

## Briefing Paper

# Appendix L Revisions

*OPTN/UNOS Membership and Professional Standards Committee*

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# Appendix L Revisions

<i>Affected Policies:</i>	<i>OPTN Bylaws Article 1.1 (Membership Guidelines), and Appendices A.1 (General Membership Requirements), A.2 (Designated Transplant Program Requirement), A.3 (Applying for Membership in the OPTN), B.1 (OPO Compliance), B.2 (OPO Performance Requirements), B.4 (Facilities and Services), B.5 (OPO Personnel), C.1 (Histocompatibility Laboratory Compliance), C.5 (Changes in Key Laboratory Personnel), C.6 (Histocompatibility Laboratory Policies and Procedures), D.1 (Transplant Hospital Compliance), D.2 (Geographic Requirements for Transplant Hospitals), D.8 (Changes in Key Transplant Program Personnel), D.10 (Investigation of Transplant Personnel), D.11 (Review of Transplant Program Functional Activity), D.12 (Additional Transplant Program Requirements), G.2 (Primary Pancreas Transplant Surgeon Requirements), G.3 (Primary Pancreas Transplant Physician Requirements), I.2 (Primary Lung Transplant Surgeon Requirements), I.3 (Primary Lung Transplant Physician Requirements), L (Reviews, Actions, and Due Process); Appendix M (Definitions)</i>
<i>Sponsoring Committee:</i>	<i>Membership and Professional Standards</i>
<i>Public Comment Period:</i>	<i>January 22, 2018 – March 23, 2018</i>

## Executive Summary

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when OPTN members fail to comply with OPTN Obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The current Bylaws require the MPSC to engage with members through predetermined steps and timelines. As a result, both the MPSC and the member are sometimes required to interact in ways that do not provide significant value. Additionally, the current Bylaws include conflicting requirements, lack consistent and sufficient detail, and are organized confusingly. The proposal improves the OPTN review process and describes the process in a way that is more detailed and easier for members to understand. With a focus on member improvement in response to noncompliance with OPTN obligations, the rewrite of Appendix L primarily supports the OPTN strategic goal of promoting living donor and transplant recipient safety.

## What problem will this proposal address?

Appendix L of the OPTN Bylaws details actions that the OPTN, through the Membership and Professional Standards Committee (MPSC) and Board of Directors, may take when OPTN members fail to comply with OPTN Obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The current Bylaws require the MPSC to engage with members through predetermined steps and timelines. As a result, the MPSC and the member are sometimes required to interact in ways that do not provide significant value. Additionally, the current Bylaws include conflicting requirements, lack consistent and sufficient detail, and are organized confusingly. The proposal improves the OPTN review process and describes the process in a way that is more detailed and easier for members to understand.

Examples of problems with the current Bylaws include:

1. Predetermined steps and timelines
2. Determining a possible action before offering the member an interview
3. Review processes described with inconsistent detail
4. Limited detail regarding MPSC inactivation requests

### 1. Predetermined steps and timelines

The Bylaws currently include three different pathways - Imminent Threat Review, Expedited Review, and Routine Review. The MPSC Chair determines the review pathway based on the urgency and severity of the issue, and the MPSC must follow the corresponding steps and timelines outlined in Appendix L. The rigidity of these review processes sometimes hinders the MPSC from conducting reviews in the most effective and improvement-focused manner.

The chart below summarizes the key steps and timing requirements for each review pathway currently in Appendix L.

**Table 1: Current Appendix L Review Pathways**

<b>Routine Review</b> <i>For all cases not determined to be Expedited or Imminent Threat Review</i>	<b>Expedited Review</b> <i>For potentially urgent/severe risks</i>	<b>Imminent Threat Review</b> <i>For urgent/severe risks</i>
Initial MPSC review within 6 months	Initial MPSC review within 42 days	Initial MPSC review within 21 days
Interview at next in-person MPSC meeting	Interview at next in-person MPSC meeting, at special in-person MPSC meeting or by conference call	Executive Committee of the Board of Directors review within 7 days, and may take action
Hearing with MPSC within 60 days	Hearing with MPSC within 60 days	Hearing with MPSC, Executive Committee or Board of Directors within 30 days
Member appearance at next Board of Directors meeting, final action	Member appearance before Board of Directors within 30 days, final action	Member appearance before Board of Directors within 30 days, final action

One example of problems with the rigidity of the current Bylaws pertains to interviews. The majority of interviews are conducted according to the Routine Review Pathway, and therefore must be conducted at the next in-person MPSC meeting. The Bylaws do not permit the MPSC to conduct an interview by conference call unless the matter is declared a potentially urgent and severe risk to patient health and public safety and therefore follows the Expedited Review Pathway. Members must use resources and spend time away from their organizations to travel to MPSC meetings in Chicago, Illinois, to participate in their interview. Because in-person MPSC meetings are typically scheduled months in advance, the MPSC cannot accommodate member requests to conduct the interview on an alternate date.

Under the current Bylaws, the MPSC is not permitted to offer a member a second interview. After an interview, if the member has not fully implemented its corrective actions and the MPSC wishes to

continue speaking with the member before determining an appropriate action, the Bylaws only permit the MPSC to offer the member a hearing. Hearings are formal proceedings that require significant resources from members, MPSC volunteers, and UNOS staff. For this reason, hearings should be reserved for when the issue warrants these resources. In many situations, the MPSC can gain sufficient insight through a less formal proceeding.

### 2. Determining a possible action before offering the member an interview

The current Bylaws require the MPSC to specify whether it is considering a Letter of Reprimand or an adverse action recommendation before the MPSC can offer a member an interview. After an interview, the MPSC is allowed to proceed with its initial recommendation or take a lesser action, but it cannot pursue a more severe action without restarting the review process and offering the member a new interview. As a result, and prior to much interaction with the member, the MPSC must determine the highest action it may take. The MPSC notifies the member of the action being considered prior to the interview, but often takes a lesser action after the interview. For example, from 2015 – 2017, the MPSC downgraded its recommendation after an interview almost 75 percent of the time. The MPSC believes operating in this manner is inefficient and likely causes the member undue stress and confusion.

### 3. Review processes described with inconsistent detail

The current Bylaws describe steps of the review process with inconsistent detail. For example, the Bylaws' description of hearings is considerably more detailed than what is provided for interviews, and even less detail is provided to describe member appearances before the Board of Directors.

### 4. Limited detail regarding MPSC inactivation requests

The current Bylaws outline the MPSC review process for transplant program functional activity and transplant program outcome reviews. In rare instances, the MPSC may recommend that the program inactivate or withdraw. This typically happens after a member has remained under review through a significant number of MPSC meetings and has not made sufficient improvement to increase their transplant activity or outcomes. While the Bylaws state that the MPSC may ask members to inactivate, the Bylaws do not clearly explain what members should expect before or after the MPSC makes such a request.

## **Why should you support this proposal?**

The proposal grants members new rights, improves the effectiveness and efficiency of OPTN reviews, and better organizes information so it is easier to read and understand. As a result, the OPTN will be better able to engage members in value-added, performance improvement-focused reviews. At the same time, the proposal allows the OPTN to continue to address potentially urgent or severe risks to patient health and public safety in a timely manner. The "How was this proposal developed?" section provides additional details regarding the examples below and other improvements.

Examples of improvements to member rights include:

- Allowing a member under review to request an informal discussion with the MPSC.
- Allowing the member to participate in an interview and hearing with the MPSC before the MPSC recommends the Board of Directors approve an adverse action. The member currently has no right to these interactions under the Imminent Threat Pathway.
- Allowing a member to be present during an MPSC presentation to the Board of Directors when the MPSC recommends that the Board of Directors take an adverse action.
- Reducing the amount of time members receiving an adverse action must wait before requesting release from 12 months to 9 months.

Examples of improvements to OPTN reviews include:

- Allowing the MPSC Chair to determine the scheduling details of MPSC informal discussions, interviews and hearings. This will allow the MPSC to conduct reviews as quickly as possible to address urgent and severe issues or grant members additional time to prepare for these interactions when appropriate.

- Expanding opportunities for the MPSC to offer a member Deferred Disposition to implement changes and demonstrate improvement.
- Allowing the Executive Committee of the Board of Directors to consider MPSC recommendations to release a member from an adverse action. This will allow for a more timely resolution of the recommendation, since the Executive Committee meets more frequently than the Board of Directors.

Examples of improvements to better organize and explain information include:

- Compiling all information related to the U.S. Secretary of Health and Human Services (HHS) in a single section.
- Replacing three different review pathways with a single review framework.
- Removing duplicative content.
- Providing consistent formatting and detail for informal discussions, interviews, hearings, and Board of Directors appearances.
- Providing consistent formatting and detail for the adverse actions of Probation and Member Not in Good Standing.

The proposal allows the OPTN to address urgent and severe risks to patient health and public safety by:

- Continuing to permit the MPSC Chair to ask members to take action to mitigate the urgency and severity of the risk.
- Providing more opportunities for the MPSC to speak directly with the member to obtain the necessary information before making a recommendation.
- Eliminating steps that take up time, such as requiring the Executive Committee to approve the review pathway.
- Allowing the Executive Committee to consider MPSC adverse action recommendations when an urgent and severe risk exists.

## How was this proposal developed?

OPTN reviews of member compliance with OPTN Obligations identified a number of unclear, and sometimes conflicting, requirements in Appendix L. In June 2016, the Executive Committee requested the MPSC initiate a project to correct these issues. The MPSC recognized this as an opportunity to not only make necessary corrections, but also to make substantial improvements to the MPSC review process. To develop the concepts and specific language included in this proposal, UNOS staff worked with a working group comprised of current MPSC members and the previous MPSC Chair and Vice Chair (who also currently serve on the Board of Directors), and with the full MPSC. Staff also conferred with HRSA representatives and the Executive Committee, and used surveys to obtain feedback from members who had recently participated in MPSC reviews on ways to improve the process. Staff and the MPSC working group routinely presented concepts to the MPSC for evaluation and approval.

At the beginning of the project, the MPSC had a number of goals. First, the MPSC wanted to correct conflicting requirements in the three review pathways, including specifying when and how to change review pathways at each step of the review process. Second, the MPSC wanted to provide as much detail as possible within the Bylaws about what to expect, including the timing, format and possible outcomes for each step of the process. Third, the MPSC wanted to increase flexibility to avoid forcing the MPSC and members to participate in unnecessary steps or steps that did not add sufficient value to the review process. Fourth, the MPSC wanted to ensure that the Bylaws will continue to allow the OPTN to address potentially urgent and severe risks to patient health and public safety in a timely manner. Lastly, the MPSC wanted to update its processes to promote positive MPSC and member interactions focused on process improvement.

The MPSC regularly discussed what amount of detail was necessary and appropriate in the proposal. On one hand, the MPSC wanted to provide specific and complete information so that members would know exactly what to expect. On the other hand, the MPSC wanted to avoid being too prescriptive, because requiring the MPSC to follow the same exact steps and timelines during every review process has

resulted in inefficient reviews. The MPSC found it difficult to simultaneously achieve both of these goals and determined that providing a framework to conduct more effective and efficient reviews would be more beneficial to members than including exhaustive detail. Rather than providing a step-by-step account of how every review will be conducted, the proposal provides enough information to explain the review framework. The MPSC felt strongly that the OPTN must provide additional resources to supplement member's understanding of the Bylaws and MPSC operations. This documentation will include resources such as frequently asked questions and "What to Expect" documents. Examples of these supplemental materials are provided as **Exhibit A** to this proposal. UNOS staff will work with the MPSC to routinely update these resources.

Similarly, the MPSC spent considerable time discussing the appropriate process to take quick action when an urgent and severe risk to patient health and public safety exists and the appropriate process to focus on member improvement rather than taking an official action. Because only a small number of cases involve urgent and severe risks to patient health and public safety, the MPSC ultimately made a conscious decision to develop the key processes with collaboration and member improvement as the primary objectives. Of course, the proposal still includes safeguards to allow the MPSC to address urgent and severe risks to patient health and public safety. However, the proposal does not carve out a separate process for these kinds of reviews as the current Bylaws do.

The final proposal incorporates many concepts and some language from the current Appendix L. Given the volume of changes, including format and organization, the proposal removes and replaces all of the current Appendix L. **Exhibit B** is a crosswalk that details whether and how current sections of Appendix L were incorporated into the proposal.

The changes in this proposal are described in detail in the sections listed below:

1. Replace three review pathways with a single review framework
2. Incorporate scheduling flexibility into the single review framework
3. Allow members under review to request an informal discussion
4. Allow the MPSC to offer multiple informal discussions and interviews
5. Allow the MPSC to offer an interview without considering an action
6. Allow the MPSC to more frequently offer Deferred Disposition
7. Require members to exhaust MPSC proceedings before appearing before the Board of Directors
8. Provide consistent formatting and detail for informal discussions, interviews, and hearings
9. Allow the Executive Committee of the Board of Directors to consider certain MPSC adverse action recommendations
10. Update the formatting and detail of appearances before the Board of Directors
11. Require the MPSC to offer an informal discussion before recommending a program inactivate or withdraw due to outcome or inactivity reviews
12. Require the MPSC to conduct informal discussions, interviews and hearings
13. Remove Letter of Reprimand as an OPTN Action
14. Clarify factors the MPSC uses to determine an appropriate action
15. Add Board of Directors discretion to Probation notification requirements
16. Reduce the length of time members must wait to request release from Probation or Member Not in Good Standing
17. Allow the Executive Committee of the Board of Directors to consider MPSC recommendations to release members from an adverse action
18. Update the definition of OPTN Obligations to include "acting to avoid risks to the health or safety of patients or the public"
19. Compile all information related to the U.S. Secretary of HHS in a single section
20. Costs and expenses
21. Corresponding changes to other Appendices

Additionally, **Exhibit C** is a draft guidance document that provides additional information about the proposal.

1. Replace three review pathways with a single review framework

The Bylaws currently include three pathways for conducting reviews - Imminent Threat Review, Expedited Review, and Routine Review. The intent of the current review pathways was to detail the steps and timing of the review process so that members knew what to expect. However, this rigidity sometimes hinders the MPSC from conducting reviews in the most effective manner. This proposal recommends condensing these three pathways to one review framework. The MPSC believes that this single framework can effectively balance accommodating members during a review while still maintaining the OPTN's ability to address urgent and severe risks to patient health and public safety in a timely manner.

The MPSC originally considered proposing two pathways - an Accelerated Review and a Routine Review. The Accelerated Review would be used for cases involving a potentially urgent or severe risk to patient health and public safety and would replace the Imminent Threat and Expedited Review pathways. The Routine Review would be used for all other cases. The goal of the current Imminent Threat Review and Expedited Reviews is to complete the MPSC review and determine the final appropriate action as quickly as possible. To achieve this goal, the Imminent Threat Review pathway does not afford a member any rights to interact with the MPSC before the MPSC recommends an adverse action. The MPSC believed this was not only unfair to members but also negatively impacted the MPSC's ability to thoroughly review the case details. The MPSC determined the goal of the Accelerated Review pathway should be to work with the member to sufficiently mitigate the potential risk as quickly as possible and then downgrade the review to a Routine Review, and that members under an Accelerated Review should still have the right to an interview, hearing, and Board appearance.

The MPSC believed at first that the process should still include a mechanism to notify the public of a potentially urgent and severe risk to patient health or public safety if the member refused to take requested steps to sufficiently mitigate the risk. As a result, the MPSC developed a process by which the OPTN – through the MPSC and Executive Committee – would distribute public notice of an ongoing investigation into a potentially urgent and severe risk that had not been mitigated. Members reviewed through this pathway would be given multiple opportunities to take sufficient mitigating action to address the risk. If a member took sufficient mitigating action, the MPSC would downgrade the review from an Accelerated to a Routine Review. If the member did not take sufficient mitigating action, the review would continue through the Accelerated Review Pathway, which included the possibility that the OPTN would distribute public notice to alert the public that the OPTN is in the midst of reviewing a potential risk to patient health and public safety, and prior to the member being afforded a hearing or an appearance before the Board of Directors.

The MPSC commented that the proposal should retain the current Bylaw provision that allows the review pathway to change as new information became available and the assessment of the urgency and severity of the risk changed. As a result, the MPSC spent significant time reviewing a process flow that detailed how an Accelerated Review would transition to a Routine Review and vice versa.

Based on its review, the MPSC determined that this approach had a number of problems. First, the process flow included too many options, and providing sufficient detail about each possible option meant that the language became difficult to understand. Second, while trying to consider the various scenarios in which a case may change review pathways, the MPSC acknowledged that there were likely to be unanticipated scenarios in the future that the proposal might not address. As a result, the MPSC concluded that including different review pathways and significant detail about each step of the pathway would unnecessarily result in a confusing document and an inefficient review process.

The MPSC also spent significant time discussing the public notice of an ongoing urgent and severe risk to patient health and public safety, including what rights the member should have before the notice was sent, what the release would say, and the potential consequences of the OPTN releasing such a statement. The MPSC noted that in almost all instances, members have taken action to mitigate the potential risk when asked. The MPSC believed the member should be entitled to interactions with the MPSC before the OPTN released any public notice. The MPSC also believed that the amount of information necessary to determine whether to recommend that the OPTN release a press release about

an ongoing investigation was very similar to the amount of information needed to determine an appropriate action. For these reasons, the MPSC determined the public notice of an ongoing investigation was not necessary and the OPTN should only issue a public notice when taking a final adverse action.

After the MPSC rejected the Accelerated Review and Routine Review approach, the MPSC focused its efforts on developing a single framework that would increase the effectiveness and efficiency of MPSC reviews, would be applicable to future unanticipated scenarios, and would allow the MPSC to address potentially urgent and severe risks in a timely manner. The MPSC agreed to keep the same review processes the MPSC currently utilizes (informal discussions, interviews, hearings and Board appearances) in the framework and worked to develop additional guidance around the purpose, timing, and format of each process.

### 2. Incorporate scheduling flexibility into the single review framework

The MPSC quickly agreed that the MPSC must continue to offer a member a hearing before recommending an adverse action to the Board of Directors and must offer a member at least one interview before offering a member a hearing. These member rights remain unchanged; however, the proposal includes a number of other changes to informal discussions, interviews, and hearings.

The MPSC acknowledged that members should be allowed to participate in interviews by teleconference in some instances, such as when an interview needs to happen quickly due to a potentially urgent and severe risk. In other instances, conducting interviews by conference call would allow the member to participate without having to spend time and resources away from their institution. However, the MPSC was unable to develop an exhaustive list of all future scenarios in which a teleconference interview should be permitted.

The MPSC considered a number of timeframes and discussed at great length how much notice a member should receive and when the review should take place. For example, the MPSC discussed when the MPSC must notify a member of the interview time and date, and when the interview must take place. The MPSC agreed that predetermined timelines for notice and scheduling are arbitrary and that the appropriate timeframes depend on too many factors to list all of them in the Bylaws. The MPSC considered using ranges, but ranges that covered the most likely scenarios were too wide to be relevant. The MPSC agreed that a better approach is to grant the MPSC Chair the flexibility to determine the time and format of the review, based on the following criteria:

- The urgency and severity of the issue
- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- Adequate time for members to demonstrate the results and sustainability of their containment and corrective action plans
- The MPSC's meeting schedule

### 3. Allow members under review to request an informal discussion

The proposal introduces a new option that allows members currently under MPSC review to request an informal discussion. The MPSC felt that members under review by the MPSC should be able to request dialogue with the MPSC while in the midst of developing, implementing, and evaluating corrective actions. It is important to highlight that the OPTN constantly monitors all members for compliance with OPTN Obligations, but not all members are under MPSC review. This provision only applies to members currently under review by the MPSC. This proposal stipulates that the MPSC Chair will decide within 14 days whether to accept the member's request, and the OPTN will notify the member of the Chair's decision. Although the MPSC intends to be responsive to members that request an informal discussion, the Committee had some concerns about receiving an abundance of requests, some of which may not be an effective use of the Committee's limited time. Therefore, the Bylaws include MPSC Chair discretion to accept or decline the member's informal discussion request.



4. Allow the MPSC to offer multiple informal discussions and interviews

Under the current Bylaws, the MPSC can only offer a member an interview if the MPSC is considering a certain action. After an interview, the MPSC's options are typically limited to offering the member a hearing or monitoring the member; the MPSC is not permitted to offer the member a second interview before taking an action. The proposal allows the MPSC to offer a member one or more interviews.

The current Bylaws are mostly silent on when and how often the MPSC may offer a member an informal discussion, particularly for a member that is already under MPSC review and may have had an interview. The proposal allows the MPSC to offer any member under review an informal discussion at any time.

Allowing the MPSC to request one or more informal discussions or interviews before taking an action will grant the member an opportunity to present new information to the MPSC. The MPSC believes it is important to provide the member with an opportunity to demonstrate that their corrective actions are effective and sustainable. In the proposal, adverse action recommendations and associated hearings will be reserved for those instances where the MPSC believes that the member is not taking appropriate action to identify and correct the issue or where, after multiple interactions with the MPSC, the member's actions do not correct the issue. As such, the MPSC expects this aspect of the proposal to reduce significantly the number of hearings that the MPSC conducts. As mentioned previously, the possibility for multiple interviews is another reason why the MPSC believes it is prudent to allow the MPSC discretion to conduct interviews via teleconference.

5. Allow the MPSC to offer an interview without considering an action

As previously mentioned, requiring the MPSC to predict the highest action it may take before the interview often results in an inflated initial recommendation. The proposal recommends allowing the MPSC to request an interview with a member when it believes an interview is warranted, and to reserve its action recommendations until afterwards. To ensure members are able to prepare for the interview, the proposal specifies that, as a part of the interview offer, the MPSC will notify the member of the concerns that prompted the interview request and what information the MPSC would like the member to present during the interview.

6. Allow the MPSC to more frequently offer Deferred Disposition

The current Bylaws define a Deferred Disposition as a "period provided to the member to demonstrate its ability and willingness to meet OPTN Obligations. If the MPSC chooses to employ a Deferred Disposition, the recommendation for adverse action will not be communicated to the Board of Directors until after Deferred Disposition. The MPSC is able to revise its recommendation at the end of the Deferred Disposition before communicating it to the Board."

The current Bylaws include a list of requirements that must take place during the Deferred Disposition period, such as an on-site review and monthly updates. The current Bylaws also include restrictions on when the MPSC may offer a member Deferred Disposition. For example, the MPSC may only offer Deferred Disposition after a hearing and before sending an adverse action recommendation to the Board of Directors. The restrictions are so prohibitive, the MPSC is almost never able to offer a member Deferred Disposition. This proposal eliminates these restrictions, and allows the MPSC discretion to:

- Offer a Deferred Disposition at any point before a hearing offer
- Determine the length of the Deferred Disposition period
- Establish the actions the member must complete during the period
- Offer the member multiple Deferred Disposition periods

Like the option to grant multiple informal discussions and interviews, the Deferred Disposition period gives members multiple opportunities to demonstrate that their corrective actions are effective and sustainable. By allowing the MPSC to interact with members using as many informal discussions, interviews, and Deferred Dispositions as necessary, the MPSC hopes to decrease the frequency of

hearings and adverse action recommendations. Because a member offered a hearing would have failed to mitigate an urgent and severe risk or have failed to demonstrate improvement after a number of earlier interactions, the MPSC felt it would not be appropriate to offer a member a Deferred Disposition period after a hearing offer.

7. Require members to exhaust MPSC proceedings before appearing before the Board of Directors

The proposal includes a new provision that members who waive their right to an interview or hearing also waive their right to any future interactions. Specifically, members that waive an interview also waive their rights to a hearing with the MPSC and to appear before the Board of Directors. Members that waive a hearing with the MPSC also waive their right to appear before the Board of Directors. Interviews and hearings allow the MPSC to conduct a thorough review of the matter before making a recommendation to the Board of Directors. Skipping these steps can result in the Board of Directors being asked to take a final action before the MPSC has had an opportunity to complete its review. Further, appearances before the Board of Directors are not intended to be a complete rehearing of the case in front of the Board of Directors rather than the MPSC. Preventing members from skipping review steps with the MPSC is meant to help clarify this delineation. Members who waive an interview or a hearing with the MPSC may still submit written information for the MPSC or the Board of Directors to review; members only waive their right to appear in person.

