

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

BYLAWS

APPENDIX C

APPENDIX C TO BYLAWS OPTN

ADOPTION OF POLICIES AND STANDARDS

- 1.01C Board of Directors.** The Board of Directors is responsible for developing and implementing, with the advice of the OPTN membership and other interested parties, policies and standards within the mission of the OPTN. The process for this effort is depicted in Figure C-1 and described in the following sections.
- 1.02C Formulation.** Proposals for new or modifications to existing policies or standards are developed by or submitted to one or more of the Committees, as defined in Article VII of the Bylaws. Proposals may be forwarded by any interested party directly to the Committee Chair or through the President or other Principal Officer or their respective representatives. Proposals may be distributed to one or more Committees as appropriate. Data, analyses, and other information deemed relevant by the reviewing Committee(s) to assess the merits and disadvantages of proposals shall be provided by the organizations awarded contracts to operate the OPTN and Scientific Registry of Transplant Recipients (SRTR) by the Health Resources and Services Administration (HRSA), within the Department of Health and Human Services (HHS), and pursuant to these contracts. In developing allocation policy, such data (stratified by appropriate and feasible geographic units) shall include effect on transplant programs that perform different transplant volumes, inter-transplant program organ-specific analyses, risk-adjusted total life-years pre- and post-transplant, risk-adjusted post-transplant patient and graft survival rates, risk-adjusted waiting time, risk-adjusted transplantation rates, performance of OPOs, performance of the OPTN contractor, and/or other data determined to be appropriate by the reviewing Committee(s). An intent is to select performance indicators to measure the effect of the proposal, using baseline data to indicate how the current policy is performing and projected data to estimate results from the policy proposal. Review of such information may result in additional questions and the need for further study and analysis, dismissal of the proposal, or formulation of a proposal that is approved by the Committee.
- 1.03C Evaluation.** Prior to submission of a policy proposal to the Board of Directors for consideration, proposals shall be distributed for public comment. Exceptions to this general rule include: matters that require immediate action due to patient health and safety factors, proposals that clarify or correct existing policy rather than substantively change policy, and proposals that are otherwise administrative versus substantive in nature. The period for public comment shall be 45 days or such lesser period as may be appropriate in light of relevant time constraints or other intervening events, while continuing to provide realistic opportunity to receive and reply to the information. Proposals issued for public comment shall be distributed via posting to the OPTN Internet Website, www.OPTN.org, and/or mailing to a list of individuals including all OPTN Members and interested persons who request to be placed on the list. Public comment proposals also shall be distributed for discussion at meetings of the Regions, as defined in Article 2.4 of the Bylaws, and interested Committees, as feasible.

Proposals issued for public comment are accompanied by briefing papers that provide historical information and rationale to help explain the intent and function of the proposal and issues that were considered in developing the proposal, as well as the actual policy proposal itself. Proposals addressing allocation policy shall specify to which organ or combination of organ types the policy is applicable and provide an executive summary summarizing the policy rationale and how the proposal meets requirements of the OPTN Final Rule, 42 CFR Part 121. Attachment I to this Appendix C provides guidance for issues that may be addressed by the reviewing Committee(s) and included in policy briefing papers as appropriate.

In the deliberation of policy proposals, Committees shall consider whether to recommend them to be mandatory, *i.e.*, designated by the Secretary of HHS as covered by Section 1138 of the Social Security Act; voluntary, *i.e.*, not designated by the Secretary as covered by Section 1138 of the Social Security Act; or adopted into HHS regulation. The Board of Directors makes the final determination regarding any recommendation to the Secretary to make a policy mandatory. Recommendations from the Board to make a policy mandatory must be approved by the Secretary or the policy remains voluntary. Voluntary OPTN policies may supplement, but should not conflict with the administration of or contradict mandatory OPTN

policies. Policies recommended for adoption into HHS regulation might include those deemed relevant and necessary for the appropriate administration of other programs related to organ procurement and transplantation within HHS. No OPTN policy will be subject to the enforcement actions specified for mandatory policies until approved by the Secretary of HHS. Compliance with OPTN policies determined to be voluntary shall be monitored by the OPTN and pursued in accordance with Appendix A of the OPTN Bylaws.

Public comments received by the close of the public comment period shall be reviewed and responded to by the reviewing Committee(s). Comments received after the response deadline may be reviewed and responded to at the discretion of the Chair(s) of the reviewing Committee(s). Following consideration of the comments and any additional information requested by the Committee(s), the Committee(s) shall make any modifications to the proposal deemed appropriate, including dismissal of the proposal for further consideration. The policy briefing paper shall be updated to include responses to the public comments and the final proposal.

1.04C Adoption. Recommendations for new or modifications to existing policy shall be offered to the Board of Directors for deliberation and action. The Board of Directors may approve the recommendation without amendment, approve the recommendation with amendment, disapprove the recommendation, refer the recommendation back to the reviewing Committee(s) or to other Committees or sources for additional consideration, or take such other action as the Board deems appropriate. Such recommendations also may be considered and acted upon by the Executive Committee in the interim between meetings of the Board of Directors and on behalf of the Board subject to final determinations by the full Board.

