan/Collaboration	1.6
Cost/Benefit	1.6

Weight: 1.8 (11.84 total score)

- **Proposed to Require Documentation of Second Unique Identifier** (*OPO Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.4
Proposed Solution	1.4
Target Population Impact	1.0
Project Plan/Collaboration	1.8
Cost/Benefit	1.2

Weight: 1.8 (12.24 total score)

- **DCD Model Elements** (*OPO Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.6
Proposed Solution	1.6
Target Population Impact	1.2
Project Plan/Collaboration	1.8
Cost/Benefit	1.2

Weight: 1.6 (11.84 total score)

- **Proposal to Revise Lung Allocation Score** (*Thoracic Organ Transplantation Committee*)

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	1.8
Target Population Impact	2.0

Project Plan/Collaboration	2.0
Cost/Benefit	1.8

Weight: 1.8 (17.28 total score)

- **Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on “HCC Hold” Without Loss of Accumulated MELD Exception Score** (*Liver and Intestinal Organ Transplantation Committee*)

The POC had some concerns about this proposal including not making this a requirement. It was noted that this proposal is intended to initiate volunteerism because the liver transplant community recognizes the issues with HCC candidates. It is difficult to fully understand the biologic behavior of some of the HCC tumors and how they will respond to treatment. This change will allow transplant centers to put patients on “HCC hold” while they evaluate the response to treatment instead of allowing them to accumulate points. The POC acknowledged that this is a reasonable first step, especially if the liver community supports it.

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.9
Proposed Solution	1.9
Target Population Impact	1.4
Project Plan/Collaboration	2.0
Cost/Benefit	1.6

Weight: 2.0 (17.4 total score)

- **Proposal to Clarify Priority Status for Prior Living Organ Donors Who Later Require a Kidney Transplant** (*Kidney Transplantation Committee*)

One POC member questioned whether 4 points was enough or did the adjustment need to be higher? It was acknowledged that this was a separate issue but the POC could provide that feedback to the Kidney Committee.

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.1
Proposed Solution	2.0
Target Population Impact	1.1
Project Plan/Collaboration	2.0
Cost/Benefit	2.0

Weight: 1.9 (15.77 total score)

- **Interim Policy for KPD** (*Kidney Transplantation Committee*)

It was noted that this is a good step forward and will probably be revised in the future based on recommendations from the upcoming consensus conference scheduled for March 2012.

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	2.0
Proposed Solution	2.0
Target Population Impact	1.9
Project Plan/Collaboration	1.9
Cost/Benefit	2.0

Weight: 2.0 (19.4 total score)

- **Open Chains and Bridge Donors Being Included in the KPD Pilot Program** (*Kidney Transplantation Committee*)

There was some concern about not including this proposal in the KPD interim policy proposal. However, it was noted that open chains and bridge donors are not currently in the guidelines and since it is a deviation from current practice and potentially more controversial, the Kidney Committee did not want to hold up the KPD interim policy in case there is negative response to this proposal.

The POC supported this proposal moving forward to public comment. POC vote: 13 in favor, 0 opposed, and 0 abstentions.

Scoring Category	Average
Significance of Problem/Quality of Supporting Data	1.9
Proposed Solution	2.0
Target Population Impact	1.7
Project Plan/Collaboration	1.9
Cost/Benefit	1.7

Weight: 2.0 (18.2 total score)

Attendance

Name	Position	Feb. 6	April 9
Stuart C. Sweet, MD, PhD	Committee Chairman	X	X
Carl L. Berg, MD	Committee Vice-Chairman	X	X
Jonathon A. Fridell, MD	At Large	X	X
Kristie A. Lemmon, MBA	At Large		X
Richard N. Formica, MD	At Large	X	X
Tim Shain	At Large		
Hueng Bae Kim, MD	At Large	X	X
Meelie A. DebRoy, MD	At Large	X	
David Mulligan, MD	At Large	X	Phone
Richard E. Pietroski, MS, CPTC	At Large	X	
Amy Waterman, PhD	At Large	X	X
Steven Webber, MBChB	At Large	X	
Nancy Metzler	At Large	X	
Lee Ann Baxter-Lowe, PhD, ABHI	At Large	X	X
Jean A. Davis	At Large	X	X
Laurie Williams, RN, BSN, CPTC	At Large	X	X
Peter Reese, MD	At Large		Phone
Michael D. Green, MD, MPH	At Large	X	
Christopher McLaughlin	HRSA	X	
Robert Walsh	HRSA	X	Phone
Monica Lin	HRSA		X
Ba Lin	HRSA		X
Bertram L. Kasiske, MD, FACP	SRTR	X	X
Jon Snyder, PhD, MS	SRTR	X	
Tabitha Leighton	SRTR	X	X
Robert Hunter	UNOS, Committee Liaison	X	X
Brian Shepard	UNOS, Director of Policy		X
Erick Edwards, PhD	UNOS, Assistant Director of Research	X	X
Ciara Samana	UNOS, Assistant Director of Policy		X
Lori Gore	UNOS, Histocompatibility Committee Liaison		X
Vipra Ghimire	UNOS, Thoracic Committee, AHIR Committee Liaison		X
Ann Harper	UNOS, Liver-Intestine Committee Liaison		X
Lee Bolton	UNOS, Living Donor Committee Liaison		X