8. Provide consistent formatting and detail for informal discussions, interviews, and hearings

The sections in this proposal pertaining to MPSC informal discussions, interviews, and hearings with members have been organized with a similar structure. Each section includes:

1. Introduction
2. Requesting or the right to an interaction with the MPSC
3. Waiving an interaction with the MPSC
4. Format
5. Outcomes

**Exhibit D** of this proposal is a table that compares each of these considerations for the three member and MPSC interactions, and additional detail about the content included in these sections is provided below:

1. **Introduction:** These sections define the purpose of the interaction and a high-level description of what the member can expect.
2. **Requesting or Right to an Interaction with the MPSC:** These sections describes when a member may request an informal discussion with the MPSC and when the MPSC must offer a member an informal discussion, interview, or hearing.
3. **Waiving an interaction with the MPSC:** These sections describe the implications of waiving one of these interactions, and that members that opt to waive an interaction may still provide additional information for the MPSC to consider
4. **Format:** The proposal specifies the minimum amount of time and the minimum number of MPSC members that must be present to conduct informal discussions, interviews, and hearings. Some of these details are inconsistently included in the current Bylaw language. This proposal includes this information to clearly establish these expectations:
  - a. Informal discussion – at least 4 MPSC members must be present
  - b. Interviews – at least 10 MPSC members must be present
  - c. Hearings – at least 10 MPSC members must be present

This is a specific example of how the MPSC focused on including the minimum requirements in the proposal. The MPSC acknowledges that in many instances, it will be preferable to have the full MPSC convene for an interview or a hearing. However, particularly when dealing with an urgent and severe risk to patient health and public safety, it is often not possible to quickly convene a quorum of the full MPSC, and the current Imminent Threat and Expedited Review Pathways allow the MPSC to convene for these purposes with 10 MPSC members. The proposal allows the MPSC to conduct an interview or a hearing as long as at least 10 MPSC members are present to allow the MPSC to respond quickly when needed. The MPSC anticipates that more than 10 MPSC members will commonly participate during these member interactions.

The proposal also expands upon the current Bylaws requirements that at least two of the MPSC members in attendance at an interview or hearing must have expertise in the organ system or specific issue that is the subject of the review. Currently, this requirement only exists in the Imminent Threat Review and Expedited Review. Furthermore, the current Bylaws do not address situations where the MPSC is unable to meet this requirement. The proposal expands this requirement to include all interviews and hearings and also details from where this expertise will come if two MPSC members are unavailable. Specifically, the proposal requires the MPSC Chair to select individuals with the appropriate expertise from other OPTN committees. These individuals may participate in all aspects of the review, but they only serve in an advisory role and do not have a vote. These individuals have volunteered to assist with OPTN matters and have already signed confidentiality agreements as a part of their service on an OPTN committee that will apply to their participation in the MPSC's peer review process.

The proposal also details the minimum amount of time the member and MPSC may have to present information:

- a. Informal discussions – at least 10 minutes for the member to present information and at least 15 minutes for questions and answers
- b. Interviews – at least 15 minutes for the member to present information and at least 30 minutes for questions and answers
- c. Hearings – at least 60 minutes each for the member and the OPTN to present information and at least 60 minutes for questions and answers

Again, these are the minimum requirements that can be increased as needed at the discretion of the MPSC Chair. Additionally, though not required by the existing Bylaws, these times are consistent with the amount of time currently granted to members during informal discussions, interviews, and hearings.

5. **Possible outcomes:** The proposal reviews the possible outcomes that could result for each member and MPSC interaction. Much of this content is contained in the current Bylaws; however, some additional considerations have been added.
  - a. Informal discussion – After the informal discussion, the group that conducted the informal discussion will present its findings to the MPSC no later than the next in-person MPSC meeting, and the MPSC will continue its review in consideration of these findings. The group that conducted the informal discussion may also request that the member submit additional information for the MPSC's review. This content is included in the current Bylaws.
  - b. Interview – After the interview, the MPSC will determine an appropriate action. Possible actions include requesting another interview, an informal discussion, or offering a Deferred Disposition. If the MPSC considers an adverse action after the interview, the member will have the right to a hearing.
  - c. Hearing – After the hearing, the MPSC will determine an appropriate action and if that action is an adverse action recommendation, then the member will be entitled to appear before the Board of Directors. The MPSC may also recommend that the Executive Committee review the MPSC's recommendation in lieu of the Board of Directors, as described below.

9. Allow the Executive Committee of the Board of Directors to consider certain MPSC adverse action recommendations

If the MPSC determines that a potentially urgent and severe risk to patient health or public safety exists and recommends that the Board of Directors place a member on Probation or declare a member Not in Good Standing, the MPSC may recommend to the OPTN President that the Executive Committee, rather than the Board of Directors, consider the MPSC's recommendation and conduct any appearances with the member. If the OPTN President agrees that an urgent and severe risk to patient health or public safety exists and that allowing the Executive Committee to consider the recommendation will allow for a more timely resolution of the matter, then the OPTN President may permit the appearance to take place before the Executive Committee instead of the Board of Directors. In these instances, all requirements, considerations, and actions described in the proposal that pertain to appearances before the Board of Directors will apply to appearances before the Executive Committee. If the OPTN President does not agree that an urgent or severe risk to patient health or public safety exists, or if the OPTN President believes the Board of Directors can consider the recommendation in a timely manner to address any potential risk, then the Executive Committee will not consider the recommendation, and the member will have the right to appear before the Board of Directors.

10. Update the formatting and detail of appearances before the Board of Directors

The proposal sections pertaining to member appearances before the Board of Directors are structured similarly to what is proposed for MPSC informal discussions, interviews, and hearings. Specifically, the proposal includes the following:

1. Introduction
2. Member right to appear before the Board of Directors
3. Accepting or waiving a Board of Directors appearance
4. Scheduling a Board of Directors appearance
5. Board of Directors appearance format
6. Burden of proof
7. Possible Board of Directors appearance outcomes

Additional details about the content included in Board of Directors appearance sections are below:

1. **Introduction:** The introduction section defines the purpose of the interaction and a gives a high-level description of what the member can expect.
2. **Member right to appear before the Board of Directors:** Members' rights to appear before the Board of Directors are consistent with the current Bylaws. Members have the right to appear before the Board of Directors if the MPSC recommends an adverse action. A change with this proposal is that members only have this right after conducting a hearing with the MPSC.
3. **Accepting or waiving a Board of Directors appearance:** When the member accepts its right to appear before the Board of Directors, the proposal requires that the member provide its specific disagreements with the OPTN's findings of fact, conclusions, or procedural issues that are the grounds for its contesting of the MPSC's recommendation. Currently, the Bylaws suggest that the member should present this information to the Board, but the proposal requires members to submit this information in writing at the time they accept their right to appear. Member appearances before the Board of Directors are not intended to be a complete review of the entire case before a different adjudicating body. This addition helps to clarify the purpose of member appearances before the Board of Directors and will give the MPSC and Board of Directors sufficient notice of the member's specific disagreements prior to the Board appearance.
4. **Scheduling a Board of Directors appearance:** The proposal states that the OPTN President will determine when a member's appearance before the Board of Directors will occur. This approach is

consistent with the MPSC Chair determining when a member and MPSC interaction will occur. Allowing the OPTN President to schedule the appearance allows the Board of Directors flexibility to address potentially urgent and severe risks in a timely manner.

5. **Board of Directors appearance format:** As previously mentioned in the “What problem will this proposal solve?” section, the current Bylaws do not include any detail on how a Board appearance is conducted. The current process includes separate member and MPSC presentations, followed by Board of Directors’ questions; the member is not present during the MPSC portion, and vice versa. In the interest of transparency and allowing the Board to hear information from both parties before asking questions, the proposal allows each to be present for the other party’s presentation. The proposal also specifies that the member and the MPSC will both have at least 10 minutes to present information to the Board. After the presentations, the member and the MPSC representatives will participate in a question and answer session with the Board of Directors. The question and answer session will last at least 15 minutes. Once the Board of Directors has asked all its questions, the member and MPSC Chair will exit the meeting to allow the Board of Directors to deliberate and reach its final decision.

To include additional flexibility for member appearances before the Board of Directors, the proposal also allows these appearances to occur via teleconference. Whether the Board of Directors appearance will be conducted in person or via teleconference will be determined by the OPTN President.

6. **Burden of proof:** The proposal includes a section detailing the member's burden of proof during an appearance before the Board of Directors. Consistent with current Bylaw requirements, the proposal states that the member will have the burden of proving that the MPSC’s recommendation lacks substantial basis or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious. The proposal’s continued inclusion of this section is intended to reinforce that member appearances before the Board of Directors must be focused on specific concerns, and are not intended to be a complete review of the entire case before a different adjudicating body.
7. **Possible Board of Directors Appearance Outcomes:** The content in this section of the proposal is the same as what is contained in the current Bylaws. After a member appears before the Board of Directors, the Board of Directors will either approve the MPSC’s adverse action recommendation or issue a lesser action. If the Board of Directors approves an adverse action, the OPTN will issue public notice of this determination and the member must provide additional notice as described in the Bylaws.

The details regarding member appearances before the Board of Directors, as compared to the details for informal discussions, interviews, and hearings, are also included in **Exhibit D** to this proposal.

11. Require the MPSC to offer an informal discussion before recommending a program inactivate or withdraw due to outcome or inactivity reviews

Current language in Appendix D outlines the MPSC review process for transplant program functional inactivity and transplant program outcome reviews. The MPSC routinely uses informal discussions during these review processes. In rare instances, the MPSC may recommend that the program inactivate or withdraw. This typically happens after a member has remained under review through a significant number of MPSC meetings and has not made sufficient improvement to increase their transplant activity or outcomes. The Bylaws currently permit the MPSC to consider an action up to and including Member Not in Good Standing if the program does not inactivate or withdraw when recommended. If the MPSC considers an adverse action, programs are currently entitled to an interview, hearing, and Board appearance as outlined in Appendix L.

While the Bylaws state that the MPSC may ask members to inactivate, the Bylaws do not clearly explain the process. To address this, the proposal adds a requirement that the MPSC must notify the member that it is considering a recommendation that the program inactivate, and offer the program an informal discussion before the MPSC recommends that the program inactivate. The MPSC believes it is important

to notify the program if the MPSC has concerns to give the member an opportunity to discuss the issue with the MPSC before the MPSC makes the recommendation to inactivate. If, after an informal discussion, the MPSC proceeds with a recommendation that the program inactivate and the member fails to do so, the MPSC may continue to consider an action up to and including Member Not in Good Standing as permitted in the current Bylaws. The member would continue to be entitled to at least one interview and a hearing with the MPSC before the MPSC made its recommendation to the Board of Directors.

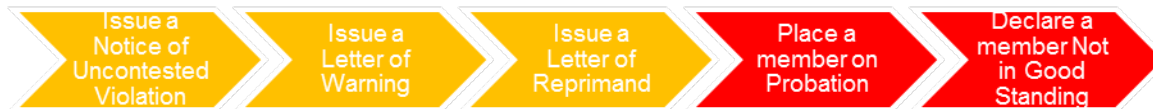
12. Require the MPSC to conduct all informal discussions, interviews, and hearings

The proposal specifies that only the MPSC will conduct informal discussions, interviews, and hearings. This differs from the current Bylaws which include provisions where the Board of Directors or the Executive Committee could conduct hearings during Imminent Threat Reviews. The proposal is recommending these changes considering the MPSC is more familiar with the history and details of the case (which could be extensive by the time of a hearing) and the general logistics of the hearing proceedings as the Board of Directors and the Executive Committee do not regularly perform these reviews.

13. Remove Letter of Reprimand as an OPTN Action

The current Bylaws include the range of OPTN actions shown in Figure 1 below.

**Figure 1: Current OPTN Actions**



The current Bylaws try to describe when the MPSC would likely take each action, but fail to sufficiently describe all instances where the MPSC may take an action or the reasons that might influence the MPSC's decision. The proposal recommends changes described below.

First, the proposal adds Close with No Action as a possible OPTN action. This is the action the MPSC most commonly takes but it is not mentioned in the current Bylaws. Second, the proposal changes the Notice of Uncontested Violation to a Notice of Noncompliance. The MPSC currently uses the Notice of Uncontested Violation to document a noncompliance in a member's record, even if no further action is needed, and would continue to do so using a Notice of Noncompliance. Historically, the MPSC has used both a Letter of Warning and a Letter of Reprimand to express significant, ongoing concerns about an issue to a member. The main distinction between the Letter of Warning and the Letter of Reprimand is that the current Bylaws require the MPSC to offer a member an interview when considering a Letter of Reprimand. As a result, the MPSC often considers Letters of Reprimand to offer members an interview and issues Letters of Warning if the MPSC does not believe an interview is necessary. Because the proposal permits the MPSC to offer the member an interview before considering an action, Letters of Reprimand would no longer be necessary to prompt an interview. The MPSC felt there is insufficient distinction between a Letter of Warning and a Letter of Reprimand to keep both in the proposal and removed the Letter of Reprimand. However, the MPSC believed it was necessary to keep two adverse actions in the proposal. The MPSC would typically reserve Probation for members that have failed to demonstrate the necessary improvement over time and would reserve Member Not in Good Standing for severe cases involving a member's failure to take requested action to mitigate an urgent and severe risk to patient health or public safety.

Figure 2 shows the new range of OPTN actions included in the proposal.

**Figure 2: Proposed OPTN Actions**



14. Clarify factors the MPSC uses to determine an appropriate action

The current Bylaws include a list of possible considerations that factor into the MPSC’s decision when determining an appropriate action. The proposal expands upon this list to bring greater attention to other critical considerations that commonly factor into MPSC action determinations, but that are not included in the current Bylaws. The additions include:

- The extent to which the member has demonstrated awareness and accountability for the noncompliance, including whether the member self-reported the noncompliance
- The extent to which the noncompliance demonstrates lack of stewardship of donated organs
- The extent to which the noncompliance is likely to recur

The MPSC stated it was particularly important to stress that both member accountability for and response to the issue impact the MPSC’s final decision. Members that are proactive in recognizing and addressing a potential issue in advance of an MPSC review are likely to receive a lesser action.

15. Add Board of Directors discretion to Probation notification requirements

This proposal makes minimal changes to Bylaws content pertaining to Probation and Member Not in Good Standing. The most significant change is that the proposal includes a provision that grants the MPSC discretion to recommend that the Board of Directors suspend or add to member Probation notification requirements. The current and proposed Bylaws require that an OPO placed on Probation must notify all hospitals that have a contractual agreement with the OPO in the OPO’s Donation Service Area (DSA). The MPSC acknowledged that the notification requirements may not be entirely applicable based on the nature of the noncompliance. Consider a scenario where an OPO is on Probation for multiple instances of delayed reporting of serology results that resulted in recipients being significantly impacted. In this hypothetical example, notifying potentially hundreds of donor hospitals about a situation that is independent from their role in the donation process may not be valuable.

OPTN leadership advised against a process that would require the Board of Directors to spend significant time reviewing the case details and notification requirements for every Probation action. As a result, the proposal allows the MPSC to make specific recommendations to the Board of Directors regarding modifying the notification requirements, and the Board of Directors will decide whether to accept the MPSC’s recommendation. The proposal does not include this provision for Member Not in Good Standing recommendations. The MPSC felt that the gravity of matters that result in the Board of Directors declaring a Member Not in Good Standing should be distributed as directed by the Bylaws, and neither the MPSC nor the Board of Directors should have discretion on this requirement.

The current Bylaws require members receiving an adverse action to notify specified organizations or individuals, but the Bylaws do not provide any guidance on what the notice must say. The MPSC briefly discussed whether to specify what the notice must say in the Bylaws. The MPSC felt that members should be free to craft the message to these organizations and individuals and therefore decided against specifying what the notice should say. However, the MPSC felt it was reasonable to require the member to refer to the OPTN public notice to provide appropriate context about the adverse action.

16. Reduce the length of time members must wait to request release from Probation or Member Not in Good Standing

For clarification purposes, the proposal eliminates any references to “Restoration of Unrestricted Membership Privileges” in the current Bylaws and replaces those with “Release from Probation or Member Not in Good Standing.”

This proposal decreases the amount of time that must pass before a member can request release from an adverse action from 12 months to 9 months. The MPSC wanted to reduce the minimum requirement because, in some instances, the MPSC has felt that a member should be released from an adverse action earlier than the Bylaws currently allow. Given the severity of an adverse action, the MPSC did not want to shorten the time frame too much. They felt reducing the time by three months, which is approximately one MPSC meeting or review cycle, would be appropriate. The MPSC noted that it is not required to approve a member’s request to be released after nine months, but would like members to have the option to request it earlier if appropriate.

17. Allow the Executive Committee of the Board of Directors to consider MPSC recommendations to release members from an adverse action

The Bylaws currently require the Board of Directors to approve the MPSC’s recommendation to release a member from an adverse action, but the Board of Directors has historically never had any significant concerns with or rejected an MPSC recommendation. With this in mind, and recognizing that the Executive Committee meets much more frequently than the Board of Directors, the proposal permits the Executive Committee to approve the recommendation. The intent is that this change will allow matters to be resolved more promptly.

18. Update the definition of OPTN Obligations to include “acting to avoid risks to the health or safety of patients or the public.”

Appendix L.15 OPTN Determination and Actions says “OPTN actions may be imposed when a member:

1. Fails to comply with OPTN Obligations as described in *L.1 Member Compliance*
2. Fails to submit or follow a corrective action plan or plan for quality improvement
3. Fails to meet personnel requirements
4. Acts in a way that poses a risk to patient health or public safety
5. Fails to act as necessary to avoid risk to patient health or public safety”

To emphasize the importance of the patient safety requirements in L.15.4 and L.15.5, the MPSC considered moving this information to the very beginning of Appendix L, in *L.1 Member Compliance*. However, the MPSC noted that *L.1 Member Compliance* already duplicated information from *Article 1.E Member Compliance*, as shown below.

**Table 2: Current Member Compliance Bylaw Language**

<i>Article 1.E Member Compliance</i>	<i>Appendix L.1 Member Compliance</i>
<p>“By accepting membership in the OPTN, each member agrees to comply with all applicable provisions of the:</p> <ol style="list-style-type: none"> <li>1. National Organ Transplant Act, as amended, <i>42 U.S.C 273 et seq.</i></li> <li>2. OPTN Final Rule, <i>42 CFR Part 121</i></li> <li>3. OPTN Bylaws</li> <li>4. OPTN Policies</li> </ol> <p>“The OPTN will conduct ongoing periodic reviews of each transplant hospital, histocompatibility and OPO member for compliance with the OPTN Final Rule, OPTN Bylaws, and OPTN Policies...”</p>	<p>“Each OPTN member agrees to comply with OPTN Obligations, which include all of the following:</p> <ol style="list-style-type: none"> <li>1. National Organ Transplant Act, as amended, <i>42 U.S.C 273 et seq.</i></li> <li>2. OPTN Final Rule, <i>42 CFR Part 121</i></li> <li>3. OPTN Bylaws</li> <li>4. OPTN Policies”</li> </ol> <p>“The OPTN will conduct ongoing period reviews and evaluations of each transplant hospital, histocompatibility laboratory member and OPO member for compliance with OPTN Obligations...”</p>



The proposal removes this and additional duplicative OPTN Obligation and compliance monitoring language currently in Appendix L and updates the information in Article 1 to include a requirement to act to avoid risks to patient health or public safety, as shown below. The proposal includes similar changes where OPTN Obligations are referenced in Appendices B, C, and D.

19. Compile all information related to the U.S. Secretary of HHS in a single section.

The proposal does not include any substantial changes regarding the U.S. Secretary of HHS's (the Secretary's) role in this process. The Secretary will continue to have access to all information, to have representatives participate as ex-officio members on the MPSC, to direct special investigations, and to take actions in addition to or in lieu of OPTN actions. The proposal also removes all references to the timing of when the OPTN will notify the Secretary of Imminent or Expedited Reviews or of any final adverse actions because the language already says the Secretary will have access to all information; the Secretary's representatives on the MPSC and Board of Directors have access to all such information; and the proposal no longer includes references to the Imminent and Expedited Review Pathways. All references to the Secretary that remain applicable based on the proposed concepts were moved to a single section at the end of the proposal.

20. Costs and Expenses

This proposal does not include any changes to this section from the current Bylaws.

21. Corresponding changes to other Appendices

Appendices A, B, C, D, G, and I of the OPTN Bylaws currently reference Appendix L and the MPSC review process. Changes to Appendix L in this proposal required changes to these other references. The changes do not add any new requirements; they are mostly formatting changes. Most changes are necessary based on the changes to the definition of OPTN Obligations as described in the section above.

## **How well does this proposal address the problem statement?**

The MPSC believes this proposal is a significant improvement over the current Appendix L language. The proposal successfully corrects the conflicting and unclear requirements present in the current Bylaws, increases flexibility in the review process, allows the MPSC to address potentially urgent and severe risks to patient health and public safety in a timely manner, and updates the MPSC review process to focus on process improvement.

The proposal's primary strengths are the improvements to the review process that allow greater collaboration between the MPSC and members. As described in the "How was this proposal developed" section, examples include allowing members currently under MPSC review to request informal discussions; allowing the MPSC to offer the member more than one interview; and granting the MPSC more opportunities to offer members Deferred Disposition periods. By increasing direct MPSC and member engagement and giving the MPSC and members tools to focus on demonstrating effective and sustainable solutions, the MPSC can reserve hearings and adverse actions for the very limited circumstances where the member has failed to make sufficient progress in containing and addressing the noncompliance that originally prompted the MPSC's review.

Another strength of this proposal is simplifying the review process (e.g., one review framework instead of three pathways; remove specific operational details from Bylaws; similar organization structure for describing informal discussions, interviews, and hearings) while still maintaining the ability to address potentially urgent and severe risks to patient health and public safety in a timely manner. The proposal also simplifies the format and detail in the Bylaws, making the Bylaws easier to read and understand. The proposal adds important details, such as information regarding member appearances before the Board of Directors; how the MPSC may incorporate additional subject matter expertise into a review; and requiring the MPSC to alert a member that it is considering requesting that the member inactivate before making

the inactivation request. Though much of this detail was based on existing practices, including it in the proposal promotes transparency.

Although the MPSC believes increased simplicity and the removal of logistical operational details from the Bylaws is a strength of this proposal, the MPSC recognizes that some may criticize these changes as negatively impacting the transparency. As discussed in the “How was this proposal developed” section, the MPSC spent significant time evaluating the appropriate level of detail in the Bylaws and believes that transparency is important. The MPSC recognized that outlining exactly how and when every step in the Bylaws would take place allows members to predict exactly what would happen at each stage of a review. However, the MPSC determined it was impossible to anticipate every scenario the MPSC would face and include the relevant steps in the Bylaws. The MPSC also noted the circumstances of a review may necessitate a different review process than what was predetermined in the Bylaws. The MPSC believed that flexibility to conduct the right kind of review was more important than predicting exactly how the review would be conducted. Finally, the MPSC believed trying to incorporate all of this information into the proposal would actually decrease transparency by making the document too difficult to understand.

Nevertheless, the MPSC still appreciates members’ wanting to have additional context and details about MPSC interactions prior to those interactions occurring. To accommodate this and to help address these concerns, the MPSC plans on providing and maintaining supplemental documentation that will provide members with additional context and detail regarding what it can expect when engaging the MPSC in an informal discussion, interview, or hearing, or when appearing before the Board of Directors. Previously referenced exhibits to this proposal are samples of the supplemental documentation that the OPTN will provide with the approval of this proposal. In addition to these materials, UNOS staff that support the MPSC are also available to answer questions and assist members through the review process.