- (i) Policies approved by the Board of Directors with or without amendment and recommended to be enforced as mandatory policies or otherwise directed for submission to the Secretary of HHS shall be forwarded to the Secretary for review and comment in accordance with Section 121.4(b)(2) of the OPTN Final Rule and at least 60 days prior to their proposed implementation. The Secretary may solicit guidance from the Secretary's Advisory Committee on Organ Transplantation in accordance with the OPTN Final Rule. Policy documentation shall include the background information and rationale used in developing the proposal (updated as may be necessary to reflect additional deliberations of the Board of Directors). Depending upon the results of the Secretary's review and action, such policies may be referred back to the Board of Directors and/or reviewing Committee(s) for additional deliberation and recommendations in accordance with the Secretary's direction or implemented in accordance with the implementation procedures described below.
- (ii) Policies approved by the Board of Directors with or without amendment and recommended for voluntary status without direction otherwise from the Secretary shall be implemented in accordance with the implementation procedures described below.
- (iii) Proposals disapproved by the Board of Directors or referred for additional input shall be forwarded to the appropriate Committee(s) or other source as indicated by the Board's action.

1.05C Implementation. Policies finally approved by the Board of Directors as voluntary or by the Board of Directors and Secretary to be enforceable as mandatory shall be implemented pending incorporation into the UNetsm computer allocation and matching algorithm, as necessary, and appropriate notice to OPTN Members and the Secretary of the new or modified policy using, for example, mailings, newsletters, or the Internet. Such policies also shall be posted to the OPTN Internet web site, www.optn.org.

1.06C Post Implementation Assessment. OPTN policies shall be re-evaluated periodically by the applicable reviewing Committees using measures established by the Committees in an effort to assess whether they are meeting stated objectives and in light of applicable scientific and technological advances. Depending on the outcomes of these assessments, proposals for additional policies or further modifications to existing policies may be formulated consistent with Section 1.02C above.

1.07C Status of OPTN Policies. All policies of the OPTN presently are voluntary. The entity awarded the current OPTN Contract (OPTN Contractor) shall work through the appropriate reviewing Committees,

using the public comment process described in Section 1.03C above, as appropriate, to evaluate these OPTN policies, making recommendations for revisions or distinction as policies of particular application to the OPTN Contractor's operations rather than OPTN operations, if and as deemed necessary, and identifying those policies they would then suggest be: (i) recommended to the Secretary as mandatory OPTN policies, (ii) recommended to remain as voluntary OPTN policies, or (iii) recommended to the Secretary for adoption into HHS regulation. These deliberations and findings shall be submitted to the Board of Directors for consideration and action as the Board deems appropriate. The Board of Directors makes the final determination regarding any recommendation to the Secretary to make a policy mandatory.

**ATTACHMENT I
TO APPENDIX C OF THE OPTN BYLAWS**

The following are guidelines for issues to consider in developing OPTN organ allocation policies:

1. Listing and de-listing criteria used in the proposal, including medical bases and analyses used in their development.
2. Organ allocation system, including:
 - a. Categories for prioritizing transplant candidates, whether they are based on medical urgency or not, and their medical basis and supporting research and medical practice.
 - b. Geographic unit(s) used for allocating organs, addressing how criteria such as place of patient residence or place of listing are attempted to be overcome by geographic allocation unit definition, in light of considerations including, for example, organ ischemic time, logistical matters, availability of specialized transplant and post-transplant care, and other constraints that result from available medical science.
 - c. Overall allocation protocol, demonstrating how organs are allocated according to degrees of medical urgency or other relevant categories within appropriate geographic unit(s) consistent with the following factors (if not sufficiently addressed in other sections): sound medical judgement, best use of donated organs, preservation of physician judgement in declining organ offers or use for the potential recipient, suitability for the specific organ or combination of organs, avoidance of organ wastage and futile transplants and promotion of patient access to transplantation and efficient management of organ placement, periodic review and revision as appropriate, and disassociation with candidate's place of residence or place of listing as feasible in light of the previously listed elements.
3. Considerations of access and socio-economic equity, including how the proposal addresses/reduces any ethnic barriers to transplantation, any disparities on the waiting list by ethnicity, pediatric patient access to transplantation, and any other barriers to transplantation such as those resulting from economic factors.
4. Review mechanisms to promote and assess policy compliance, including prospective review protocols, as appropriate, retrospective review protocols, educational measures, and appropriate actions that might be recommended to the Secretary of HHS in the event of non-compliance.
5. Transition provisions to address patients on the waiting list under the former policy and their equitable treatment under the policy proposal, including anticipated impact of the proposal on these patients and preservation of their former priority, within reasonable limits and to the extent appropriate.
6. Performance indicators and evaluation components of the policy, including the performance indicators to be used to evaluate the policy's effect and their bases, the measure(s) for the performance indicators, baseline data for evaluating performance of the current policy using the indicators, projected data showing expected benefit from the proposal with respect to the performance indicators, and a plan for periodic review to assess effectiveness of the policy in achieving its goals.
7. Consideration for systems that test methods of improving organ allocation (variances), including an assessment of whether they are accompanied by a research design and include data collection and analysis plans and time limitations, standards/parameters for approving variances, and a determination of whether existing variances would be continued under the policy proposal.