## Was this proposal changed in response to public comment?

No. The MPSC made some minor clarification and formatting edits to the proposed Bylaws language post-public comment (**Exhibit E**), but it did not make any changes in direct response to the feedback provided during public comment. The MPSC discussed all the public comment feedback provided in response to this proposal during its March 27 teleconference. The following summarizes the public comments and the MPSC’s response:

### Individual Comments

- The overwhelming number of comments received through the OPTN website and at OPTN/UNOS regional meetings indicated support for the changes presented in the proposal. Through the OPTN website and OPTN/UNOS regional meetings, this proposal received 113 individual comments- 106 of which indicated that they “supported” or “strongly supported” the proposed changes; the remaining seven expressed that they were “neutral” on the proposed changes.

*MPSC Response:* The MPSC appreciates respondents taking the time to review the proposal and express their support.

- Included in the individual responses were a few specific comments and recommendations for the MPSC to consider. The MPSC reviewed and responded to these additional considerations individually:
  - One commenter who expressed strong support for the proposal added, “While I agree with allowing the MPSC to more frequently offer Deferred Disposition, I am concerned with offering the member multiple Deferred Disposition periods. I think a limit should be set as to how many (or total time) there should be before an action is taken. Otherwise you might have a program on perpetual Deferred Disposition. In the format of the informal discussions, interviews and hearings, the proposal details the minimum amount of time for presenting information. I agree with this, but suggest that a maximum time be set as well. Otherwise you might have a filibuster situation.”

*MPSC Response:* The MPSC appreciates the response and considered these recommendations while developing this proposal. The MPSC ultimately decided against upper limits in these situations to allow the MPSC to tailor its reviews to the circumstances of any given case. It will be the MPSC's and MPSC Chair's responsibility to set appropriate limits to avoid "filibuster situations," "perpetual Deferred Disposition," and other unproductive conditions during MPSC and member interactions.

- One commenter who expressed support for the proposal added, "I would remind the MPSC that center performance criteria in D.12.A were discussed by the MPSC in about 2013 and were to be reviewed within 2 or 3 years to decide if too many centers were being determined to be 'under-performers'. Many peer review publications in the last few years show this is the case and that this large number of 'flagged' programs results in decreased transplantation rates throughout this country."

*MPSC Response:* The MPSC appreciates this feedback. The MPSC did not consider substantive changes to OPTN Bylaws D.12.A. as a part of this proposal. The MPSC limited changes to D.12.A. to those that are required to align the section with substantive Appendix L changes. That said, the MPSC continues to monitor the effectiveness of member performance screening criteria. Recent efforts to address member performance reviews include: 1) an MPSC-sponsored proposal during the summer 2016 public comment cycle that addressed OPTN Bylaws D.12.A. (the MPSC ultimately did not present this proposal for the OPTN/UNOS Board of Directors' consideration due to public comment feedback); 2) an operational rule for kidney transplant program outcome reviews that excludes programs from review if they did not meet the expected thresholds due to transplants involving a kidney from a donor with a KDPI of 85 or greater and a recipient with an EPTS score greater than 80; and 3) the Collaborative Innovation and Improvement Network (COIIN) project.

- One commenter recognized improvement of OPTN Bylaws Appendix L and the processes described in the proposal; however, the commenter believes that the proposal still includes significant flaws and provided additional recommendations for the Committee to consider.
  - "One additional detail that the drafters may wish to consider is the requirement that an official list of issues be maintained by committee staff so that an agreed upon set of facts and/or an agreed upon resolution of a specific issue can be deleted from the list. This may sound too perfunctory and obvious, but I have witnessed numerous occasions in which a member has been led to believe that a specific issue has been resolved, only to see the issue resurrected in a subsequent portion of the review process in a manner that leads to significant frustration and a sense of having been dealt with unfairly."

*MPSC Response:* The MPSC appreciates the commenter's response and additional consideration. The MPSC agrees that clear and ongoing communication with the member during the review process is critical. The MPSC also agrees that a tool to track the MPSC's concerns and the member's progress towards satisfactorily resolving the issue would be useful for both parties.

It is worth noting that MPSC reviews are dynamic; the MPSC may change its assessment of whether a member has satisfactorily addressed an issue as additional information becomes available. Similarly, the scope of a review may expand if the MPSC's review reveals additional significant issues that need to be addressed. The MPSC does not intend for the tool to be used in a way that prohibits the MPSC from thoroughly evaluating and assessing the situation. However, the MPSC acknowledges that a tracking tool would be particularly helpful in situations where the MPSC's concerns or the scope of the review change over time. The MPSC is committed to developing and implementing the requested issue tracking tool quickly, but the MPSC does not believe it is necessary or appropriate to include this level of detail in the proposal. The MPSC already uses similar operational tools such as surveys and templates, none of which are referenced in the current Bylaws or the proposal. The MPSC

believes incorporating this level of operational detail in the Bylaws is unnecessary and could limit the MPSC's ability to create, modify, or discontinue use of these tools in a timely manner when appropriate.

- "I am hopeful that the drafters' warning that the proposed revisions are meant to emphasize reliability and predictability in the processes rather than an explicit set of detailed procedures is referring specifically to the revised provisions regarding Hearings. The drafters may feel as if it is critical for the MPSC Chair and others to reserve the right to conduct a Hearing that is tailored to the specific facts and issues that comprise a specific review process. But I am concerned that the proposed revisions will ultimately prove unsatisfactory if the current processes of 'direct testimony' and 'cross examination' and notions of 'burden of proof' are allowed to continue to dominate...I would urge the drafters to consider setting forth additional procedural safeguards aimed at ensuring a non-time pressured, thorough and comprehensive exchange of views in the Hearing setting that reflect those priorities as explicitly as the revisions provide in the informal discussion and Interview phases."

*MPSC Response:* The Committee appreciates the commenter's assessment of the hearing process and these additional considerations.

By allowing multiple informal discussions, multiple interviews and a greater likelihood for Deferred Disposition, the proposal provides increased opportunities for the MPSC and the member to thoroughly discuss issues in a non-time pressured setting. The MPSC hopes that these opportunities will reduce the number of hearings, if not avoid them entirely. However, if a hearing is still necessary, the MPSC believes that certain formalities of a hearing are appropriate. For example, the MPSC believes members and the MPSC should continue to have the right to be represented by an attorney. However, the MPSC agrees that other aspects of the current hearing process, such as the direct witness testimony and cross examination, may not be the most effective or efficient way to conduct every hearing. The proposed hearing language does not require that these aspects of the hearing process remain going forward. The MPSC is dedicated to constantly reviewing the format of the hearing process and, under the framework proposed in the Bylaws, the MPSC can implement changes to the hearing process in the future.

The MPSC believes the proposed hearing language establishes an appropriate minimum framework for hearings that can be adapted as needed. The MPSC did not identify "additional procedural safeguards" to introduce into the proposal at this time, but the MPSC is happy to consider suggestions the commenter or others may have to improve the hearing process.

#### Regional Meeting Comments

- All 11 OPTN/UNOS regions unanimously supported the proposal. Discussion at the regional meetings yielded a few specific comments and recommendations for the MPSC to consider. The MPSC expressed its appreciation for the support provided at the regional meetings, and responded to the additional considerations individually:
  - At the Region 1 meeting, members expressed concerns that the proposed flexibility may increase the burden on MPSC members with a drastically higher work load.

*MPSC Response:* The MPSC appreciates Region 1's support and these concerns. The MPSC understands that these changes may lead to more work for the MPSC in some instances. However, the MPSC believes that these changes will yield more meaningful interactions with members. Additionally, the proposal includes considerations that will simplify these processes for the MPSC and members (e.g., ability to have interviews via teleconference).

- At the Region 3 meeting, members suggested it would be beneficial to require that two MPSC members have content expertise during informal discussions.

*MPSC Response:* Subject matter experts are commonly present on the MPSC, and the MPSC will always work to include experts on all of its reviews. Informal discussions are intended to be information gathering conversations among peers. The MPSC is concerned that this perspective may be lost if larger panels are needed to conduct the informal discussion, and with the inclusion of additional experts outside of the MPSC. Nothing in the proposal prohibits the MPSC from obtaining additional expertise for informal discussions if necessary, and the MPSC has done so in the past, even when not required by the Bylaws. However, the MPSC felt requiring at least two subject matter experts for every informal discussion may limit the MPSC's ability to quickly hold a discussion with a member for a seemingly straightforward issue, such as clarifying the MPSC's concerns described in a letter or further explaining why the MPSC requested specific information. With this perspective, and for the sake of maintaining member confidentiality, the MPSC did not support Bylaws changes that may potentially require prematurely asking experts outside the committee to interact with members during informal discussions. The proposal continues to require at least two subject matter experts participate in interviews and hearings.

- At the Region 8 meeting, members also added that reviewers need expertise in the matter under review.

*MPSC Response:* The MPSC agrees that expertise is critical, and the MPSC has traditionally worked to make sure that appropriate expertise is a part of every review. Proposed changes to Appendix L formalize the expectation for subject matter experts, and how that experience is obtained if not directly from the MPSC. The MPSC did not propose including this level of detail in the Bylaws for informal discussions with respects to the informal nature of these interactions and member confidentiality, as noted above.

- Region 8 also requested that the MPSC remove inquiries from required paperwork about topics not related to the matter under review. For example, requests for information about the number of nutritionists or information about social workers may not pertain to performance-related reviews. The member stated that these additional questions create extra burden for the members.

*MPSC Response:* The MPSC carefully considers every request asked of members during a review. Inquiries about topics that may seem unrelated to the matter under review are not arbitrary. Such inquiries are intended to give the MPSC a greater perspective of the member's operations as it works through the review.

- Region 9 expressed its support but has concerns that the MPSC remains a punitive body and lessons learned are not shared with the transplant community.

*MPSC Response:* The MPSC acknowledges the perception by some that the peer review process is punitive, and it routinely evaluates ways to appropriately address that perception. Monitoring will always be an MPSC responsibility; however, the MPSC hopes that the proposed changes to Appendix L will allow the MPSC to conduct reviews in a more effective and efficient manner and will provide members a greater opportunity to demonstrate effective quality improvement practices before the MPSC takes an action.

As for sharing lessons learned, the MPSC frequently presents updates from the past year at annual meetings, and it discusses potential educational topics that can be shared with the community at the end of each in-person meeting. The MPSC has made a number of referrals to the OPTN/UNOS Operations and Safety Committee's Patient Safety Advisory Group that have resulted in educational offerings. Nevertheless, the MPSC understands that there is an ongoing interest in lessons learned through MPSC reviews. The MPSC is working with the UNOS Member Quality Department to find additional ways to share this information with the community, and within the bounds of confidential medical peer review under which the MPSC functions.

Transplant Society Comments

- The MPSC received public comment feedback on the proposal from the American Society of Transplantation (AST), the Association of Organ Procurement Organizations (AOPO), the American Society of Histocompatibility and Immunogenetics (ASHI) and the American Society of Transplant Surgeons (ASTS). AST, AOPO, and ASHI expressed support for the proposal. ASTS applauded the MPSC's efforts, but expressed a number of concerns with the proposal. The MPSC discussed each of the concerns posed by ASTS, and responded as follows:
  - "We doubt that the new proposal will be viewed by our membership as a significant advance, as it falls short of our membership expectations of real regulatory relief that would help advance the field."

*MPSC Response:* The MPSC appreciates members' desire for decreased regulation. While the proposal does not reduce the number of OPTN Policy and Bylaw requirements, the MPSC believes the proposal does represent a significant improvement over the current Bylaws, and will allow the OPTN to conduct reviews in a more effective and efficient manner.

- "Of particular concern is the subjectivity of determining imminent threat to the health of the public, particularly in a discipline as complex as transplantation."

*MPSC Response:* Language in the proposal regarding the MPSC's review of potentially "urgent and severe risks to patient health and public safety" is currently in the Bylaws, and stems from obligations established by the Final Rule. The Final Rule requires that the OPTN Board of Directors, "shall advise the Secretary of the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which...indicate a risk to the health of patients or to the public safety." The MPSC appreciates the desire for greater detail around these assessments but believes that these Bylaws should be consistent with language in the Final Rule. Additionally, the MPSC agreed that it wouldn't be reasonable to write Bylaws that include every possible consideration and scenario that may prompt a review due to patient health and public safety concerns.

- "Similar to the original version, it is clearly stated (now multiple times in the new document) that the burden of proof is on the program to 'prove that the MPSC's recommendation lacks substantial basis or the conclusions drawn are arbitrary, unreasonable, or capricious.' This is an extremely high bar for any Transplant Center and, at its root, is unfair because the MPSC acts as the investigator and prosecutor in making the allegation and then acts as judge and jury, rendering the recommendation for punishment."

*MPSC Response:* The MPSC is empathetic to this point but is unclear on appropriate post-public comment changes to address the concern. As noted in the comment, this standard is included in the current Bylaws and not changed with this proposal. The MPSC also noted other reviews in the medical field where the burden of proof lies with the group or individual under review. The proposal does not include any reference to burden of proof during an informal discussion, an interview, or a hearing. Instead, the proposed language suggests that the member is expected to satisfactorily address concerns the MPSC communicated to the member in advance of the interaction. Language regarding the member's burden of proof appears in the proposal in Section L.11. (Appearances before the Board of Directors). The MPSC continues to believe it is appropriate to prove to the Board of Directors' satisfaction that the MPSC recommendation lacks substantial basis or that the MPSC's conclusions are arbitrary, unreasonable, or capricious, if the member does not want the Board of Directors to approve the MPSC's recommendation. To improve fairness and transparency in the Board of Directors review process, the proposal allows the member to be present when the MPSC makes its recommendation to the Board of Directors.

- Regarding L.5. Investigation of Potential Noncompliance with OPTN Obligations, "At present, any written correspondence between the MPSC and the program may or may not detail the nature of the exact violation/noncompliance. We feel that the OPTN should clearly state the nature of the

potential non-compliance to be investigated. The member may then provide the most relevant information to the OPTN related to any questions of non-compliance with membership requirements or professional standards. In addition, this level of detail should be restated on each correspondence thereafter. This will alleviate any confusion by the program as to why the correspondence is occurring in the first place.”

*MPSC Response:* The MPSC appreciates this comment and will continue to work on ways to reduce member confusion when interacting the Committee. Initial correspondences between UNOS staff and members may not specify a particular policy or bylaw requirement as these communications are a means to gather information to determine whether any potential noncompliance occurred and, if necessary, obtain appropriate information for the MPSC’s review. Once the MPSC has reviewed the matter, the Committee specifies in its communications which OPTN Obligations are the focus of the review. This process will continue with these proposed Bylaws changes. The proposal also requires the MPSC to clearly communicate any issues the MPSC would like the member to address when offering the member an informal discussion, an interview, or a hearing.

- Regarding L.8. Informal Discussions, “Any correspondence between a program and the MPSC, either written, by phone, or in person, should be considered 'formal.' This should be relabeled to reflect the seriousness of the situation. Perhaps 'Initial' discussion.”

*MPSC Response:* The MPSC debated what to call this MPSC and member interaction before distributing the proposal for public comment. The Committee ultimately reached consensus around “informal discussion” to underscore the conversational and information sharing nature intended for these discussions. The Committee appreciates that these are serious conversations and the perspective that labeling them as “informal” could be seen as a misnomer; however, the Committee does not believe that the “informal discussion” label is misleading or problematic for members. This perspective is based on previous informal discussions conducted by the MPSC, follow-up with members that have participated in an informal discussion, and no other feedback provided during public comment that raised this concern.

In reviewing this suggestion, the MPSC spent some time considering alternative labels for these MPSC and member interactions. The MPSC considered the suggestion from ASTS to call these interactions “initial discussions” but the Committee thought this would be more confusing as the proposed informal discussions are not always the initial step of an MPSC and member interaction. Committee members brainstormed other suggestions, but ultimately, the Committee agreed to proceed with labeling these interactions as “informal discussions.”

- Regarding L.8.D. Informal Discussion Format, “Depending on the exact nature of the potential violation/noncompliance, 10 minutes is likely not enough time to adequately cover a specific case in question, program policy/procedure, and/or administrative issue being discussed.”

*MPSC Response:* The minimum time proposed is based on the amount of time currently provided to members. Prior to developing this proposal, UNOS Member Quality staff surveyed members who have participated in informal discussions with the MPSC. Survey responses indicated that members felt the amount of time to present information was sufficient. Additionally, these proposed Bylaws reflect lower limits for member and MPSC interactions. The MPSC appreciates that the complexity of some situations may require additional time to have a complete discussion. In those circumstances, the MPSC will allow members the time needed to thoroughly review all the relevant information. The Committee’s primary goal is to obtain a complete picture of the member’s situation, and it will work with the member to set appropriate time frames to achieve this goal.

- Regarding L.9.C. Interview Format, “This section is especially troubling with regard to potentially complex surgical cases such as heart transplant, high MELD liver transplant, and/or dual organ cases. In our opinion, 2 experts may not be adequate. Furthermore, the current document assumes this expertise will be present within the OPTN committees itself. While that may be true for some unknown fraction of cases, the current revision leaves no room for the program to provide its own experts, in addition to OPTN, which may help clarify and/or reinforce certain clinical standards of practice, surgical decision-making, and the current state of a given discipline. Giving programs the ability to have an outside clinician, with a robust practice, the opportunity to review specific issues would be extremely helpful in certain circumstances regardless of the ultimate outcome. As result, we feel that the OPTN should consider a policy where members can bring their own experts forward in either interviews or hearings.”

Regarding L.10.C. Hearing Format, “Again, given the seriousness of any potential violation/noncompliance, the current document stops short of what is needed. See above. However, this issue now becomes extremely important as the process progresses. At the level of a hearing, in addition to legal representation, a program may not be able to adequately defend its position to the MPSC if the appropriate amount of experience with the matter is not present.”

*MPSC Response:* Members may currently consult or bring their own experts when interacting with the MPSC. Members are not limited in how they may present information or expertise for the MPSC’s consideration. The proposal does not change this. Members interacting with the MPSC are welcome to use any experts that may be helpful to clarify details surrounding any matter that the MPSC is reviewing. To clarify this, the MPSC will work to update the toolkit that supplements these proposed changes and that will be available for members. The toolkit will be updated to specify that members may use additional experts as necessary to convey and clarify for the MPSC all the critical information pertaining to the member’s case.

- Regarding L.11.D. Board of Directors Appearances Format, “In general, it is concerning that waiving a right to a hearing automatically waives the right to appear before the Board of Directors. More importantly, the order of the proceedings in front of the Board of Directors becomes important for the program in question. Given that the burden of proof is on the program, the MPSC chair should be first to present the information stating and reinforcing the noncompliance against a program. Forcing a program to present information first, followed by the MPSC, puts the program at a sizable disadvantage.”

*MPSC Response:* The MPSC feels strongly that it is necessary for the MPSC to conduct a thorough review, including any interviews and hearings, before the MPSC forwards an adverse action recommendation to the Board of Directors. Previous instances where the member has bypassed the MPSC and proceeded directly to the Board of Directors has resulted in confusion and dissatisfaction with the process for not only the member, but also for the MPSC and the Board of Directors. The MPSC believes that requiring members to complete the MPSC review process will increase the likelihood that the MPSC and the member will resolve the issue without involving the Board of Directors. The MPSC also believes, if it is still necessary after the hearing to forward a matter to the Board of Directors, that the MPSC review process will ensure the Board of Directors has all the necessary information to make a decision.

Regarding the presenting order at a Board of Directors appearance, the Committee discussed making changes to the proposed Bylaws but ultimately decided not to. The proposed Bylaws allow both the member and the MPSC to be present during the other’s presentation, and during any questions that the Board of Directors has for the member or the MPSC. The MPSC believes



these improvements allow for greater transparency for the MPSC and the member, and allows for the Board of Directors to reach greater clarity by asking questions of both parties simultaneously.

- Regarding L.12.A. Deferred Disposition, “Again, this puts all programs at a distinct disadvantage. At the very least, a program should have the right to a 'Formal Discussion' with the MPSC which outlines (in detail) the reasons for not offering or ending a Deferred Disposition period.”

*MPSC Response:* The current Bylaws allow the MPSC to offer the member a Deferred Disposition period, but puts a number of limits on when the MPSC may do so. These limits have resulted in the MPSC rarely being able to take this action. One aim of this proposal is to allow the MPSC more latitude to offer members a Deferred Disposition. Much like other non-adverse actions, decisions about a Deferred Disposition are left to the discretion of the MPSC.

In considering this comment, the MPSC discussed whether the proposed Bylaws should be changed so that members would be entitled to a discussion with the MPSC about Deferred Disposition decisions. Upon the conclusion of this discussion, the MPSC did not think post-public comment Bylaws changes were necessary. The MPSC was concerned adding a discussion requirement may result in unnecessary delays during the review of urgent and severe risks to patient safety and public health and that members may try to use this process to challenge non-adverse actions. The MPSC also noted that nothing in the proposal would prohibit the member from requesting, or the MPSC from offering, an informal discussion if discussions about Deferred Disposition warranted an additional conversation. The MPSC can imagine scenarios in which the MPSC may speak to the member about such issues, but did not feel it was necessary to put a requirement to do so in every instance in the proposal.

- Regarding L.12.B. Types of actions, “Within the amended Appendix L, a letter of reprimand has been removed. This is concerning as it creates a fast track to probation or member not in good standing.”

Regarding L.15.D. MPSC Actions without Board Referral, which the proposal recommends deleting, “Letter of reprimand has been removed. See L.12.B. above.”

*MPSC Response:* A focus of the Committee throughout the development of this proposal is to avoid adverse action recommendations, except in dire circumstances and when members fail to adequately address the issues that prompted MPSC review. The Committee never considered an adverse action fast track as rationale for removing Letter of Reprimand as an OPTN action.

During the development of this proposal, the MPSC raised questions about whether there was a distinguishable difference between a Letter of Reprimand and a Letter of Warning. The Committee recognized the main difference is that a Letter of Reprimand entitles the member to an interview. Traditionally, if the MPSC did not believe that the potential noncompliance warranted an adverse action recommendation but it was interested in speaking with the member further, the MPSC would recommend a Letter of Reprimand and offer the member an opportunity for an interview. In consideration of proposed changes that allow the MPSC to offer a member an interview at any time, the MPSC concluded that there would be an insignificant difference between a Letter of Warning and a Letter of Reprimand under the proposed changes to Appendix L. Therefore, the MPSC decided to propose deleting Letter of Reprimand as a formal OPTN action. The MPSC anticipates that removing a Letter of Reprimand is more likely to result in an increase in Letters of Warning than to result in an increase in adverse action recommendations.

- Regarding L.12.D.1.c. Probation Monitoring Requirements, “This section is vague. Programs should have a clear view of what ongoing monitoring actually means. For example, what information will be required by the program and at what time intervals? Does the probation period

require site visitation? If so, how many? At what time intervals? Appendix L: Original Version. L6. Requests for root cause analysis and corrective action plan - This section was very helpful in terms of what the program can expect.”

Regarding L.15.E.1. Probation, which the proposal recommends deleting, “Again, at least a broad description of Corrective Action Requirements of Probation can be helpful to the program in question.”

*MPSC Response:* The MPSC acknowledged the need to improve the current Bylaw descriptions regarding adverse action monitoring. The current Bylaws require members be under review for at least 12 months and to notify certain groups or individuals of the adverse action, but does not provide any additional detail or requirements. However, the MPSC recognized that monitoring requirements are dependent upon the issue under review. The MPSC did not want to add requirements that might not be applicable in all situations and would potentially create an unnecessary burden on members and the MPSC. Therefore, the MPSC decided not to add specific requirements regarding Probation; the MPSC will determine appropriate monitoring requirements as needed. The MPSC felt it was appropriate to require that Members Not in Good Standing must provide routine updates to the MPSC and must participate in an on-site visit, and added this information to the corresponding Member Not in Good Standing section of the proposal.

Appreciating that the Probation section referenced does not include significant detail or requirements, the MPSC considered removing it entirely during the development of the proposal. The MPSC decided to retain this section to establish that the MPSC conducts the Probation monitoring, not the Board of Directors. Additionally, retaining this section allows the proposed Bylaws for Probation and Member Not in Good Standing to have a similar structure.

Following the public comment period, the MPSC did make a number of minor changes for formatting and to further clarify some of the proposed language. This list of changes is included as **Exhibit E**. The Committee reviewed these changes during its April 17 teleconference, and then unanimously supported a resolution to approve the Bylaws changes offered in the Appendix L proposal, as provided in the meeting materials and discussed during the teleconference, for the Board of Directors’ consideration at its June 2018 meeting (23 support, 0 oppose, 0 abstentions).

## **Which populations are impacted by this proposal?**

The proposal recommends modifying OPTN Bylaws that establish how the OPTN reviews potential noncompliance with OPTN Obligations and the actions that the OPTN may take in response. The changes in this proposal do not directly impact any particular patient populations. Indirect impacts to transplant patient populations are anticipated from the considerations in this proposal that are intended to support and advance OPTN reviews that are process improvement-focused. Instances of member noncompliance that ultimately result in learning opportunities and process improvement stand to reduce the likelihood of the noncompliance recurring at the member institution, and potentially, at other member institutions as well. Minimizing future noncompliance and the resulting effects on transplant patients should positively impact all transplant patient populations.

## **How does this proposal impact the OPTN Strategic Plan?**

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The proposal has potential to improve waitlisted patient, living donor, and transplant recipient outcomes by better allowing members and the MPSC to work together to identify and implement effective and sustainable process improvements associated with MPSC outcome reviews.
4. *Promote living donor and transplant recipient safety:* The proposal is anticipated to have the greatest impact on this OPTN Strategic plan goal by allowing the MPSC to work with members to develop methods to quickly mitigate any potentially urgent and severe risks to patient health and public safety. Minimizing the recurrence of future noncompliance will avoid the negative impact on living donor and transplant recipient safety resulting from that particular noncompliance.
5. *Promote the efficient management of the OPTN:* The proposal will clarify members' due process rights and increase the efficiency of due process proceedings for both OPTN members and the MPSC.

## How will the OPTN implement this proposal?

This proposal will not require programming in UNet<sup>SM</sup>.

The MPSC will present these changes for the OPTN/UNOS Board of Directors' consideration at its June 2018 meeting. Assuming the Board adopts these changes, they would become effective following notice to members, immediately after the Board of Directors' decision. These Bylaws changes will become effective immediately so that members are afforded the benefits of this proposal as soon as possible. The MPSC also believes that immediate implementation is prudent because this proposal does not impact member responsibilities to comply with OPTN Obligations or how members will be monitored for compliance; rather, the proposal addresses how members who are noncompliant with OPTN Obligations are reviewed. Therefore, members should not have to adapt their internal processes to prepare for these Bylaws changes. Finally, immediate implementation will eliminate the possibility that the MPSC would have to conduct a review under the current system while the changes are in a status of "approved, but not yet implemented."

The OPTN will transition all members actively under MPSC review at the time the new process is implemented to the new review system. If transitioning to the new Bylaws in the middle of an ongoing review would negatively impact the member's rights, the OPTN will consult with the member and may finish the review using the old Bylaw requirements. The MPSC does not anticipate this will be necessary given the nature of the changes, but will evaluate cases individually as needed to address any unintended consequences.

## How will members implement this proposal?

No action will be required of members upon the implementation of this proposal. The proposal addresses how members that are noncompliant with OPTN Obligations are reviewed; it does not impact member responsibilities to comply with OPTN Obligations. Following implementation, members recognized by the OPTN as being potentially noncompliant with OPTN Obligations will be reviewed by the MPSC as detailed in the proposal. Members will be expected to be responsive to any MPSC request, which is unchanged from the current Bylaws.

## Transplant Hospitals

The overwhelming majority of transplant hospitals will not be impacted by this proposal. Transplant hospitals engaged by the MPSC with matters that prompt an interview request could potentially see some cost savings under the proposal. The largest savings would be realized through the possibility of having interviews via teleconference instead of at an MPSC in-person meeting, and through the MPSC's

flexibility of being able to continue working with members after an interview instead of the current common outcome of advancing to a hearing.

## **OPOs**

The overwhelming majority of OPOs will not be impacted by this proposal. OPOs engaged by the MPSC with matters that prompt an interview request could potentially see some cost savings under the proposal. The largest savings would be realized through the possibility of having interviews via teleconference instead of at an MPSC in-person meeting, and through the MPSC's flexibility of being able to continue working with members after an interview instead of the current common outcome of advancing to a hearing.

## **Histocompatibility Laboratories**

The overwhelming majority of histocompatibility laboratories will not be impacted by this proposal. Histocompatibility laboratories engaged by the MPSC with matters that prompt an interview request could potentially see some cost savings under the proposal. The largest savings would be realized through the possibility of having interviews via teleconference instead of at an MPSC in-person meeting, and through the MPSC's flexibility of being able to continue working with members after an interview instead of the current common outcome of advancing to a hearing.

## **Will this proposal require members to submit additional data?**

No, this proposal does not require additional data collection.

## **How will members be evaluated for compliance with this proposal?**

This proposal does not impact member responsibilities to comply with OPTN Obligations. The proposal addresses how members who are noncompliant with OPTN Obligations are reviewed. Members are currently expected to be responsive to MPSC requests, and this proposal does not change this expectation. As such, there are no member compliance considerations that directly result from this proposal.

## **How will the sponsoring Committee evaluate whether this proposal was successful post implementation?**

The MPSC will monitor if these changes yield consequences that it did not anticipate. Should the changes result in any unanticipated negative consequences, the MPSC would work towards another solution that corrects those. A reduction in the number of hearings conducted by the MPSC, whether individual members engaged by the MPSC are repeatedly noncompliant with the same OPTN Obligation, and the timeliness of addressing potentially urgent and severe risks to patient health or public safety are three specific considerations that the MPSC will monitor. UNOS staff and the MPSC will continue to solicit feedback from members who participate in the MPSC review process to identify improvement opportunities.

## Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **RESOLVED**, that changes to OPTN Bylaws Article 1.1 (Membership Guidelines), and Appendices  
2 A.1 (General Membership Requirements), A.2 (Designated Transplant Program Requirement), A.3  
3 (Applying for Membership in the OPTN), B.1 (OPO Compliance), B.2 (OPO Performance  
4 Requirements), B.4 (Facilities and Services), B.5 (OPO Personnel), C.1 (Histocompatibility  
5 Laboratory Compliance), C.5 (Changes in Key Laboratory Personnel), C.6 (Histocompatibility  
6 Laboratory Policies and Procedures), D.1 (Transplant Hospital Compliance), D.2 (Geographic  
7 Requirements for Transplant Hospitals), D.8 (Changes in Key Transplant Program Personnel),  
8 D.10 (Investigation of Transplant Personnel), D.11 (Review of Transplant Program Functional  
9 Activity), D.12 (Additional Transplant Program Requirements), G.2 (Primary Pancreas Transplant  
10 Surgeon Requirements), G.3 (Primary Pancreas Transplant Physician Requirements), I.2 (Primary  
11 Lung Transplant Surgeon Requirements), I.3 (Primary Lung Transplant Physician Requirements),  
12 L (Reviews, Actions, and Due Process), M (Definitions), as set forth below, are hereby approved,  
13 effective June 13, 2018.  
14

### **Article I: Membership**

#### **1.1 Membership Requirements Guidelines**

##### **E. Member Compliance**

18 By accepting membership in the OPTN, each member agrees to comply with all OPTN  
19 Obligations, which include all of the following applicable provisions of the:

- 20  
21 1. All applicable provisions of the:  
22 a. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.  
23 b. OPTN Final Rule, 42 CFR Part 121  
24 c. OPTN Bylaws  
25 d. OPTN Policies  
26 2. Acting to avoid risks to patient health or public safety  
27 3. Fulfilling all requests for information  
28

##### **F. Member Reviews and Evaluations**

30 The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital,  
31 histocompatibility, and OPO member for compliance with OPTN Obligations. ~~the OPTN Final~~  
32 ~~Rule, OPTN Bylaws and OPTN Policies. All OPTN members are monitored for compliance with~~  
33 ~~the OPTN Final Rule, OPTN Bylaws and OPTN Policies. All compliance monitoring is performed~~  
34 ~~using guidelines developed by the OPTN Contractor. Any member who no longer qualifies as an~~  
35 ~~OPTN member according to the requirements of these Bylaws will be dealt with according to~~  
36 ~~Appendix L: Reviews, Actions and Due Process of these Bylaws.~~  
37

##### **G. Reporting Potential Noncompliance with OPTN Obligations**

39 Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform  
40 the OPTN as soon as the member becomes aware of the issue, including potential  
41 noncompliance by the member itself.  
42

43 All incidences of potential noncompliance are referred for further review as outlined in these  
44 Bylaws. Any member who fails to comply with OPTN Obligations may be subject to actions as set  
45 forth in these Bylaws.

46  
47 ~~At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when~~  
48 ~~the Secretary has reason to believe that the member may be acting in a way that poses a risk to~~  
49 ~~patient health or public safety.~~

## 50 51 **FH. Affiliated Organizations**

52 The OPTN Bylaws do not in any way require an OPTN member to:

- 53  
54 1. Become a member of any organization that is a parent, sponsor, contractor, or affiliated  
55 organization of the OPTN.  
56 2. Comply with bylaws of any parent, sponsor, contractor, or affiliated organization of the OPTN.  
57 3. Assume any corporate duties or obligations of any parent, sponsor, contractor, or affiliated  
58 organization of the OPTN.  
59

## 60 **GI. Removal of Members**

61 Transplant hospital members who no longer qualify as an OPTN member will be ~~treated~~ reviewed  
62 according to Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process~~  
63 ~~of these Bylaws.~~

64  
65 All other OPTN members who no longer qualify for OPTN membership may be removed as  
66 members through any of the following procedures:  
67

- 68 ■ The member itself may request to voluntarily withdraw from OPTN membership by forwarding  
69 a written request to the Executive Director.  
70 ■ The OPTN may notify the member in writing that, unless the member demonstrates within  
71 ~~sixty (60)~~ days of notification that it continues to meet applicable membership criteria, the  
72 member's OPTN membership will be terminated, even if the member does not request  
73 removal.  
74

75 If, within ~~sixty (60)~~ days of notification, the member demonstrates, to the satisfaction of the  
76 OPTN, that the member meets OPTN membership requirements, the OPTN will withdraw its  
77 notice of termination.  
78

79 If the member fails to demonstrate that it continues to meet OPTN membership requirements, its  
80 membership in the OPTN will terminate on the 60th day after notification of termination by the  
81 OPTN. The member can appeal this decision to the Secretary of the U.S. Department of Health  
82 and Human Services (HHS). In the event a member exercises this right of appeal, the member  
83 will notify the OPTN Contractor of this by any method that can be tracked and provides proof of  
84 receipt, such as:  
85

- 86 ■ Commercial overnight delivery service  
87 ■ Secure electronic communication  
88 ■ Registered or certified mail, return receipt requested  
89

Pending a decision on the appeal, the removal process will continue unless the Secretary of HHS directs otherwise. If the appeal is denied, the process will be continued or reinitiated, as applicable. Any other decision by the Secretary of HHS will be submitted to the Membership and Professional Standards Committee (MPSC) or Board of Directors to act on the Secretary's decision.

Any member removed from OPTN membership for any reason may later reapply for membership.

The Board of Directors will periodically review these requirements and update these Bylaws with additional membership requirements for members. Failure to fulfill such requirements will be cause for any corrective action described in Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

## 1.2 Transplant Hospital Members

A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.

### E. Removal of Transplant Hospital Members

Transplant hospital members who no longer meet the qualifications as an OPTN member will be ~~treated~~ reviewed according to Appendix L: Reviews and Actions. ~~Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

## Appendix A: Membership Application and Review

This appendix outlines the application process for membership in the OPTN. It includes information about completing the membership application, the application review process, and application approval for transplant hospital, organ procurement organization (OPO), histocompatibility laboratory, individual, Medical/Scientific, public organization, and business members.

### A.1 General Membership Requirements

~~To become a member and maintain membership status in the OPTN, organizations and individuals must do all of the following:~~

- ~~1. Complete the OPTN membership application process.~~
- ~~2. Consistently meet all OPTN obligations established by the OPTN Board of Directors.~~
- ~~3. Comply with the OPTN Charter, Bylaws, and Policies.~~

For more information on membership types, terms, voting privileges, and responsibilities, see *Article I: Membership* of these Bylaws.

### A.2 Designated Transplant Program Requirement

~~Every transplant hospital member must have current approval as a designated transplant program for at least one organ. A transplant hospital can receive approval as a designated transplant program for one or more organs through the application process described in this Appendix A. Transplant hospitals must complete separate applications for each organ-specific designated transplant program at the hospital.~~

135 **A.13 Applying for Membership in the OPTN**

136 The Membership and Professional Standards Committee (MPSC) reviews each application for  
137 membership ~~under confidential medical peer review~~ and makes recommendations for approval or  
138 rejection of the application to the Board of Directors.

139  
140 The Board of Directors makes all final decisions regarding membership and designated transplant  
141 program applications.

142  
143 Every transplant hospital member must have current approval as a designated transplant program for at  
144 least one organ. Any hospital applying for transplant hospital membership must also submit the required  
145 application for approval as a designated transplant program for at least one organ.

146  
147 Applications for OPTN Membership and designated transplant program approval must be submitted on  
148 the form provided by the OPTN Contractor, and signed by a representative of the applicant who can  
149 certify that the information, including any supporting documents, is accurate.

150  
151 **A. Conditions for Application**

152 By submitting a signed application for membership in the OPTN, each applicant and member  
153 agrees to *all* of the following:

- 154  
155 1. That any and all information collected as part of the application may be released to the  
156 Department of Health and Human Services (HHS). Members also agree that any and all  
157 information provided as part of the monitoring and enforcement of OPTN membership  
158 requirements, policies and Federal regulations may be released to HHS.
- 159 2. If an adverse ruling is made regarding membership or designated transplant program  
160 approval, the member will exhaust the administrative remedies provided in these Bylaws and  
161 applicable Federal regulations before resorting to formal legal action.
- 162 3. That the applicant has received and read the current OPTN Charter, Bylaws, and Policies  
163 and agrees to be bound by the terms of these documents during the application process and  
164 if granted membership.
- 165 4. That transplant hospital, OPO, and histocompatibility laboratory members will provide  
166 evidence of current liability insurance of at least one million dollars from an insurer that is  
167 either licensed or approved by the insurance regulatory agency of the state where the  
168 applicant's principal office is located. A current certificate of insurance must be available and  
169 provided to the OPTN Contractor on request. In place of liability insurance, the member can  
170 provide proof of coverage through a self-insurance fund, and must provide documentation  
171 that the fund provides equivalent coverage.
- 172 5. To accept the conditions of the Statement of Release and Immunity from Liability as written  
173 below.

174  
175 **Statement of Release and Immunity from Liability**

176 As used in this section, the following definitions apply:

- 177  
178 1. *OPTN Contractor and its representatives* means the corporation currently  
179 operating the OPTN under contract with HHS, its officers, its Board of Directors,  
180 its appointed representatives or employees, consultants, the Contractor's  
181 attorneys, assistants or designees, and all members, organizations or other  
182 persons who have any responsibility for obtaining or evaluating applicant or  
183 member qualifications or acting upon the application for membership or



184 designated transplant program status. This includes any authorized  
185 representative of any of the entities or persons noted in this paragraph.

186  
187 2. *A third party means* all individuals or government agencies, organizations,  
188 associations, partnerships and corporations, from whom information has been  
189 requested by the OPTN Contractor or its authorized representatives. This  
190 includes anyone who requests or receives information from the OPTN and its  
191 authorized representatives.

192  
193 The following are conditions that apply to any applicant or OPTN member. An applicant  
194 accepts the following conditions throughout the application process, whether or not the  
195 applicant is granted membership or approval as a designated transplant program:

196  
197 a. To the fullest extent permitted by law, the applicant or member gives absolute  
198 immunity to, and releases the OPTN Contractor, its representatives, and any  
199 third party from any and all liability resulting from any acts, communications,  
200 reports, recommendations, or disclosures involving an applicant or member. This  
201 includes disclosures to, from, or by any third party, including other members,  
202 concerning activities within the scope of the OPTN Contract including but not  
203 limited to:

- 204 i. Applications for membership or designation as a transplant program;
- 205 ii. Proceedings regarding monitoring and enforcement of membership
- 206 requirements, change in membership or designated transplant program
- 207 status, termination of membership, or other policies of or regulations
- 208 concerning the OPTN
- 209 ~~iii. Hearings and appellate reviews~~
- 210 ~~iv. Other committee activities relating to the membership status or~~
- 211 ~~designated transplant program status of an applicant or member. This includes~~
- 212 ~~statements, investigations, materials provided, or inquiries, oral or written,~~
- 213 ~~relating to an applicant's or member's qualifications, as well as the review of all~~
- 214 ~~relevant records and documents~~

215  
216  
217 b. Any act, communication, report, recommendation or disclosure, with respect to  
218 any applicant or member made in good faith and at the request of the OPTN  
219 Contractor and its representatives, anywhere and at any time, for the purposes  
220 described in (a) above are privileged to the fullest extent permitted by law as part  
221 of the OPTN medical peer review. The medical peer review privilege extends to  
222 any third parties who either supply or are supplied information and are authorized  
223 to receive, release or act upon the same.

224 c. The immunity and release from liability provided in this section shall not apply to  
225 acts of willful misconduct by the OPTN Contractor and its representatives.

226  
227 **B. Initial Review of the Membership Application**

228 To initiate the review of any new membership application, the applicant must deliver a completed  
229 application, including all requested supporting documentation to the Chair of the MPSC, the  
230 Executive Director, or their designated representative. The MPSC will not accept applications for  
231 review that are incomplete or missing supporting documentation.

232  
233 Designated staff of the OPTN Contractor will conduct a preliminary review of all submitted  
234 applications to ensure that they are complete. This initial review will occur for all application types.

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New membership applications that are not completed correctly or are missing information will be considered incomplete. The OPTN Contractor will not forward incomplete applications to the MPSC for review. The MPSC Chair, the Executive Director, or their designated representative will notify the applicant if an application is incomplete and provide guidelines for correctly completing the application. It is ultimately the applicant’s responsibility to obtain and submit the missing information necessary for the application to be reviewed.

**C. MPSC Review of the Completed Membership Application**

The Board of Directors makes all final decisions regarding membership and transplant program applications. Before being considered by the Board, the MPSC reviews all applications and submits a written report with recommendations regarding the application to the Board of Directors. The MPSC Chair, or a chosen representative, may appoint an MPSC subcommittee of at least four MPSC members to review the completed application and supporting documentation. The MPSC subcommittee may make recommendations regarding applications for membership or approval as a designated transplant program. The MPSC subcommittee’s recommendations are advisory to the MPSC and the Board of Directors.

**MPSC Subcommittee Review and Recommendation**

A unanimous decision of approval by the MPSC subcommittee reviewing the application will result in interim approval of the application. Interim approval means that the member may function as an OPTN member while awaiting review by the entire MPSC and the Board of Directors. A member granted interim approval does not have voting privileges on OPTN matters.

If any member of the MPSC subcommittee recommends rejection of the application, the applicant will not receive interim approval, and the application will be reviewed by the entire MPSC at its next meeting.

**MPSC Review and Recommendation**

All applications reviewed by the MPSC subcommittee are sent to the entire MPSC for review at its next meeting. Based on the review at this meeting, the Chair will submit a written report with recommendations regarding the application to the Board of Directors. This report includes:

1. The reason for each recommendation, supported by citations to the completed application and any other documentation considered by the MPSC.
2. All dissenting or minority views that differ from the final recommendation, also supported by citations to the completed application and any other documentation considered by the MPSC.

**Interim MPSC Approval of the Membership Application**

An application approved by the entire MPSC receives interim approval until final review by the Board of Directors. This approval is in effect until a final determination is made by the Board of Directors.

- 282 Interim approval will:  
283  
284 1. Grant the applicant OPTN membership or designated transplant program approval,  
285 as applicable.  
286 2. Expire when and if the full Board rejects the interim action.  
287

### 288 **Interim MPSC Rejection of the Membership Application**

289 The MPSC must offer the applicant an interview if the MPSC recommends that the Board  
290 of Directors rejects a membership application. The applicant may also be entitled to a  
291 hearing with the MPSC and an appearance before the Board of Directors prior to the  
292 Board of Directors taking a final action on any MPSC recommendation. Any interviews,  
293 hearings, or Board of Directors appearances that occur as part of the membership  
294 application process will be held according to *Appendix L: Reviews and Actions*.  
295

296 Any applicant rejected for membership by the MPSC may request due process. For more  
297 information about the due process options available after a membership rejection, see  
298 *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. If it is going to do so,  
299 the applicant must exercise its due process rights before the adverse recommendation is  
300 submitted to the Board of Directors by the MPSC.  
301

### 302 **D. Final Board of Director’s Review of the Membership Application**

303 When the MPSC recommends that an application be approved, the MPSC Chair will forward the  
304 MPSC’s report and recommendation to the Board of Directors.  
305

306 The Board of Directors will review the application and act on it during its next regular meeting if  
307 the following conditions are met:

- 308  
309 1. The Board of Directors receives the recommendation from the MPSC at least 10 business  
310 days before the meeting.  
311 2. A quorum is present at the meeting.

312  
313 Any application not received at least 10 business days before the meeting will not be considered  
314 until the next regular Board meeting at which a quorum is present. If the MPSC gave the  
315 application interim approval, a decision to defer the matter will continue the interim approval until  
316 the next regular meeting of the Board of Directors where a quorum is present.  
317

318 A majority vote of the Directors present at any meeting at which a quorum is present is required  
319 to approve a new member.  
320

321 ~~A recommendation for rejection by the Board of Directors entitles the applicant to due process as~~  
322 ~~specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The applicant may~~  
323 ~~also make a written appeal to the Secretary within 30 days of the final rejection of the application~~  
324 ~~by the Board of Directors.~~  
325

### 326 **E. Appeals to the Secretary**

327 Applicants rejected for membership in the OPTN or for designation as a transplant program may  
328 appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the  
329 application. The Secretary may deny the appeal or direct the OPTN to take action consistent with  
330 the Secretary’s response to the appeal.  
331

## 332 **Appendix B: Membership Requirements for Organ** 333 **Procurement Organizations (OPOs)**

334 An OPO member is any OPO that has been designated by the Secretary of the U.S. Department of  
335 Health and Human Services (HHS) under *Section 1138(b)* of the Social Security Act or any organization  
336 that meets all requirements under *Section 1138(b)*, except for OPTN membership.

337  
338 Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has  
339 a distinct governing body separate from any transplant hospital or commonly controlled group of  
340 transplant hospitals it serves.

341  
342 A hospital-based OPO is not independent from the transplant hospital it serves. Hospital-based OPOs are  
343 held to the same standards and requirements as OPO members, but do not have a vote on OPTN  
344 business separate from the vote granted the transplant hospital member that controls it.

345  
346 For more information on membership types, terms, voting privileges, and responsibilities, see *Article I:*  
347 *Membership* of these Bylaws.

### 349 **B.1 OPO Compliance**

350 By accepting membership in the OPTN, OPOs agree to comply with all OPTN Obligations according to  
351 Article 1.1.E: Member Compliance. ~~applicable provisions of the:~~

- 352  
353 ~~1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~  
354 ~~2. OPTN Final Rule, 42 CFR Part 121~~  
355 ~~3. OPTN Bylaws~~  
356 4. OPTN Policies

357 ~~The OPTN will conduct ongoing periodic reviews and on-site evaluations of each OPO for compliance~~  
358 ~~with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. OPOs must also fulfill all requests for~~  
359 ~~information from the OPTN Contractor as required to determine compliance. All compliance monitoring is~~  
360 ~~performed using procedures developed by the OPTN Contractor. Any OPO that no longer qualifies as an~~  
361 ~~OPTN member according to the requirements of these Bylaws will be dealt with according to *Appendix L:*~~  
362 ~~*Reviews, Actions, and Due Process* of these Bylaws.~~

363  
364 If any regulatory agency takes a final adverse action against an OPO, the OPO must notify the OPTN  
365 Contractor in writing within 10 business days. The OPO must also provide all documents relating to the  
366 final adverse action to the OPTN Contractor.

### 368 **B.2 OPO Performance Requirements**

369 The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if  
370 the difference in observed and expected organ yield can be accounted for by some unique aspect of the  
371 Donation Service Area or OPO in question. ~~The evaluation may include a peer visit to the OPO at the~~  
372 ~~OPO's expense.~~

373  
374 Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified  
375 threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for  
376 different organs, and may be reviewed and modified by the MPSC after distribution to the transplant  
377 community and subsequent Board approval.

378  
379 The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for  
380 each organ type, will include *all* of the following:  
381

- 382 1. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-  
383 Expected per 100 donors < -10).  
384 2. A ratio of observed to expected yield less than 0.90.  
385 3. A two-sided p-value is less than 0.05.

386  
387 All three criteria must be met for an OPO to be identified for MPSC review.  
388

389 If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the  
390 OPO or Donation Service Area in question, the member, in cooperation with the MPSC, will adopt and  
391 promptly implement a plan for performance improvement. The member's failure to adopt and promptly  
392 implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and  
393 may result in an OPTN action according to Appendix L: Reviews and Actions. The member's failure to do  
394 so will constitute a violation of OPTN obligations.

395  
396 As part of this process, the MPSC may conduct a peer visit to the OPO at the member's expense. The  
397 MPSC may also require, at its discretion, that the member participate in an informal discussion. The  
398 informal discussion will be conducted according to Appendix L: Reviews and Actions.  
399

## 400 **B.4 Facilities and Services**

401 OPOs must have extensive facilities to be fully operational. OPOs must also provide a number of services  
402 as part of their daily operations. These required facilities and services are described in the sections that  
403 follow.  
404

### 405 **E. Organ Allocation Plans**

406 Each OPO is responsible for equitable and efficient organ allocation within their DSAs that  
407 adheres to OPTN obligations. To meet this requirement, each OPO must have the necessary  
408 procedures and technology to communicate information to distribute organs to transplant  
409 candidates at transplant hospitals within and beyond its service area.  
410

411 Each OPO must have a plan to equitably allocate donated organs among transplant patients that  
412 is consistent with the obligations of the OPTN. An OPO must demonstrate ~~is it~~ has policies and  
413 procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these  
414 requirements will be considered a noncompliance with OPTN Obligations that may result in an  
415 OPTN action according to Appendix L: Reviews and Actions. Failure to comply with these  
416 requirements could result in corrective action as described in Appendix L: Reviews, Actions, and  
417 Due Process of these Bylaws, if applicable, or result in a recommendation to the Board of  
418 Directors to notify the Secretary of HHS.  
419

## 420 **B.5 OPO Personnel**

421 Each OPO must have personnel who are qualified to effectively recover organs from all donors in its  
422 DSA. Each OPO must have the necessary staff to recover and distribute organs according to OPTN  
423 obligations, including an administrative director, a medical director, an organ donation coordinator, and an  
424 organ procurement specialist.  
425

### 426 **E. Failure to Report Changes in Key OPO Personnel**

427 An OPO's failure to notify the OPTN Contractor of a change in the administrative or medical  
428 director will be considered a noncompliance with OPTN Obligations that may result in an OPTN  
429 action according to Appendix L: Reviews and Actions.  
430

431 ~~Failure to inform the OPTN Contractor of changes in the administrative director or medical~~  
432 ~~director may result in corrective action as described in Appendix L: Reviews, Actions, and Due~~  
433 ~~Process of these Bylaws, including adverse actions as defined in L.15. OPTN Determinations and~~

434 *Actions.*

435  
436  
437  
438  
439

The OPO must notify the MPSC if it has not filled a vacant administrative or medical director position within six months. The MPSC could then recommend that the OPTN Board of Directors notify the Secretary of HHS of the OPO's failure to fill the position.

440 **Appendix C:**  
441 **Membership Requirements for Histocompatibility**  
442 **Laboratories**

443 **C.1 Histocompatibility Laboratory Compliance**

444 Each histocompatibility laboratory member must comply with all OPTN Obligations according to Article  
445 1.1.E: Member Compliance and both ~~all~~ of the following:

446

447 ~~1. All application provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~

448 ~~2. All application provisions of the OPTN Final Rule, 42 CFR Part 121~~

449 ~~3. The OPTN Charter~~

450 ~~4. All OPTN Bylaws and Policies~~

451 ~~5.~~ 1. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR §  
452 493.1278, unless exempt

453 2. The requirements, as they apply to solid organ and islet transplantation, of the American Society  
454 for Histocompatibility and Immunogenetics (ASHI) 2013 Revised Standards for Accredited  
455 Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory  
456 General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality  
457 Checklist as of April 21, 2014. This requirement does not mandate membership in either ASHI or  
458 CAP.

459

460 If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory  
461 must notify the OPTN Contractor in writing within 10 business days. The histocompatibility laboratory  
462 must also provide all documents relating to the final adverse action to the OPTN Contractor.

463

464 **C.5 Changes in Key Laboratory Personnel**

465 **B. Failure to Notify the OPTN Contractor of Key Personnel Changes**

466 A histocompatibility laboratory's failure to inform the OPTN Contractor of a change in the  
467 laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the  
468 required Personnel Change Application within the periods specified will be considered a  
469 noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix  
470 L: Reviews and Actions.

471

472 ~~Any histocompatibility laboratory that fails to inform the OPTN Contractor of a change in the~~  
473 ~~laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the~~  
474 ~~required Personnel Change Application within the periods specified above will be reviewed by the~~  
475 ~~MPSC. The MPSC may impose a sanction, including, but not limited to, any of the following:~~

476

477 ~~1. Notice of Uncontested Violation~~

478 ~~2. Letter of Warning~~

479 ~~3. Letter of Reprimand~~

480

481 Failure to inform the OPTN Contractor of changes in key personnel or to submit the required  
482 Personnel Change Application will result in a recommendation that the Board of Directors take  
483 appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of  
484 Health and Human Services (HHS) of the violation.  
485

### 486 **C. Rejected Key Personnel Change Applications**

487 The MPSC must offer the applicant an interview if the MPSC rejects a Key Personnel Change  
488 application. The applicant may also be entitled to a hearing with the MPSC and an appearance  
489 before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that  
490 occur as part of the Key Personnel Change application process will be conducted according to  
491 Appendix L: Reviews and Actions.  
492

## 493 **C.6 Histocompatibility Laboratory Policies and Procedures**

### 494 **C. Periodic Reviews**

495 ~~In order to determine compliance with the requirements and regulations according to C.1.~~  
496 ~~Histocompatibility Laboratory Compliance, histocompatibility laboratory members will be~~  
497 ~~reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN~~  
498 ~~Contractor. Failure to comply with these rules and requirements will be cause for corrective action~~  
499 ~~as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~  
500

### 501 **D. Regulatory Agency Adverse Actions**

502 ~~If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the~~  
503 ~~laboratory must notify the OPTN Contractor within 10 business days. The histocompatibility~~  
504 ~~laboratory must also provide any documents relating to the final adverse action to the OPTN~~  
505 ~~Contractor, along with the final determination of the regulatory agency.~~  
506

### 507 **C.E. Inactive Status**

508 A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from  
509 membership will be ineligible and may not provide histocompatibility testing to any OPTN  
510 members.  
511

## 512 **Appendix D: Membership Requirements for** 513 **Transplant Hospitals and Transplant Programs**

### 514 **D.1 Transplant Hospital Compliance**

515 By accepting membership in the OPTN, transplant hospitals agree to comply with all OPTN Obligations  
516 according to Article 1.1.E: Member Compliance.  
517

518 If any regulatory agency takes a final adverse action against a transplant hospital, the transplant hospital  
519 must notify the OPTN Contractor in writing within 10 business days. The transplant hospital must also  
520 provide all documents relating to the final adverse action to the OPTN Contractor.  
521

522 ~~Transplant hospital members agree to:~~

- 523
- 524 ~~1. Review and abide by the OPTN Final Rule, Bylaws, Policies and applicable provisions of the National~~  
525 ~~Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
- 526 ~~2. Comply with all obligations of OPTN membership.~~
- 527 ~~3. Submit to reviews and on-site evaluations to monitor compliance with membership requirements.~~

- 528 ~~4. Fulfill all requests for information.~~  
529 ~~5. Notify the OPTN Contractor within 10 business days if any regulatory agency takes a final adverse~~  
530 ~~action against the transplant hospital and then provide any documents relating to the final adverse~~  
531 ~~action to the OPTN Contractor.~~

532  
533 For more information, see ~~Article I: Membership of these Bylaws.~~

## 534 **D.2 Geographic Requirements for Transplant Hospitals**

535 A transplant hospital must be entirely within a single donation service area (DSA) and all of its operating  
536 room facilities used for organ transplantation must be under common executive leadership and  
537 governance oversight, demonstrated to the satisfaction of the OPTN.

538  
539 All transplant hospital operating rooms where transplants are performed must also meet at least *one* of  
540 these requirements:

- 541  
542
  - Are within a geographically contiguous campus
  - 543 ▪ Are within a one mile walking distance from the main hospital's physical address

544 Each operating room that the transplant hospital may use to perform transplants must be documented  
545 with the OPTN prior to its use for transplant surgery. This operating room documentation requirement  
546 includes any additional transplant operating rooms that are not listed on the transplant hospital's initial  
547 application. Documentation of the operating rooms where organ transplants may occur must at least  
548 include *all* of the following:

- 549  
550
  1. Maps that illustrate the transplant hospital campus and the location of each operating room facility
  - 551 2. Building name and address
  - 552 3. Floor number
  - 553 4. Unit identifier

554  
555 Transplant hospitals that do not meet these requirements will not be approved as a single transplant  
556 hospital and will require separate OPTN memberships, unless the transplant hospital is approved  
557 according to *D.2.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established*  
558 *Geographic Boundaries*. ~~Any application recommended for rejection by the MPSC or the Board of~~  
559 ~~Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due*~~  
560 ~~*Process* of these Bylaws.~~

## 561 **C. Review of Pediatric Transplant Activity at Transplant Hospitals** 562 **that Share a Campus** 563

564 Transplant hospitals that primarily serve pediatric patients, and that share a campus with another  
565 transplant hospital, will be reviewed periodically by the MPSC to verify that it performed 50  
566 percent or more of its transplants in patients less than 18 years of age during the previous 12  
567 months. Any transplant hospital that is identified as not meeting this 50 percent threshold in any  
568 12 month period will have the opportunity to explain its pediatric inactivity in a report to the  
569 MPSC.

570  
571 As part of its review of pediatric transplantation activity at transplant hospitals that share a  
572 campus, the MPSC may require that the member participate in an informal discussion. ~~The~~  
573 ~~informal discussion will be conducted according *Appendix L: Reviews and Actions*. The informal~~  
574 ~~discussion may be with the MPSC, a subcommittee, or a work group, as determined by the~~  
575 ~~MPSC. The informal discussion will be conducted according to the principles of confidential~~  
576 ~~medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these~~  
577 ~~Bylaws. The discussion is not an adverse action or an element of due process. A member who~~  
578 ~~participates in an informal discussion with the MPSC is entitled to receive a summary of the~~



579 discussion.

580

581 The MPSC may recommend that a transplant hospital sharing a campus with another transplant  
582 hospital inactivate due to one hospital no longer primarily serving pediatric patients. A member's  
583 failure to inactivate when the MPSC recommends it do so will be considered a noncompliance  
584 with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and  
585 Actions. ~~If the hospital fails to inactivate when the MPSC recommends it do so, the MPSC may~~  
586 ~~recommend that the Board of Directors take appropriate action as defined in Appendix L:~~  
587 ~~Reviews, Actions, and Due Process of these Bylaws.~~

588

589

## 590 **D.8 Changes in Key Transplant Program Personnel**

### 591 **E. Failure to Notify the OPTN Contractor of Key Personnel Changes**

592 A member's failure to notify the OPTN of a primary surgeon or physician change or to submit the  
593 required Personnel Change Application within the periods specified will be considered a  
594 noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix  
595 L: Reviews and Actions.

596

597 ~~Any member who fails to inform the OPTN Contractor of a change in the primary surgeon or~~  
598 ~~primary physician or to submit the required Personnel Change Application within the periods~~  
599 ~~specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including any~~  
600 ~~of the following:~~

601

602 ■ ~~A Notice of Uncontested Violation~~

603 ■ ~~Letter of Warning~~

604 ■ ~~Letter of Reprimand~~

605

606 ~~Each of these sanctions and other adverse actions that may be taken by the MPSC are further~~  
607 ~~described in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

608

609 ~~Failure to inform the OPTN Contractor of changes in primary surgeon or primary physician or to~~  
610 ~~submit the required Personnel Change Application will result in a recommendation that the Board~~  
611 ~~of Directors take appropriate adverse actions. Additionally, the Board of Directors may notify the~~  
612 ~~Secretary of Health and Human Services (HHS) of the violation.~~

613

### 614 **F. Processing Applications for Changes to Key Personnel**

615 When processing applications to change key personnel, the MPSC Chair is authorized to appoint  
616 an Ad hoc Subcommittee of at least two Committee members, other than the MPSC chair. This  
617 Ad hoc Subcommittee will review the credentials of the proposed new key personnel.

618

619 The Subcommittee may grant, with agreement of the MPSC Chair, interim approval effective until  
620 review by the entire MPSC at its next meeting. Interim approval will not extend beyond the next  
621 meeting of the entire MPSC and will automatically expire if the entire MPSC does not approve the  
622 interim approval.

623

624 Designated transplant programs must have qualified key personnel for the program at all times,  
625 including during the entire application process for changes in key personnel, regardless of the  
626 status of the application.

627

628 The MPSC must offer the member an interview if the MPSC rejects a Key Personnel Change  
629 application. The member may also be entitled to a hearing with the MPSC and an appearance  
630 before the Board of Directors. Any interviews, hearings, or Board of Directors appearances that

631 occur as part of the Key Personnel Change application process will be conducted according to  
 632 Appendix L: Reviews and Actions.

633  
 634 **D.10 Investigation of Transplant Personnel**

635 The transplant hospital must investigate any personnel on staff at a designated transplant program if  
 636 directed to do so by the MPSC. The MPSC will request an investigation to examine an individual's role in  
 637 a matter reviewed or currently under review by the MPSC, and explain the reason for the investigation  
 638 request to the transplant hospital. The transplant hospital must inform the MPSC when it has started the  
 639 investigation and when it completes the investigation. The transplant hospital must also provide  
 640 documentation that it conducted the investigation according to the requirements of these Bylaws.

641  
 642 The hospital's investigation must use the hospital's standard medical peer review process for conducting  
 643 inquiries of potential professional misconduct and conclude with appropriate action consistent with this  
 644 process.

645  
 646 A member's failure to investigate designated transplant program staff as directed will be considered a  
 647 noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L:  
 648 Reviews and Actions.

649  
 650 ~~Failure to comply with these requirements will result in a recommendation to the Board of Directors to~~  
 651 ~~notify the Secretary, or a recommendation to take appropriate action according to Appendix L: Reviews,~~  
 652 ~~Actions, and Due Process these Bylaws.~~

653  
 654 **D.11 Review of Transplant Program Functional Activity**

655  
 656 **A. Functional Inactivity**

657 Each transplant program must remain functionally active by performing a minimum number of  
 658 transplants. ~~Transplant program functional activity will be reviewed periodically by the MPSC. Any~~  
 659 ~~program identified as functionally inactive will have the opportunity to explain its inactivity in a~~  
 660 ~~report to the MPSC.~~ For purposes of these Bylaws, functional inactivity is defined as the failure to  
 661 perform a transplant during the periods defined in ~~the table below:~~ according to Table D-1 below.

662  
 663 **Table D-1: Functional Inactivity Periods**

<b>Program Type</b>	<b>Inactive Period</b>
<i>Kidney, Liver or Heart</i>	<i>3 consecutive months</i>
<i>Pancreas or Lung</i>	<i>6 consecutive months</i>
<i>Stand-alone pediatric transplant programs</i>	<i>12 consecutive months</i>

664  
 665 Functional inactivity thresholds have not been established for pancreatic islet, intestinal, and VCA  
 666 transplant programs.

667  
 668 **C. Review of Member Functional Inactivity**

669 Transplant program functional inactivity will be reviewed periodically by the MPSC. Any program  
 670 identified as functionally inactive will have the opportunity to explain its inactivity in a report to the  
 671 MPSC.

672  
 673 As part of its review of a program's functional inactivity, the MPSC may require, that the member  
 674 participate in an informal discussion. The informal discussion will be conducted according to  
 675 Appendix L: Reviews and Actions.

676  
 677 The MPSC may recommend that a program inactivate or withdraw its designated transplant  
 678 program status due to the program's functional inactivity. The MPSC must offer the member an

679 informal discussion before recommending that the program inactivate or withdraw its designated  
680 transplant program status. A program's failure to inactivate or withdraw its designated transplant  
681 program status when the MPSC recommends it do so will be considered a noncompliance with  
682 OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and  
683 Actions. ~~If the program fails to inactivate or withdraw its designated transplant program status~~  
684 ~~when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors~~  
685 ~~take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these~~  
686 ~~Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's~~  
687 ~~inactivity.~~

688

## 689 **D.12 Additional Transplant Program Requirements**

### 690 **A. Transplant Program Performance**

691 *Appendix D.12.A does not apply to VCA transplants.*

692

693 The MPSC will conduct reviews of transplant program performance to identify underperforming  
694 transplant programs and require the implementation of quality assessment and performance  
695 improvement measures. One measure of transplant program performance is triggered through a  
696 review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics  
697 produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to  
698 identify transplant programs that have lower than expected outcomes.

699

700 For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a  
701 transplant program if it has a higher hazard ratio of mortality or graft failure than would be  
702 expected for that transplant program. The criteria used to identify programs with a hazard ratio  
703 that is higher than expected will include *either* of the following:

704

- 705 1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
- 706 2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

707

708 For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a  
709 transplant program if the program has one or more events in a 2.5 year cohort.

710

711 The MPSC review will be to determine if the higher hazard ratio or events can be explained by  
712 patient mix or some other unique clinical aspect of the transplant program. If a program's  
713 performance cannot be explained by patient mix or some other unique clinical aspect of the  
714 transplant program, the program, in cooperation with the MPSC, will adopt and promptly  
715 implement a plan for quality improvement. The member's failure to adopt and promptly implement  
716 a plan for quality improvement will be considered a noncompliance with OPTN Obligations and  
717 may result in an OPTN action according to Appendix L: Reviews and Actions. ~~constitute a~~  
718 ~~violation of OPTN obligations.~~

719

720 As part of this process, the MPSC may conduct a peer visit to the program at the member's  
721 expense. The MPSC may also require, at its discretion, that the member participate in an informal  
722 discussion. The informal discussion will be conducted according to Appendix L: Reviews and  
723 Actions. ~~The informal discussion may be with the MPSC, a subcommittee, or a work group, as~~  
724 ~~determined by the MPSC. The informal discussion will be conducted according to the principles of~~  
725 ~~confidential medical peer review, as described in Appendix L of these Bylaws. The informal~~  
726 ~~discussion is not an adverse action or an element of due process. A member who participates in~~  
727 ~~an informal discussion with the MPSC is entitled to receive a summary of the discussion.~~

728

729 The MPSC may recommend that a member inactivate a program, or a component of a program,  
730 or withdraw its designated transplant program status based on patient safety concerns arising  
731 from review of the program's graft and patient survival. The MPSC must offer the member an  
732 informal discussion before recommending that the program inactivate or withdraw its designated

733 transplant program status. A program's failure to inactivate or withdraw its designated transplant  
734 program status when the MPSC recommends it do so will be considered a noncompliance with  
735 OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and  
736 Actions. ~~If the program fails to inactivate or withdraw its designated transplant program status~~  
737 ~~when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors~~  
738 ~~take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these~~  
739 ~~Bylaws.~~

## 740 **Appendix G: Membership and Personnel**

### 741 **Requirements for Pancreas and Pancreatic Islet**

### 742 **Transplant Programs**

#### 743 **G.2 Primary Pancreas Transplant Surgeon Requirements**

##### 744 **C. Alternate Pathway for Predominantly Pediatric Programs**

745 If a surgeon does not meet the requirements for primary pancreas transplant surgeon through  
746 either the 2-year transplant fellowship pathway or clinical experience pathway as described  
747 above, transplant programs that serve predominantly pediatric patients may petition the MPSC in  
748 writing to consider the surgeon for primary transplant surgeon if the program can demonstrate  
749 that the following conditions are met:

- 751 1. The surgeon's pancreas transplant training or experience is equivalent to the fellowship or  
752 clinical experience pathways as described in *Sections G.2.A or G.2.B* above.
- 753 2. The surgeon has maintained a current working knowledge of all aspects of pancreas  
754 transplantation and patient care, defined as direct involvement in pancreas transplant patient  
755 care within the last 2 years.
- 756 3. The surgeon submits a letter of recommendation from the training program's primary surgeon  
757 and director at the fellowship training program or transplant program last served by the  
758 surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon,  
759 as well as the surgeon's personal integrity, honesty, and familiarity with and experience in  
760 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may  
761 request additional recommendation letters from the primary physician, primary surgeon,  
762 director, or others affiliated with any transplant program previously served by the surgeon, at  
763 its discretion.
- 764 4. The hospital participates in an informal discussion with the MPSC.

765 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
766 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
767 determinations are:

- 770 ■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant  
771 approval of a designated transplant program.
- 772 ■ Effective temporarily, pending final decision by the MPSC or Board.

773 The MPSC must offer the member an interview if the MPSC recommends that the Board of  
774 Directors rejects a membership application. The member may also be entitled to a hearing with  
775 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
776 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
777 appearances that occur as a part of a membership application process will be held according to  
778 Appendix L: Reviews and Actions.  
779

780  
781 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
782 ~~applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these~~  
783 ~~Bylaws.~~

### 784 **G.3 Primary Pancreas Transplant Physician Requirements**

#### 785 **C. Alternative Pathway for Predominantly Pediatric Programs**

786  
787 If a physician does not meet the requirements for primary physician through the transplant  
788 fellowship or clinical experience pathways as described above, transplant programs that serve  
789 predominantly pediatric patients may petition the MPSC in writing to consider the physician for  
790 primary transplant physician if the program can demonstrate that the following conditions are met:

- 791 1. That the physician's pancreas transplant training or experience is equivalent to the fellowship  
792 or clinical experience pathways as described in *Sections G.3.A and G.3.B* above.
- 793 2. The physician has maintained a current working knowledge of all aspects of pancreas  
794 transplantation, defined as direct involvement in pancreas transplant patient care within the  
795 last 2 years.
- 796 3. The physician submits a letter of recommendation from the primary physician and transplant  
797 program director at the fellowship program or transplant program last served by the physician  
798 outlining the physician's overall qualifications to act as a primary transplant physician, as well  
799 as the physician's personal integrity, honesty, and familiarity with and experience in adhering  
800 to OPTN obligations, and any other matters judged appropriate. The MPSC may request  
801 additional recommendation letters from the primary physician, primary surgeon, director, or  
802 others affiliated with any transplant program previously served by the physician, at its  
803 discretion.
- 804 4. The hospital participates in an informal discussion with the MPSC.

805  
806 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
807 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
808 decisions are:

- 809 ■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant  
810 approval of a designated transplant program.
- 811 ■ Effective temporarily, pending final decision by the MPSC or Board.

812  
813 The MPSC must offer the member an interview if the MPSC recommends that the Board of  
814 Directors rejects a membership application. The member may also be entitled to a hearing with  
815 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
816 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
817 appearances that occur as a part of a membership application process will be held according to  
818 *Appendix L: Reviews and Actions*.

819  
820 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
821 ~~applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these~~  
822 ~~Bylaws.~~

826 **Appendix I: Membership and Personnel Requirements**  
827 **for Lung Transplant Programs**

828 **I.2 Primary Lung Transplant Surgeon Requirements**

829 **D. Alternative Pathway for Predominantly Pediatric Programs**

830 If a surgeon does not meet the requirements for primary lung transplant surgeon through either the  
831 training or clinical experience pathways described above, hospitals that serve predominantly  
832 pediatric patients may petition the MPSC in writing to consider the surgeon for primary transplant  
833 surgeon if the program can demonstrate that the following conditions are met:  
834

- 835 1. The surgeon's lung transplant training or experience is equivalent to the residency,  
836 fellowship, or clinical experience pathways as described in *Sections 1.2.A through 1.2.C*  
837 above.
- 838 2. The surgeon has maintained a current working knowledge of all aspects of lung  
839 transplantation and patient care, defined as direct involvement in lung transplant patient care  
840 within the last 2 years.
- 841 3. The surgeon submits a letter of recommendation from the primary surgeon and transplant  
842 program director of the fellowship training program or transplant program last served by the  
843 surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon,  
844 as well as the surgeon's personal integrity, honesty, and familiarity with and experience in  
845 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may  
846 request additional recommendation letters from the primary physician, primary surgeon,  
847 director, or others affiliated with any transplant program previously served by the surgeon, at  
848 its discretion.
- 849 4. The hospital participates in an informal discussion with the MPSC.

850  
851 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
852 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
853 determinations are:  
854

- 855 ■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant  
856 approval of a designated transplant program.
- 857 ■ Effective temporarily, pending final decision by the MPSC or Board.

858  
859 The MPSC must offer the member an interview if the MPSC recommends that the Board of  
860 Directors rejects a membership application. The member may also be entitled to a hearing with  
861 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
862 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
863 appearances that occur as a part of a membership application process will be held according to  
864 Appendix L: Reviews and Actions.  
865

866 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
867 ~~applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these~~  
868 ~~Bylaws.~~  
869

870 **I.3 Primary Lung Transplant Physician Requirements**

871 **C. Alternative Pathway for Predominantly Pediatric Programs**

872 If a physician does not meet the requirements for primary physician through any of the transplant

873 fellowship or clinical experience pathways as described above, hospitals that serve predominantly  
874 pediatric patients may petition the MPSC in writing to consider the physician for primary transplant  
875 physician if the program can demonstrate that the following conditions are met:

- 876
- 877 1. That the physician’s lung transplant training or experience is equivalent to the fellowship or  
878 clinical experience pathways as described in *Sections 1.3.A* and *1.3.B* above.
  - 879 2. The physician has maintained a current working knowledge of all aspects of lung  
880 transplantation, defined as direct involvement in lung transplant patient care within the last 2  
881 years.
  - 882 3. The physician submits a letter of recommendation from the primary physician and transplant  
883 program director of the fellowship training program or transplant program last served by the  
884 physician outlining the physician’s overall qualifications to act as a primary transplant  
885 physician, as well as the physician’s personal integrity, honesty, and familiarity with and  
886 experience in adhering to OPTN obligations, and any other matters judged appropriate. The  
887 MPSC may request additional recommendation letters from the primary physician, primary  
888 surgeon, director, or others affiliated with any transplant program previously served by the  
889 physician, at its discretion.
  - 890 4. The hospital participates in an informal discussion with the MPSC.

891  
892 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
893 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
894 decisions are:

- 895
- 896 ■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant  
897 approval of a designated transplant program.
  - 898 ■ Effective temporarily, pending final decision by the MPSC or Board of Directors.

899  
900 The MPSC must offer the member an interview if the MPSC recommends that the Board of  
901 Directors rejects a membership application. The member may also be entitled to a hearing with  
902 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
903 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
904 appearances that occur as a part of a membership application process will be held according to  
905 Appendix L: Reviews and Actions.

906  
907 Any application recommended for rejection by the MPSC or the Board of Directors may entitle the  
908 applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these  
909 Bylaws.  
910

## 911 ~~**Appendix L: Reviews, Actions, and Due Process**~~

### 912 ~~**L.1. Member Compliance**~~

913 ~~Each OPTN member agrees to comply with OPTN Obligations, which include all of the following:~~

- 914
- 915 ~~1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
  - 916 ~~2. OPTN Final Rule, 42 CFR Part 121~~
  - 917 ~~3. OPTN Bylaws~~
  - 918 ~~4. OPTN Policies~~

919  
920 ~~At any time, the OPTN Board of Directors or the OPTN Executive Committee may recommend that the~~  
921 ~~Secretary of the U.S. Department of Health and Human Services (HHS) take appropriate action as~~  
922 ~~outlined in the OPTN Final Rule.~~

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**A. Periodic Reviews**

The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital, histocompatibility laboratory member, and OPO member for compliance with OPTN Obligations. All compliance monitoring is performed using guidelines developed by the OPTN. Any member who fails to fulfill all the applicable OPTN Obligations may be subject to actions as set forth in these Bylaws.

**B. Failure to Pay OPTN Fees**

The failure of an OPO, transplant hospital, or histocompatibility laboratory member to pay, within 30 days, any OPTN fee, charge, or other monetary obligation to the OPTN Contractor will be considered a violation of OPTN Obligations.

**L.2. Compliance Monitoring**

The OPTN Executive Director monitors compliance of members with OPTN Obligations, and refers all incidences of potential non-compliance for further review as outlined in these Bylaws.

The Executive Director may delegate these monitoring duties to any number of designees to ensure that the necessary actions are taken to meet the requirements of these Bylaws.

**L.3. Reporting Potential Violations and Non-compliance**

Any member who becomes aware of a potential violation of or non-compliance with OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential violations or non-compliance by the member itself.

**L.4. Methods for Correspondence and Providing Notice**

Unless otherwise noted, all correspondence between members and the OPTN required by this *Appendix L* must be sent by a method that can be tracked and that provides proof of receipt, such as:

- Commercial overnight delivery service
- Secure electronic communication
- Registered or certified mail, return receipt requested

The Executive Director will send notice to members when they are required to respond to an OPTN action or request. When the member receives notice, the member must respond within the specified time, as defined in these Bylaws. Time limits specified for providing notice, including requests for interviews, hearings, and to appear before the OPTN Board of Directors, begin on the date the notice is sent from the Executive Director.

**L.5. Medical Peer Review**

The OPTN will conduct all deliberations and take all actions according to applicable confidential medical peer review laws. As appropriate and consistent with applicable laws, all of the following deliberations and actions of any OPTN Committee, the OPTN Executive Committee, the OPTN Board of Directors, and the OPTN Contractor will be kept confidential during the review of:

1. Potential violations of or non-compliance with OPTN Obligations.
2. Matters relating to potential threats to patient health and public safety.



970 3. Applications for membership, designated transplant program status, or a change in Key  
971 Personnel.

972  
973 Members must keep these records, review activity, and documents confidential to promote quality  
974 improvement and full disclosure by OPTN members.  
975

976 **A. Secretary's Access to Information**

977 The medical peer review privilege will not be extended to withhold any document from the  
978 Secretary of HHS, or the Secretary's designee. The OPTN Contractor is required to provide the  
979 Secretary with any information acquired or produced under the OPTN Contract, including  
980 information that would otherwise be protected by the medical peer review privilege. As specified  
981 in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the  
982 Secretary that the Secretary requests, in the format requested by the Secretary.  
983

984 **B. Health Resources and Services Administration (HRSA)  
985 Representation**

986 The Project Officer for the OPTN Contract and the Director of the Division of Transplantation  
987 within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex officio*,  
988 non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting  
989 members of the Executive Committee and Board, they, or their designees, are granted full access  
990 to all deliberations, determinations and actions. Representatives of HRSA are also *ex officio*, non-  
991 voting members of the Membership and Professional Standards Committee (MPSC) and granted  
992 full access to all MPSC deliberations, determinations, and actions as well. Other designees of the  
993 Secretary may also attend OPTN meetings.  
994

995 **L.6. Requests for Root Cause Analysis and Corrective Action**

996 The OPTN Board of Directors, the MPSC, or any standing subcommittee of the MPSC or their designee  
997 may require a member to take corrective action to address any potential violation or noncompliance.  
998 Corrective action can include any of the following:  
999

- 1000 1. Root cause analysis
- 1001 2. Corrective action plan
- 1002 3. Plan for quality improvement
- 1003 4. On-site monitoring
- 1004 5. Desk monitoring
- 1005 6. Self-assessments
- 1006 7. External expert consultants

1007  
1008 **A. Initiating Corrective Action**

1009 If it appears that an OPO, transplant hospital, or histocompatibility laboratory member may have  
1010 failed to meet OPTN Obligations, the MPSC or the Board of Directors may request that the  
1011 member performs a root cause analysis and then develops and implements a corrective action  
1012 plan or plan for quality improvement to address any potential violations or non-compliance.  
1013

1014 **B. Fulfilling Requests for Root Cause Analysis and Corrective Action**

1015 The Executive Director will promptly give notice to the member when requesting any corrective  
1016 action. The member must also submit any requested documentation to the Executive Director at  
1017 this time.

1018  
1019

### **L.7.— Special Secretarial Reviews**

1020 The Secretary of HHS may request that the OPTN Contractor performs a Special Review under guidance  
1021 from the Secretary. A Special Review is a review of the member in the manner and within the period  
1022 specified by the Secretary. This may include, but is not limited to, requests for root cause analysis,  
1023 corrective action, and due process proceedings completed in the period and as specified by the  
1024 Secretary, and as defined Sections L.6 and L.9 through L.14 in this Appendix L. Members must fully  
1025 comply with all OPTN Contractor requests as part of a Special Review.

1026  
1027 The Secretary may impose sanctions or take other appropriate action at any time when a member poses  
1028 a risk to the health of patients or to the public safety.

### **L.8.— Review Pathways for Potential Violations**

1031 The OPTN will review potential violations of and non-compliance with OPTN Obligations by one of three  
1032 pathways as defined below:

- 1033  
1034 1. An **Imminent Threat Review** will be conducted when the MPSC Chair determines that there is a  
1035 potential violation of or non-compliance with OPTN Obligations, which may pose an urgent and  
1036 severe risk to patient health or public safety. The MPSC Chair may choose this pathway when the  
1037 member is not taking action to mitigate the potential threat, or the Chair believes that the potential  
1038 threat may not be mitigated through routine procedures.
- 1039 2. An **Expedited Review** will be conducted when the MPSC Chair determines that a potential violation  
1040 of or non-compliance with OPTN Obligations may pose a potential risk to patient health or public  
1041 safety, which is not currently urgent but could become urgent or severe if not addressed using an  
1042 Expedited Review process. When a matter is reviewed using the Expedited Review pathway, a  
1043 hearing is offered to the member on an expedited schedule.
- 1044 3. A **Routine Review** will be conducted for any potential violation of or non-compliance with OPTN  
1045 Obligations when the MPSC Chair determines that an Expedited Review or an Imminent Threat  
1046 Review is not warranted.

1047  
1048 When investigating any potential violation or non-compliance and determining a review pathway, the  
1049 OPTN Contractor will take appropriate action as described in Sections L.9 through L.14 that follow.

### **L.9.— Preliminary Investigation of Potential Violations**

1052 When the OPTN learns of a possible failure of a member to comply with any aspect of applicable OPTN  
1053 Obligations, the Executive Director will conduct a preliminary investigation. This investigation will consider  
1054 whether the potential violation suggests a risk to patient health or public safety, and the urgency and  
1055 severity of the risk.

1056 If additional information is required in conducting the preliminary investigation of any potential violation,  
1057 the member must respond to requests from the OPTN. A member's documented history of violations and  
1058 non-compliance, or systemic problems and operational failures, could warrant review of the member  
1059 through the Imminent Threat or Expedited Review pathway.

#### **A.— Referral of Potential Violations to the MPSC Chair**

1062 If the preliminary investigation concludes that the potential violation may pose an urgent and  
1063 severe risk to patient health or public safety, the matter will be referred to the MPSC Chair within  
1064 24 hours.

1065  
1066 If the preliminary investigation concludes that the risk to patient health or public safety is not an  
1067 urgent and severe risk, but a substantial risk remains, the matter will be referred to the MPSC

1068 Chair within 7 days.

1069

1070 **B. ~~Notice to the Secretary after Preliminary Investigation~~**

1071 If the potential violation is referred to the MPSC Chair with a recommendation to follow the  
1072 Imminent Threat Review pathway, the Executive Director will provide notice to the Secretary  
1073 within 24 hours of the referral.

1074

1075 The OPTN will notify the Secretary within 7 days when a preliminary investigation determines that  
1076 the member has not violated OPTN Obligations but that a risk to patient health or public safety  
1077 exists.

1078

1079 **L.10. ~~Determination of Review Pathway~~**

1080 **A. ~~MPSC Chair's Determination of Urgency and Severity~~**

1081 The OPTN will refer a potential violation to the MPSC Chair if the preliminary investigation  
1082 determines that the potential violation may pose an urgent and severe risk to patient health or  
1083 public safety. The MPSC Chair will consider the available information and determine the  
1084 appropriate review pathway. In making this determination, the MPSC Chair may consult with the  
1085 Executive Director, OPTN President, HRSA representatives, and any others, as determined by  
1086 the Chair. If the MPSC Chair is unavailable, the MPSC Vice Chair may make this determination.  
1087 The MPSC Chair must make this decision within 72 hours after the preliminary investigation is  
1088 completed.

1089

1090 **B. ~~Requests to Take Action to Mitigate Imminent Threat~~**

1091 If the MPSC Chair determines that an urgent and severe risk appears to be present, the MPSC  
1092 Chair may request that the member voluntarily cease performing certain transplants or take a  
1093 specified action to mitigate the threat to patient health or public safety. If the member takes the  
1094 requested action to mitigate the threat within 24 hours, the matter may proceed through the  
1095 Expedited Review pathway.

1096

1097 **C. ~~Notice of Chair's Determination~~**

1098 The MPSC Chair will provide notice to the Secretary of the Review pathway within 72 hours of the  
1099 determination.

1100

1101 **D. ~~Changing Review Pathways~~**

1102 The MPSC Chair may change the review pathway of a potential violation at any time as  
1103 information is gathered and the assessment of the urgency and severity of the risk to patient  
1104 health or public safety changes.

1105

1106 **L.11. ~~OPTN Investigations~~**

1107 After the preliminary investigation of a potential violation or incident of non-compliance and the review  
1108 pathway has been determined, additional investigation will occur as required. The investigation of any  
1109 potential violation or non-compliance conducted by the OPTN may include, but is not limited to, any of the  
1110 following:

1111

- 1112 1. ~~Data review~~
- 1113 2. ~~Document review~~
- 1114 3. ~~Interviews with the member's representatives~~
- 1115 4. ~~On-site visits by OPTN Contractor staff~~
- 1116 5. ~~On-site visits by peer review teams~~

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**~~L.12. Imminent Threat Reviews~~**

~~When the MPSC Chair determines that a potential violation of or non-compliance with OPTN Obligations presents an urgent and severe risk to patient health or public safety, and the member has not voluntarily taken the requested action to mitigate the risk, the potential violation will proceed through the Imminent Threat Review pathway. The OPTN Executive Director will notify the member immediately when the MPSC Chair determines that a potential violation will proceed through the Imminent Threat Review pathway.~~

**~~A. Imminent Threat Review Investigation~~**

~~The OPTN must complete an investigation of the potential violation within 14 days of the initial determination by the MPSC Chair that the potential violation will proceed through the Imminent Threat Review pathway.~~

**~~B. Imminent Threat Review Committee~~**

~~Within 21 days of the determination of the imminent threat review pathway, the Imminent Threat Review Committee will complete its review of the matter and forward its recommendations to the MPSC Chair.~~

**~~1. Composition of the Imminent Threat Review Committee~~**

~~The Imminent Threat Review Committee may be the MPSC, any standing subcommittee of the MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A subcommittee must include at least 5 members of the MPSC, and 2 of the members must have expertise in the organ system or specific issue that is the subject of the review.~~

**~~2. Imminent Threat Review Committee Recommendation~~**

~~The Imminent Threat Review Committee will determine whether the matter should continue to follow the Imminent Threat Review process.~~

~~If the Imminent Threat Review Committee determines that an urgent and severe risk to patient health or public safety no longer exists, it will determine whether the matter should proceed through the Expedited Review or Routine Review pathway.~~

**~~3. Notice after Imminent Threat Review Committee Recommendation~~**

~~When the Imminent Threat Review Committee determines that a potential violation will continue through the Imminent Threat Review pathway, the OPTN Executive Director will:~~

- ~~a. Provide notice to the member of the Imminent Threat Review Committee's action within 24 hours by an approved method as described in *Section L.4. Methods for Correspondence and Providing Notice*. The member will have 24 hours after receiving notice to respond to the Executive Director regarding the Imminent Threat Review Committee's recommendations.~~
- ~~b. Provide notice of the Imminent Threat Review Committee's recommendation to the Secretary within 24 hours.~~
- ~~c. Refer the matter to the OPTN Executive Committee within 72 hours.~~
- ~~d. Include a recommendation for an adverse action, and whether the matter should be referred to the Secretary for further action.~~

1162 **C. Interviews in Imminent Threat Reviews**

1163 When a potential violation proceeds through the Imminent Threat Review pathway, members are  
1164 *not* entitled to an interview before the MPSC, even though the recommended action is an adverse  
1165 action.  
1166

1167 **D. OPTN Executive Committee Determination**

1168 The Executive Committee of the OPTN will convene within 7 days of the Imminent Threat Review  
1169 Committee's determination.  
1170

1171 If the Executive Committee determines that an urgent and severe risk to patient health or public  
1172 safety no longer exists, it will decide whether the matter should proceed through the Expedited  
1173 Review or Routine Review pathway.  
1174

1175 If the matter continues to proceed through the Imminent Threat Review pathway, the Executive  
1176 Committee will make the following determinations:  
1177

- 1178 1. Whether to accept the recommendation of the Imminent Threat Review  
1179 Committee, or take another action. An adverse action is effective immediately  
1180 upon the determination by the Executive Committee, prior to any hearing.
- 1181 2. Whether the MPSC, Executive Committee, or Board of Directors will be the  
1182 hearing body if the member requests a hearing. Members of the Imminent Threat  
1183 Review Committee may also participate in the Imminent Threat Hearing Panel.

1184  
1185 **E. Notice after OPTN Executive Committee's Determination**

1186 The OPTN Executive Director will provide notice of the Executive Committee's determinations:  
1187

- 1188 1. To the HHS Secretary within 24 hours.
- 1189 2. To the member within 24 hours.

1190  
1191 The Executive Committee will provide a written summary of this review to the Executive Director  
1192 within 48 hours to be forwarded to the Secretary. The Executive Committee may determine when  
1193 any notice to the membership or public required by Executive Committee actions will occur. The  
1194 member may request a copy of the supporting documentation, which will be provided at the  
1195 member's expense.  
1196

1197 **F. Requesting a Hearing in Imminent Threat Reviews**

1198 The member has 7 days following notice of the Executive Committee's determination to request a  
1199 hearing as described in *Section L.18.B: Requesting a Hearing*. The hearing will occur not less  
1200 than 7 days or more than 30 days from the date of the Executive Director's receipt of the request  
1201 for a hearing.

1202 **G. Imminent Threat Hearing Process**

1203 If the member exercises its right to a hearing, the hearing will be conducted under the procedures  
1204 described in *Section L.18: Hearings* that follows, with these modifications:  
1205

- 1206 1. The hearing will occur after the Executive Committee's review and determination of  
1207 the adverse action.
- 1208 2. The Hearing Panel report will be issued within 14 days of the conclusion of the  
1209 hearing.

1210 3. If the Imminent Threat Hearing Panel determines that no adverse action is warranted,  
1211 the Hearing Panel may immediately remove the designation of Member Not in Good  
1212 Standing or Probation and provide appropriate notice without Board of Directors'  
1213 approval.  
1214

### 1215 **L.13. Expedited Reviews**

1216 Any potential violation of or non-compliance with OPTN Obligations that poses a potential risk to patient  
1217 health or public safety, which could become urgent or severe, will follow the Expedited Review pathway.  
1218

#### 1219 **A. Expedited Review Investigation**

1220 The OPTN must complete an investigation of the potential violation within 21 days of the initial  
1221 determination by the MPSC Chair that the potential violation will proceed through the Expedited  
1222 Review pathway.  
1223

#### 1224 **B. Expedited Review Committee**

1225 Within 42 days of the determination of the expedited review pathway, the Expedited Review  
1226 Committee will complete its review and forward its recommendations to the MPSC Chair.  
1227

##### 1228 **1. Composition of the Expedited Review Committee**

1229 The Expedited Review Committee may be the MPSC, any standing subcommittee of the  
1230 MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A  
1231 subcommittee must include at least 5 members of the MPSC and 2 of the members  
1232 should have expertise in the organ system or specific issue that is the subject of the  
1233 review.

##### 1234 **2. Expedited Review Committee Recommendations**

1235 The Expedited Review Committee will consider instances of potential non-compliance  
1236 with OPTN Obligations. The Expedited Review Committee may determine that there was  
1237 no violation, issue a letter of warning, or issue a notice of uncontested violation. The  
1238 Expedited Review Committee may also recommend a Letter of Reprimand or an adverse  
1239 action.  
1240

1241 If the Expedited Review Committee recommends a Letter of Reprimand or an adverse  
1242 action, then the member is entitled to an interview before the MPSC.

##### 1243 **3. Notice after Expedited Review Committee's Recommendations**

1244 The MPSC Chair will provide notice of the Expedited Review Committee's determination  
1245 by an approved method as described in *Section L.4: Methods for Correspondence and*  
1246 *Providing Notice*. If the recommendation is for an adverse action, then the OPTN  
1247 Executive Director will provide notice of the Expedited Review Committee's determination  
1248 to the Secretary within 24 hours.

#### 1249 **C. Interviews in Expedited Reviews**

1250 The member will be entitled to an interview before the MPSC when the Expedited Review  
1251 Committee considers issuing a Letter of Reprimand or an adverse action. The member will have  
1252 the right to request an interview to be held at the next in-person meeting of the MPSC. If the next  
1253 in-person meeting of the MPSC is scheduled more than 60 days later, at the discretion of the  
1254 MPSC Chair, a special in-person meeting may be required or an interview may be conducted by  
1255 teleconference or electronic media.

1256  
1257 If the member exercises its right to an interview, the interview will be conducted as described in  
1258 *Section L.17: Interviews* that follows.

1259  
1260 **1. Requesting an Interview**

1261 The member has 14 days following notice of the Expedited Review Committee's  
1262 recommendation to request an interview before the MPSC as described in *Section*  
1263 *L.17.B: Requesting an Interview*.

1264  
1265 **D. Requesting a Hearing in Expedited Reviews**

1266 Following the interview before the MPSC, whether accepted by the member or not, the MPSC will  
1267 consider the Expedited Review Committee's recommendation and may recommend to the Board  
1268 of Directors to impose an adverse action on the member. The MPSC will provide Notice of the  
1269 recommended adverse action to the member. The member has 14 days following notice of the  
1270 MPSC's recommendation for an adverse action to request a hearing as described in *Section*  
1271 *L.18.B: Requesting a Hearing*.

1272  
1273 Hearings will be scheduled no fewer than 7 days or more than 60 days from the date that the  
1274 Executive Director receives the request for hearing. Hearings may be scheduled more than 60  
1275 days from the request date at the discretion of the MPSC Chair, and if the member and Chair  
1276 agree on the date.

1277  
1278 **E. Expedited Review Hearing Panel**

1279 The Expedited Review Hearing Panel will be appointed by the MPSC Chair and composed of at  
1280 least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of  
1281 the members must have expertise in the organ system or specific issue that is the subject of the  
1282 review.

1283  
1284 The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of the  
1285 Expedited Review Committee may also participate in the Expedited Review Hearing Panel.

1286  
1287 **F. Expedited Review Hearing Process**

1288 If the member exercises its right to a hearing, the hearing will be conducted under the procedures  
1289 described in *Section L.18: Hearings* that follows, with these modifications:

- 1290  
1291 1. The Hearing Panel report will be issued within 21 days of the conclusion of the hearing.  
1292 2. The Board will consider and act on the Hearing Panel report within 30 days of receiving the  
1293 report.

1294  
1295 **L.14. Routine Reviews**

1296 A Routine Review will be conducted for any potential violation of OPTN Obligations when an Expedited  
1297 Review or an Imminent Threat Review is not warranted.

1298  
1299 **A. Routine Review Investigations**

1300 The OPTN will complete a routine review investigation of the matter and refer it to the Routine  
1301 Review Committee within 6 months.

1302  
1303 **B. Routine Review Committee**

1304 The Routine Review Committee will be composed of any standing subcommittee of the MPSC or,

1305 at the discretion of the MPSC Chair, the entire MPSC. The Routine Review Committee may meet  
1306 by teleconference or electronic media, as needed, for the purpose of considering any new and  
1307 ongoing potential policy violations.  
1308

1309 **1. Notice after Routine Review Committee's Determinations**

1310 The Routine Review Committee will notify the member of its determination and any  
1311 recommendation for a specific action. If the Committee recommends an action that would  
1312 entitle the member to an interview, members will be notified of their right to an interview  
1313 at the time they are informed of the Committee's determination.  
1314

1315 **C. Interviews in Routine Reviews**

1316 The member will be entitled to an interview when the Routine Review Committee is considering  
1317 making a recommendation for a Letter of Reprimand or an adverse action. Interviews will be  
1318 scheduled at the next in-person meeting of the MPSC or standing subcommittee of the MPSC.  
1319

1320 **1. Requesting an Interview**

1321 The member has 14 days to request an interview as described in *Section L.17.B:*  
1322 *Requesting or Waiving the Right to an Interview* following notice of the Routine Review  
1323 Committee's determination.  
1324

1325 **D. Hearings in Routine Reviews**

1326 **1. Requesting a Hearing**

1327 The member has 14 days following notice of the Routine Review Committee's  
1328 recommendation for an adverse action to request a hearing as described in *Section*  
1329 *L.18.B: Requesting or Waiving the Right to a Hearing.*

1330  
1331 Hearings will be scheduled no fewer than 7 days or more than 60 days from the date the  
1332 OPTN Executive Director receives the request for hearing. Hearings may be scheduled  
1333 more than 60 days from the request date at the discretion of the MPSC Chair, and if the  
1334 member and MPSC Chair agree on the date.  
1335

1336 **2. Routine Review Hearing Panel**

1337 The Routine Review Hearing Panel will be appointed by the MPSC Chair and composed  
1338 of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc  
1339 committee. Two of the members must have expertise in the organ system or specific  
1340 issue that is the subject of the review.  
1341

1342 The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of  
1343 the Routine Review Committee may also participate in the Routine Review Hearing  
1344 Panel.  
1345

1346 **3. Routine Review Hearing Process**

1347 If the member exercises its right to a hearing, the hearing will be conducted using the  
1348 procedures described in *Section L.18: Hearings*, with the following additional notifications  
1349 to the member:  
1350



- 1351 a. ~~That all documentation about the member that was generated by or submitted to the~~  
1352 ~~MPSC, the OPTN Executive Committee, or the OPTN Board before the~~  
1353 ~~recommendation or action, will be made available to the member, upon request.~~  
1354 b. ~~The Hearing Panel report will be issued within 30 days of the conclusion of the~~  
1355 ~~hearing.~~  
1356 c. ~~The Board of Directors will consider and act on the Hearing Panel report at its next~~  
1357 ~~regularly scheduled meeting following receipt of the report.~~  
1358

## 1359 **L.15. OPTN Determinations and Actions**

1360 OPTN actions may be imposed when a member:

- 1361  
1362 1. ~~Fails to comply with OPTN Obligations as described in L.1. Member Compliance.~~  
1363 2. ~~Fails to submit or follow a corrective action plan or plan for quality improvement.~~  
1364 3. ~~Fails to meet personnel requirements.~~  
1365 4. ~~Acts in a way that poses a risk to patient health or public safety.~~  
1366 5. ~~Fails to act as necessary to avoid risk to patient health or public safety.~~  
1367

### 1368 **A. Determining Appropriate Action**

1369 Factors considered in reviewing potential violations and incidents of non-compliance include but  
1370 are not limited to:

- 1371  
1372 1. ~~Whether the potential violation poses an urgent and severe risk to patient health or public~~  
1373 ~~safety.~~  
1374 2. ~~Whether the potential violation poses a substantial risk to the integrity of or trust in the OPTN.~~  
1375 3. ~~Whether patient medical records or other documentation provide sufficient detail to determine~~  
1376 ~~the presence of mitigating factors at the time the potential violation occurred.~~  
1377 4. ~~Whether the member can show evidence of corrective action upon learning of the potential~~  
1378 ~~violation.~~  
1379 5. ~~The overall OPTN compliance history of the member, including but not limited to, MPSC~~  
1380 ~~reviews and actions in the member's history.~~

1381  
1382 The OPTN may impose a separate action for each violation or may choose to impose a single  
1383 action for all related violations that can be addressed by a single action.  
1384

### 1385 **B. Corrective Action**

1386 The OPTN may require a member to take corrective action in addition to imposing an adverse  
1387 action, or instead of imposing an adverse action, including:

- 1388  
1389 1. ~~Root cause analysis~~  
1390 2. ~~Corrective action plan~~  
1391 3. ~~Plan for quality improvement~~  
1392 4. ~~On-site monitoring~~  
1393 5. ~~Desk monitoring~~  
1394 6. ~~Self-assessments~~  
1395 7. ~~External expert consultants~~  
1396

1397 If the MPSC or any standing subcommittee of the MPSC requires a member to take corrective  
1398 action to address any issues of noncompliance, the member must take corrective action as  
1399 specified and within the period provided. If the member fails to fulfill the corrective action

1400 requirements, the OPTN may make any determination or take any action as outlined in this  
1401 *Appendix L*.

1402

1403 **C. ~~Deferred Disposition with Monitoring Period~~**

1404 If the MPSC recommends an adverse action against a member, and the member has had an  
1405 interview before the MPSC, the MPSC may delay proceeding with the matter for a Deferred  
1406 Disposition period. Deferred Disposition will only be considered in cases where the member has  
1407 implemented a corrective action plan or plan for quality improvement within the 60 days prior to  
1408 the interview and where the potential violation or non-compliance under review is not egregious  
1409 or severe.

1410

1411 Deferred Disposition is not an action, but rather a timeout period provided to the member to  
1412 demonstrate its ability and willingness to meet OPTN Obligations. If the MPSC chooses to  
1413 employ a Deferred Disposition, the recommendation for adverse action will not be communicated  
1414 to the Board of Directors until after Deferred Disposition. The MPSC is able to revise its  
1415 recommendation at the end of the Deferred Disposition before communicating it to the Board.

1416

1417 Deferred Disposition is not appropriate if the member has received *either*:

1418

1419 1. A Letter of Warning, Letter of Reprimand, or an MPSC recommendation for an adverse action  
1420 in the previous 2 years from the date of the interview.

1421

1422 2. Two or more Notices of Uncontested Violation in the previous 2 years from the date of the  
1423 interview.

1423

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**1. ~~Additional Considerations for Deferred Disposition~~**

The MPSC may also consider any of the following:

- ~~The overall performance and compliance history of the member, including its response to previous MPSC actions, and particularly requests for corrective action or plans for quality improvement.~~
- ~~Any recent changes in the member's staffing, including changes in those responsible for oversight of the member.~~
- ~~An MPSC assessment of the appropriateness or thoroughness of the corrective action plan or plan for quality improvement addressing the matter under review.~~

The MPSC is not required to offer a Deferred Disposition after an interview with the member and may proceed with its recommendation of the adverse action without a Deferred Disposition. If the member declines the Deferred Disposition, the MPSC will proceed with its recommendation of the adverse action.

**2. ~~Notice of Deferred Disposition~~**

Notice of an MPSC determination of Deferred Disposition is not an adverse action recommendation that entitles the member to a hearing.

Deferred Disposition will include a 6-month monitoring period, beginning on the date of the interview. During this period, the member will have to demonstrate compliance with OPTN Obligations as outlined in its corrective action plan or plan for quality improvement. An on-site review of the member will be completed during the monitoring period.

**3. ~~Monitoring during Deferred Disposition~~**

1450 The member's compliance will be monitored by a subcommittee of the MPSC. The  
1451 subcommittee will provide updates of that monitoring to the MPSC at any regular  
1452 meetings of the MPSC scheduled during the Deferred Disposition.

1453  
1454 **4. Recommendation of an Adverse Action during or after Deferred**  
1455 **Disposition**

1456 If the member does not demonstrate to the MPSC's satisfaction that the member has  
1457 achieved compliance during the Deferred Disposition, the MPSC will proceed with its  
1458 recommendation of an adverse action. The MPSC may proceed with its recommendation  
1459 of the adverse action at any point during Deferred Disposition. If the MPSC proceeds  
1460 with its recommendation of an adverse action, the member will be notified of its right to a  
1461 hearing.

1462  
1463 **5. Actions if Member Demonstrates Compliance after Deferred**  
1464 **Disposition**

1465 The MPSC may consider imposing a non-adverse action or taking no action if the MPSC  
1466 believes that the member has demonstrated compliance with OPTN Obligations or  
1467 sufficient quality improvement at the end of the Deferred Disposition.

1468  
1469 **D. MPSC Actions without Board Referral**

1470 The MPSC, or any standing subcommittee of the MPSC, may take any of the following actions or  
1471 recommendations directly:

- 1472
- 1473 ■ Issue a Notice of Uncontested Violation
- 1474 ■ Issue a Letter of Warning
- 1475 ■ Consider Issuing a Letter of Reprimand

1476  
1477 These actions and recommendations do not require Board of Directors approval. The Board of  
1478 Directors and the Secretary of HHS will be notified any time a Notice of Uncontested Violation,  
1479 Letter of Warning, or Letter of Reprimand is issued, or anytime Deferred Disposition is offered.

1480  
1481 **1. Notice of Uncontested Violation**

1482 The MPSC, or any standing subcommittee of the MPSC, will issue a Notice of  
1483 Uncontested Violation for a violation of OPTN Obligations when:

- 1484
- 1485 a. There is substantial evidence of mitigating factors based on medical judgment.
- 1486 b. There is believed to be no likelihood of recurrence.
- 1487 c. The member does not challenge that the violation occurred.

1488  
1489 The member is not entitled to an interview.

1490  
1491 **2. Letter of Warning**

1492 The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Warning for  
1493 a violation of OPTN Obligations when:

- 1494
  - 1495 a. Medical judgment is credibly put forth as a partial mitigating factor.
  - 1496 b. There is believed to be no likelihood of recurrence.
- 1497

1498 ~~Letters of Warning may also be issued in those cases where the compliance history of~~  
1499 ~~the member warrants an action higher than Notice of Uncontested Violation. The member~~  
1500 ~~is not entitled to an interview.~~

1501  
1502 **3. Letter of Reprimand**  
1503 ~~The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Reprimand~~  
1504 ~~for a violation of OPTN Obligations when medical judgment does not appear to be a~~  
1505 ~~credible mitigating factor. Letters of Reprimand may also be issued in those cases where~~  
1506 ~~the compliance history of the member warrants an action higher than Notice of~~  
1507 ~~Uncontested Violation or Letter of Warning. The member is entitled to an interview before~~  
1508 ~~a Letter of Reprimand is issued.~~

1509  
1510 **E. Adverse Actions that Require Board Approval**

1511 ~~The adverse actions of Probation and Member Not in Good Standing can only be imposed by the~~  
1512 ~~Board of Directors. If a member receives an adverse action, the Executive Director will give notice~~  
1513 ~~to the public of the adverse action as specified by the Board of Directors. This notice may include,~~  
1514 ~~but is not limited to, communication using the OPTN website.~~

1515  
1516 **1. Probation**  
1517 ~~The MPSC may recommend that the Board of Directors place a member on Probation, or~~  
1518 ~~the Board may do so on its own. Probation is an adverse action under these Bylaws, and~~  
1519 ~~the OPTN Executive Director will give notice to all members when a member is placed on~~  
1520 ~~Probation.~~

1521  
1522 **a. Corrective Action Requirements of Probation**  
1523 ~~The adverse action of Probation will require that the member adheres to corrective action~~  
1524 ~~requirements as specified by the MPSC, which may include, but are not limited to:~~

- 1525  
1526 ~~i. Required development and submission of a corrective action plan or plan for~~  
1527 ~~quality improvement as specified by the MPSC, any standing subcommittee of~~  
1528 ~~the MPSC, the Executive Committee, or the Board of Directors. The member~~  
1529 ~~must demonstrate that it has adhered to the plan and that it has corrected any~~  
1530 ~~noncompliant activity within the Probation effective period.~~  
1531 ~~ii. Unscheduled on-site reviews by the OPTN Contractor staff or peer review~~  
1532 ~~teams throughout the Probation period.~~  
1533 ~~iii. Specified submission of reports, data, or other evidence to the OPTN that~~  
1534 ~~documents correction of the non-compliant activity throughout the period of~~  
1535 ~~Probation.~~

1536  
1537 **b. Notification Requirements of Probation**  
1538 ~~The adverse action of Probation will require that the member provide notice of the~~  
1539 ~~adverse action as follows:~~

1540

<b>If the member is a...</b>	<b>Then notice must be provided to ...</b>
Transplant hospital	All patients, as defined in these Bylaws, of the designated transplant program receiving the adverse action, including any new transplant program patients, during the entire effective period of the adverse action.
OPO	All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the laboratory.

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Members must provide notices as described above within 30 days of receiving notification from the OPTN that it has been given the adverse action of Probation. The notice to transplant program patients must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors.

**2. Member Not in Good Standing**

The MPSC may recommend that the Board of Directors declare the member to be a Member Not in Good Standing, or the Board of Directors may do so on its own. Member Not in Good Standing is an adverse action under these Bylaws.

**a. Results of Member Not in Good Standing**

The adverse action of Member Not in Good Standing will include:

- i. Formal notice to the Secretary of HHS.
- ii. Loss of member voting privileges in OPTN affairs.
- iii. Loss of the privilege of any personnel associated with the member to serve on any Committee or the Board of Directors, or to hold office.
- iv. Formal notification, along with any subsequent changes in status, to the entire OPTN membership.
- v. Formal notification, along with any subsequent changes in status, to the member's Chief Executive Officer or Administrator.
- vi. Formal notification, along with any subsequent changes in status, to the state health commissioner or other appropriate state representative with oversight of health care institutions doing business in the member's state.
- vii. Any actions that can be taken under Probation.

**b. Notification Requirements of Member Not in Good Standing**

A member receiving the adverse action of Member Not in Good Standing must provide notice of the adverse action as follows:

<b>If the member is a...</b>	<b>Then notice must be provided to ...</b>
Transplant hospital	All transplant hospital patients as defined in these Bylaws, including any new transplant hospital patients, during the entire effective period of the adverse action.

If the member is a...	Then notice must be provided to ...
OPO	All Hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).
Histocompatibility laboratory	All members that have a contractual agreement with the Laboratory.

1574  
 1575 Members must provide notices as described above within 30 days of receiving  
 1576 notification from the OPTN that it has been given the adverse action of Member Not in  
 1577 Good Standing.

1578  
 1579 The notice to transplant hospital patients must be provided in writing, in each patient's  
 1580 spoken language, and as specified by the Executive Committee or Board of Directors.  
 1581

1582 **F. Recommendations and Requests to the Secretary**

1583 The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic  
 1584 reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant  
 1585 hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN  
 1586 Obligations or indicate a risk to the health of patients or to the public safety, and will provide any  
 1587 recommendations for appropriate action by the Secretary. Appropriate actions, include, but are  
 1588 not limited to those described in the OPTN final rule, as described in Section L.16: that follows.  
 1589

1590 At any time, the Board may make recommendations to the Secretary for specific actions, on its  
 1591 own or after receiving a recommendation from the MPSC.  
 1592

1593 **L.16. Secretarial Actions**

1594 Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

- 1595
- 1596 1. Violates the National Organ Transplant Act (NOTA).
- 1597 2. Violates the OPTN Final Rule, 42 CFR Part 121.
- 1598 3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more  
 1599 information on mandatory policies, see Section L.16.A: OPTN Policies Approved by the Secretary as  
 1600 Mandatory.
- 1601 4. Engages in behavior that poses a risk to patient health or public safety.  
 1602

1603 Termination of membership requires Secretarial approval. Membership can only be removed if the OPTN  
 1604 member no longer meets the requirements for membership as described in the OPTN Final Rule.  
 1605

1606 In addition to Termination of membership in the OPTN described above, the Secretary may take  
 1607 appropriate actions, which include, but are not limited to:

- 1608
- 1609 a. Removal of one or more of the member's designated transplant programs. After designated  
 1610 transplant program status is removed, the Program will no longer be eligible to receive organs for  
 1611 transplantation within the OPTN.
- 1612 b. Termination of the member's reimbursement under Medicare or Medicaid.
- 1613 c. Termination of a transplant hospital's participation in Medicare or Medicaid.
- 1614 d. Request for information from the OPTN.
- 1615 e. Any other action that the Secretary considers necessary.  
 1616

1617 **A. OPTN Policies Approved by the Secretary as Mandatory**

1618 When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of  
1619 HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are  
1620 enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of  
1621 Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other  
1622 actions by the Secretary.

1623  
1624 ~~Section 121.11(b)(2) of the OPTN final rule requires OPTN members that are OPOs and~~  
1625 ~~transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the~~  
1626 ~~Secretary certain information in the form required and in accordance with the schedule~~  
1627 ~~prescribed.~~

1628  
1629 Data specified by the Secretary under this authority includes all data requested on forms  
1630 approved by the Office of Management and Budget (OMB), including all applications reviewed by  
1631 the OPTN. The Secretary may take an action described above for failure of a member to submit  
1632 accurate and complete data as required by the Secretary (including on OMB approved forms).  
1633 Failure to submit accurate and complete data may also result in civil or criminal penalties.

1634  
1635 **B. Effective Date of Actions Recommended by the Board**

1636 Actions recommended by the OPTN Board of Directors and taken by the Secretary for non-  
1637 compliance with mandatory policies will not become effective until the member has waived its  
1638 right to a hearing or the applicable hearing proceedings have been concluded.

1639  
1640 If the Board finds, based on available evidence, that the member's potential violation poses a  
1641 severe and urgent risk to patient health or public safety, the Board may recommend that a  
1642 Secretarial action be made effective immediately, before completing any required interview or  
1643 hearing.

1644  
1645 **L.17. Interviews**

1646 An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural  
1647 rules followed for hearings. The member will be informed of the reasons for the interview and may  
1648 present any information it considers useful and relevant.

1649  
1650 **A. Members' Right to an Interview**

1651 The member will have the right to an interview when:

- 1652  
1653 1. A Letter of Reprimand is recommended.  
1654 2. An adverse action is recommended.  
1655 3. A membership application or application for designated transplant program status is  
1656 rejected.  
1657 4. A pediatric membership exception request is rejected.  
1658

1659 However, a member has no right to an interview when a potential violation is being reviewed  
1660 through the Imminent Threat Review pathway. After the interview is completed, the MPSC will  
1661 promptly provide a summary of the interview to the member.  
1662

1663 **B. Requesting or Waiving the Right to an Interview**

1664 The member must submit its written interview request to the Executive Director using one of the  
1665 approved methods described in *L.4. Methods for Correspondence and Providing Notice*.

1666  
1667 A member may waive its right to an interview in writing. In addition, a member who fails to request

1668 ~~an interview within the specified time waives any right to an interview. Waiver of the right to an~~  
1669 ~~interview means that:~~

- 1670
- 1671 ~~1. If the recommended action is a non-adverse action, the action will be issued.~~
  - 1672 ~~2. If the recommended action is an adverse action, the member is entitled to a~~  
1673 ~~hearing.~~

1674

1675 **C. ~~Notice of Interview~~**

1676 ~~When the Executive Director receives a request for an interview from the member within the time~~  
1677 ~~and in the manner required, the interview will be conducted at the next in-person meeting of the~~  
1678 ~~MPSC.~~

1680 **D. ~~Notice to Member after an Interview~~**

1681 ~~The MPSC Chair will promptly provide notice to the member of the MPSC's recommendations or~~  
1682 ~~actions resulting from the interview. The notice will:~~

- 1683
- 1684 ~~1. Briefly advise the member of the nature of the action.~~
  - 1685 ~~2. Advise the member of the right to a hearing, if applicable, according to the provisions~~  
1686 ~~of these Bylaws.~~
  - 1687 ~~3. Specify the maximum number of days that the member has to submit a request for a~~  
1688 ~~hearing.~~

1689

1690 **E. ~~Informal Discussion~~**

1691 ~~The MPSC, or any subcommittee of the MPSC, may request that the member participate in an~~  
1692 ~~informal discussion to provide additional details regarding a potential violation of or non-~~  
1693 ~~compliance with OPTN Obligations or to gain additional information regarding member~~  
1694 ~~performance. The discussion is informal, and may be conducted by teleconference or electronic~~  
1695 ~~media. This informal discussion is intended to provide the member the opportunity to provide~~  
1696 ~~clarification of the matter, and could lead to a more timely and effective assessment and~~  
1697 ~~resolution of the matter.~~

1699 **L.18. ~~Hearings~~**

1700 ~~If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse~~  
1701 ~~action without recommendation from the MPSC, the member is entitled to a hearing.~~

1703 **A. ~~Members' Right to a Hearing~~**

1704 ~~The member has a right to a hearing when an adverse action is:~~

- 1705
- 1706 ~~1. Recommended by the MPSC.~~
  - 1707 ~~2. Recommended by a subcommittee of the MPSC, if the action is the rejection of an~~  
1708 ~~initial membership application or application for designated transplant program~~  
1709 ~~status.~~
  - 1710 ~~3. A result of a determination regarding a potential violation undergoing an Imminent~~  
1711 ~~Threat Review.~~
  - 1712 ~~4. Taken by the Board of Directors or the Executive Committee notwithstanding a~~  
1713 ~~favorable recommendation by the MPSC or standing subcommittee of the MPSC~~  
1714 ~~under circumstances where no right to a hearing existed.~~



1715 5. ~~Taken by the Board of Directors or the Executive Committee on its own without a~~  
1716 ~~prior recommendation by the MPSC.~~

1717  
1718 The member also has a right to a hearing when the MPSC or a subcommittee of the MPSC  
1719 rejects a pediatric membership exception request.

1720  
1721 If the Board of Directors determines, based on available evidence that a potential violation of  
1722 OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the  
1723 Board may take action even if the member has not had the opportunity for a hearing.

1724  
1725 **B. ~~Requesting or Waiving the Right to a Hearing~~**

1726 The member must submit its written hearing request to the OPTN using one of the approved  
1727 methods described in ~~Section L.4: Methods for Correspondence and Providing Notice.~~

1728  
1729 A member may waive its right to a hearing in writing. In addition, a member who fails to request a  
1730 hearing within the specified time waives any right to a hearing. Waiver of the right to a hearing  
1731 means that the member accepts the adverse action or recommendation and the following  
1732 outcomes will apply:

- 1733  
1734 1. ~~An adverse recommendation by the MPSC or the Executive Committee will~~  
1735 ~~become effective after the final decision of the Board of Directors.~~  
1736 2. ~~An adverse action by the Board of Directors will become effective and considered~~  
1737 ~~the final decision by the Board.~~

1738  
1739 If the member will be represented by an attorney at the hearing, the request for a hearing must  
1740 identify by name the attorney who will represent the member, and include the attorney's business  
1741 address and contact information.

1742  
1743 **C. ~~Notice of Hearing~~**

1744 When the Executive Director receives a request for a hearing within the period and in the required  
1745 manner, the Executive Director will send notification of the time, place, and date of the hearing to  
1746 the member at least 7 days before the hearing.

1747  
1748 The hearing notice will include a concise statement of the adverse recommendation or action that  
1749 is the subject of the hearing, and be delivered to the member using an approved method as  
1750 described in ~~Section L.4: Methods for Correspondence and Providing Notice.~~

1751  
1752 At this time, all documentation about the member that was available to the MPSC, the Executive  
1753 Committee, or the Board at the time of deliberation, will be provided to the member, upon request  
1754 and at the member's expense.

1755  
1756 **D. ~~Appointment of Hearing Panels~~**

1757 Hearing Panels will be appointed according to the review pathway of the potential violation as  
1758 described in:

- 1759  
1760 ■ ~~Section L.12: Imminent Threat Reviews~~  
1761 ■ ~~Section L.13: Expedited Reviews~~  
1762 ■ ~~Section L.14: Routine Reviews~~

1763  
1764 Alternatively, at the discretion of the President, those Board members who are in attendance at a

1765 ~~regular or special meeting of the Board may conduct the hearing, provided that the members~~  
1766 ~~comprise a quorum of the full Board. One of the members will be designated as Chair of the~~  
1767 ~~Hearing Panel.~~

1768  
1769

### **E. ~~Hearing Participants~~**

1770 ~~Hearing participants will be:~~

1771  
1772  
1773

- ~~1. The Hearing Panel.~~
- ~~2. The member being reviewed for the adverse recommendation or action.~~

1774  
1775

### **F. ~~Service on Hearing Panels~~**

1776 ~~Hearing Panel members must avoid conflicts of interest according to *Article 2.7: Conflicts of*~~  
1777 ~~*Interest* of these Bylaws, and will be disqualified from serving on a Hearing Panel if the member~~  
1778 ~~has been directly involved in compiling evidence or providing expert consultation to the OPTN on~~  
1779 ~~the matter being reviewed.~~

1780  
1781

### **G. ~~Appearance and Representation at Hearings~~**

1782 ~~The member who requested the hearing must appear in person at the hearing. A member who~~  
1783 ~~fails without good cause to appear at a requested hearing will waive its rights to a hearing. The~~  
1784 ~~member, the body whose recommendation resulted in the hearing, and the Hearing Panel may be~~  
1785 ~~represented by an attorney.~~

1786  
1787

### **H. ~~Presiding Officer~~**

1788 ~~The Chair of the MPSC or the Chair's designee will be the presiding officer. The presiding officer~~  
1789 ~~will manage the hearing to ensure that all participants in the hearing have the opportunity to~~  
1790 ~~present relevant evidence and to conduct any necessary cross-examination required for a full~~  
1791 ~~disclosure of the facts.~~

1792  
1793

~~The presiding officer will determine the order of procedure during the hearing and make all rulings~~  
~~on interpretation or construction of the OPTN Obligations, relevant documents, OPTN~~  
~~requirements on procedure, and on the admissibility of evidence. The presiding officer makes all~~  
~~decisions regarding the exclusion of irrelevant, immaterial, redundant, or repetitive evidence.~~

1796  
1797  
1798

### **I. ~~Rights of Hearing Participants~~**

1799 ~~During a hearing, the member and the Hearing Panel will have the right, subject to the presiding~~  
1800 ~~officer's rulings, to:~~

1801

- ~~■ Call and examine witnesses.~~
- ~~■ Introduce exhibits.~~
- ~~■ Cross-examine any witness on any matter relevant to the issue.~~
- ~~■ Impeach any witness.~~
- ~~■ Refute any evidence.~~

1807  
1808  
1809  
1810  
1811

~~The Hearing Panel may call and question any member representatives who are present at the~~  
~~hearing, even if they do not testify as witnesses for the member or the member chooses not to~~  
~~testify on its own behalf.~~

1812 **J. Procedure and Evidence**

1813 The hearing need not be conducted strictly according to rules of law relating to the examination of  
1814 witnesses or presentation of evidence. The presiding officer may permit admission of any relevant  
1815 information, regardless of whether such evidence would be admitted in a court of law.

1816  
1817 Each party will, before or during the hearing, be entitled to submit documents concerning any  
1818 relevant issue, and these documents will become part of the hearing record. The presiding officer  
1819 may, but is not required to, order that oral evidence is taken only on oath or affirmation. The oath  
1820 or affirmation may be administered by any person designated by the presiding officer and who is  
1821 authorized to notarize documents in the state where the hearing is held.

1822  
1823 **K. Official Notice**

1824 In reaching a decision, the Hearing Panel may take official notice at any time during the hearing  
1825 of any generally accepted technical, scientific, or medical information relating to the issues under  
1826 consideration.

1827  
1828 When the Hearing Panel takes official notice of any information, participants will be informed of  
1829 the information considered and that information will be noted in the hearing record. Any  
1830 participant may request that information be given official notice. Hearing participants may  
1831 challenge any information given official notice, either by providing evidence or expert witness  
1832 testimony.

1833  
1834 **L. Burden of Proof**

1835 The body whose adverse recommendation or action resulted in the hearing must present  
1836 evidence to support the adverse recommendation or action, including an explanation of the action  
1837 or recommendation, and the reason it was taken. The member will then have the burden of  
1838 proving and persuading, by clear and convincing evidence, that the adverse recommendation or  
1839 action lacks substantial basis or that such basis or the conclusions drawn are arbitrary,  
1840 unreasonable, or capricious.

1841  
1842 **M. Hearing Record**

1843 The Hearing Panel will keep a record of the hearing that includes a hearing transcript and any  
1844 documents reviewed during the hearing. A court reporter will prepare the written transcript. All  
1845 exhibits admitted into evidence at the hearing and all documents submitted to the Hearing Panel  
1846 will be incorporated in the record until the hearing is declared adjourned.

1847  
1848 **N. Postponement**

1849 Request for postponement of a hearing will be granted by the MPSC Chair only for good cause  
1850 and only if the request is made as soon as is reasonably possible.

1851  
1852 **O. Presence of Hearing Panel**

1853 The Hearing Panel must be present throughout the hearing and deliberations. If a Panel member  
1854 is absent from any part of the proceedings, the Panel member will not be permitted to participate  
1855 in the Panel's deliberations or the decision.

1856  
1857 **P. Recesses and Adjournment**

1858 The Chair of the Hearing Panel may recess the hearing and reconvene within 60 days or when  
1859 reasonably practical for the convenience of the participants, to obtain material new or additional  
1860 information, or to consult with experts.

1861  
1862 When the presentation of oral and written evidence is concluded, the hearing will be closed. The  
1863 Hearing Panel will then, at a time convenient to the Panel, conduct its deliberations away from the  
1864 parties. When the Hearing Panel completes its deliberations, the hearing will be declared finally  
1865 adjourned.  
1866

1867 **Q. — Action after Hearing**

1868 At the conclusion of their deliberations, the Hearing Panel will do *one* of the following:

- 1869 ■ Issue a recommendation for an adverse action.
- 1870 ■ Issue a lesser action.
- 1871 ■ Recommend that the MPSC close the review of the potential violation without issuing any
- 1872 action.
- 1873

1874 A hearing cannot remain open or be re-opened after the hearing panel has taken an action.

1875  
1876  
1877 **R. — Hearing Panel Report**

1878 Following preparation of the hearing record, the Hearing Panel will make a written report of its  
1879 findings and recommendations and will forward it, together with the hearing record, to the Board  
1880 of Directors. At the same time, a copy of the Hearing Panel report will be forwarded to the  
1881 member. The Hearing Panel report will be approved by the presiding officer before it is provided  
1882 to the Board of Directors and member.  
1883

1884 All findings and recommendations by the Hearing Panel will be supported by references to the  
1885 hearing record. The presiding officer may extend the time for making the Hearing Panel's written  
1886 report at his or her discretion by giving written notice to the participants.  
1887

1888 **S. — Notice after Hearing**

1889 The Executive Director will promptly send a copy of the result of the Hearing to the member by an  
1890 approved method as described in *Section L.4: Methods for Correspondence and Providing*  
1891 *Notice*. A copy of the result also will be provided to the Board of Directors.  
1892

1893 **T. — Effect of Favorable Result**

1894 If the Hearing Panel closes the matter without recommending an adverse action, then no further  
1895 due process is required.  
1896

1897 **U. — Effect of Adverse Result**

1898 If the result of the hearing continues to be adverse to the member, the adverse recommendation  
1899 will be forwarded to the Board of Directors to make a final decision. The member will have the  
1900 right to request to appear before the Board of Directors before a final action is taken by the  
1901 Board.  
1902

1903 **L.19. — Final Decision of the Board of Directors**

1904 **A. — Right to Appear before the Board**

1905 Before the Board of Directors takes final action regarding any recommendation for adverse  
1906 action, the member has the right to appear before the Board and submit a written statement and  
1907 provide oral statement that details any disagreement with the findings of fact, conclusions, or  
1908 procedural issues raised at any step in the review process.

1909  
1910 The member requesting to appear before the Board must submit a written request to the OPTN  
1911 Executive Director using one of the approved methods as described in *Section L.4: Methods for*  
1912 *Correspondence and Providing Notice*. Members must provide to the Executive Director any  
1913 written statements that will be submitted to the Board at least 15 days before the scheduled  
1914 appearance.

1915  
1916 At least 25 days before the member is scheduled to appear before the Board, the Executive  
1917 Director will provide notice to the member of the time, place, and date.

1918  
1919 **B. Board of Directors Action**

1920 After the conclusion of appropriate due process proceedings and after the MPSC forwards a  
1921 recommendation to the Board of Directors, the Board will make its final decision in the matter. At  
1922 this time, the Board will send written notice of its decision to the member and to the Secretary of  
1923 HHS within 3 business days of the final decision. Written notice will be sent by an approved  
1924 method as described in *Section L.4: Methods for Correspondence and Providing Notice*.

1925  
1926 The Board may take longer than 3 days to provide notice of its decision for good reason, as  
1927 determined by the Secretary. A majority vote by a quorum is required for the Board to take any  
1928 action permitted by these Bylaws.

1929  
1930 **1. Terms of Probation**

1931 A Board action placing a member on Probation will be effective only after hearing  
1932 proceedings have been concluded, or the member has waived its right to a hearing, and  
1933 final Board action is taken.

1934  
1935 Probation may also be made effective at any time the Board finds, based on available  
1936 information, that the potential violation of OPTN Obligations may pose an urgent and  
1937 severe risk to patient health or public safety.

1938  
1939 **2. Terms of Member Not in Good Standing**

1940 When the Board takes the adverse action of Member Not in Good Standing, the action  
1941 will be effective only after hearing proceedings have been concluded, or the member has  
1942 waived its right to a hearing, and final Board action is taken.

1943  
1944 Member Not in Good Standing may also be made effective at any time the Board finds,  
1945 based on available information, that the potential violation of OPTN Obligations may pose  
1946 an urgent and severe risk to patient health or public safety.

1947  
1948 **3. Board Recommendations to the Secretary**

1949 A Board of Directors' recommendation that the Secretary take action against a member  
1950 will not become effective until after applicable hearing proceedings have been concluded  
1951 or the member has waived its right to a hearing, unless the Board finds, at any time,  
1952 based on available information, that the potential violation of OPTN Obligations may pose  
1953 an urgent and severe risk to patient health or public safety.

1954  
1955 The action that the Board recommends the Secretary take will not become effective until  
1956 the Secretary of HHS accepts the Board's recommendation, or takes other action that the  
1957 Secretary determines is appropriate.

1958  
1959 **C. Notice**

1960 Notice of a final decision by the Board of Directors that the member has been placed on  
1961 Probation or declared a Member Not in Good Standing will be circulated to all members as

1962 described in ~~Section L.15: OPTN Determinations and Actions~~. OPTN membership will be notified  
1963 of final decisions by the Board to recommend to the Secretary of HHS Suspension or Termination  
1964 of membership only after the Secretary approves the recommendation.  
1965

## ~~L.20. Restoration of Unrestricted Membership Privileges~~

1967 If a member that is given Probation or declared a Member Not in Good Standing has presented evidence  
1968 to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions  
1969 prescribed as a result of the adverse action, the MPSC may recommend that the Board of Directors  
1970 restore unrestricted membership privileges.  
1971

1972 If Secretarial Action has been taken against a member as described in ~~Section L.16: Secretarial Actions~~,  
1973 only the Secretary of HHS can restore its unrestricted membership privileges. The MPSC may  
1974 recommend that the Secretary of HHS restore unrestricted membership privileges if Secretarial Action  
1975 has been taken against a member if the member has presented evidence to the MPSC that it has fully  
1976 complied with OPTN Obligations, including completion of any actions prescribed as a result of the  
1977 adverse action.  
1978

1979 If a membership was suspended or terminated by the Secretary, the member must complete and submit  
1980 an application for OPTN membership, as described in ~~Appendix A: Membership Application and Review~~.  
1981

### ~~A. Request for Restoration of Membership Privileges~~

1983 A member may request restoration of membership privileges after it demonstrates to the  
1984 satisfaction of the MPSC that:  
1985

- 1986 ~~1. The member is in compliance with OPTN Obligations.~~
- 1987 ~~2. The member has fully implemented any corrective action plan or a plan for quality~~  
1988 ~~improvement previously required by the MPSC.~~
- 1989 ~~3. The member has demonstrated that the underlying cause for the adverse action has~~  
1990 ~~been corrected, or eliminated.~~
- 1991 ~~4. The type of violation that resulted in the adverse action is not likely to recur.~~
- 1992 ~~5. There are no pending compliance issues that may lead to a potential violation or non-~~  
1993 ~~compliance that would require an Imminent Threat Review.~~

1994  
1995 The burden is on the member at all times to demonstrate that restoration of membership  
1996 privileges is appropriate.  
1997

### ~~B. Minimum Requirements to Request Restoration of Membership Privileges~~

2000 The MPSC will only consider requests for restoration of membership privileges during its regularly  
2001 scheduled meetings and the member may not request restoration of membership privileges until  
2002 *both* occur:  
2003

- 2004 ~~1. At least twelve months have passed since the approval and implementation of the MPSC~~  
2005 ~~prescribed corrective action plan.~~
- 2006 ~~2. At least twelve months have passed since the approval of the final action by the Board of~~  
2007 ~~Directors or the Secretary of HHS.~~

2008  
2009 If the MPSC denies the member's request for restoration of membership privileges, the member  
2010 may renew its request 6 months from the date the MPSC denied the request.  
2011

2012 **C. Additional Requirements**

2013 At its discretion, the MPSC may require any of the following before it considers a request for  
2014 restoration of privileges:

- 2015
- 2016 1. An unannounced OPTN Contractor on-site review.
  - 2017 2. An unannounced peer on-site review.
  - 2018 3. Data and document review.
  - 2019 4. A presentation to the MPSC by the member.
- 2020

2021 **D. Hearing**

2022 If the MPSC denies the member's request for restoration of privileges and the member has met  
2023 the conditions identified above, then the member will be entitled to a hearing at the next regularly  
2024 scheduled MPSC meeting. The member must submit a written hearing request using one of the  
2025 approved methods described in *Section L.4: Methods for Correspondence and Providing Notice*.  
2026 The hearing will be held at the member's expense, as outlined in *Section L.23: Costs and*  
2027 *Expenses*.

2028

2029 **E. Restoration of Privileges after Violation of Mandatory Policies under**  
2030 **Section 121.10(c) of the OPTN Final Rule**

2031 If the member presents evidence to the MPSC's satisfaction that a member found to be in  
2032 violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule has fully  
2033 complied with OPTN Obligations, including completing any corrective actions prescribed, the  
2034 MPSC will recommend to the Board of Directors that full membership privileges be restored.

2035

2036 **L.21. Lesser Adverse Actions**

2037 The MPSC may consider a lesser adverse action if a member requests either restoration of unrestricted  
2038 membership or a lesser adverse action. The MPSC may recommend to the Board of Directors the lesser  
2039 adverse actions of Probation or, if the existing action is Probation, a trial restoration period.

2040

2041 The MPSC may consider the recommendation if the member has demonstrated to the MPSC's  
2042 satisfaction all of the following:

- 2043
- 2044 1. The member is now in compliance with OPTN Obligations.
  - 2045 2. The underlying cause for the adverse action is corrected.
  - 2046 3. The corrective action plan or plan for quality improvement has been implemented.
  - 2047 4. The type of violation that resulted in the adverse action is not likely to recur.
  - 2048 5. There are no pending compliance issues that may lead to a potential violation or non-compliance  
2049 that would require an Imminent Threat Review.

2050

2051 The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate.

2052

2053 **A. Requesting a Lesser Adverse Action**

2054 The burden is on the member at all times to demonstrate that a lesser adverse action is  
2055 appropriate. However, the MPSC will only consider requests during its regularly scheduled  
2056 meetings.

2057

2058 The member may not request a lesser adverse action until *both* occur:

2059

- 2060 1. ~~At least twelve months have passed since the approval and implementation of~~  
2061 ~~the MPSC prescribed corrective action plan.~~  
2062 2. ~~At least twelve months have passed since the approval of the final action by the~~  
2063 ~~Board of Directors or the Secretary of HHS.~~

2064  
2065 In its discretion, the MPSC may require an unannounced on-site review or peer on-site review  
2066 before considering the request.  
2067

## 2068 **B. ~~Considering Requests for Lesser Adverse Actions~~**

2069 The consideration of lesser adverse actions does not entitle the member to an interview or  
2070 hearing under these Bylaws. If the MPSC denies the request by the member and the member  
2071 believes that the MPSC acted arbitrarily and capriciously, the member will be entitled to a hearing  
2072 regarding the recommendation for the action of Probation or trial reinstatement period at the next  
2073 regularly scheduled meeting of the MPSC. The hearing will be held at the member's expense.  
2074

2075 If the MPSC denies the member's request for a lesser adverse action, the member may renew its  
2076 request 6 months after the MPSC denies the request.  
2077

## 2078 **L.22. ~~Rejected Membership Applications~~**

2079 If an application for membership, designated transplant program status, or a Change in Key Personnel is  
2080 rejected the applicant has the same due process rights given to a member as outlined in this *Appendix L*.  
2081

2082 An applicant for membership or designated transplant program status has the right to appeal to the  
2083 Secretary of HHS decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding  
2084 these applications according to Section 121.10(c) of the OPTN Final Rule.  
2085

2086 If an applicant exercises this right of appeal before exhausting the procedural rights granted in these  
2087 Bylaws, the applicant will provide written notice to the Executive Director by an approved method as  
2088 described in *Section L.4: Methods for Correspondence and Providing Notice*. When the Executive  
2089 Director receives notice, it will notify the Secretary of the appeal within 3 business days, or a longer  
2090 period if necessary, as determined by the Secretary. Pending a decision on the appeal, due process  
2091 procedures will continue unless the Secretary directs otherwise.  
2092

2093 ~~If the appeal to the Secretary is denied, the rejection process may continue, according to *Appendix A:*~~  
2094 ~~*Membership Application and Review* of these Bylaws. Any other decision by the Secretary on the appeal~~  
2095 ~~will be submitted to the MPSC or Board for action consistent with the Secretary's decision.~~  
2096

## 2097 **L.23. ~~Costs and Expenses~~**

### 2098 **A. ~~Reimbursement of OPTN Contractor Costs and Expenses~~**

2099 Reasonable costs and expenses of conducting interviews and hearings as described in these  
2100 Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to:

- 2101 1. ~~Travel and lodging expenses of member, volunteers, and OPTN Contractor~~  
2102 ~~representatives.~~  
2103 2. ~~Compensation of OPTN Contractor representatives.~~  
2104 3. ~~Court reporter fees.~~  
2105 4. ~~The costs of preparing copies of the hearing record.~~  
2106 5. ~~The member's costs of preparing for and attending the interview or hearing.~~  
2107 6. ~~The OPTN's costs of obtaining and compiling evidence and exhibits.~~  
2108



2109  
2110 OPTN Contractor representatives may include:

- 2111
- 2112 \*—OPTN Contractor staff
- 2113 \*—Outside counsel
- 2114 \*—Consultants
- 2115 \*—Volunteers
- 2116 \*—Expert witnesses
- 2117

2118 The presiding officer, after consultation with the Executive Director, will decide the nature and  
2119 amount of expenses to be reimbursed. Reasonable costs and expenses may be estimated and  
2120 billed, wholly or partially, to the member in advance or may be billed, wholly or partially, to the  
2121 member as the matter is reviewed. If actual costs and expenses otherwise reimbursable by the  
2122 member for the entire matter before the MPSC are less than \$500.00, or if member is not  
2123 determined to be in violation of OPTN Obligations, no reimbursement will be due from the  
2124 member. In addition, any amounts previously reimbursed or deposited will be returned. If the  
2125 member has multiple matters before the MPSC within any 12-month period, the \$500.00 amount  
2126 will apply to all such matters cumulatively.  
2127

2128 **B. Reasonable Costs and Expenses**

2129 Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be  
2130 reimbursed by the member, including any of the following:

- 2131 1. Conducting other than routine on-site reviews.
- 2132 2. Reviewing and monitoring corrective action plans or plans for quality improvement.
- 2133 3. Conducting due process proceedings.
- 2134 4. Monitoring and conducting evaluations of transplant programs with lower than  
2135 expected survival rates as described in *Section D.12.A: Transplant Program Survival*  
2136 *Rates* of these Bylaws, including on-site visits and monitoring plans for quality  
2137 improvement.  
2138

2139  
2140 **C. Advanced Deposit for Reimbursable Costs and Expenses**

2141 The Executive Director may require that the member make and maintain a deposit with the OPTN  
2142 Contractor in an amount equal to the currently projected costs and expenses of any of the  
2143 following:

- 2144 1. OPTN Contractor on-site reviews
- 2145 2. OPTN member Peer on-site reviews
- 2146 3. The interview
- 2147 4. The hearing
- 2148
- 2149

2150 The failure to make the required deposit within 10 days after the Executive Director requests an  
2151 advance deposit will be considered a waiver of the member's interview or hearing rights.  
2152 Following such a waiver, the MPSC and the Board of Directors may impose any actions, including  
2153 adverse actions.  
2154

2155 **D. Default in Payment of Reimbursable Cost and Expenses**

2156 Any member who fails to reimburse costs and expenses within 30 days after receiving notice may be  
2157 referred to the Secretary for Termination of OPTN membership.

2158 **Appendix L: Reviews and Actions**

2159 By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations  
2160 according to Article 1.1: Member Requirements. This Appendix outlines how the OPTN reviews potential  
2161 noncompliance with OPTN Obligations, the process for other reviews as specified in OPTN Policies and  
2162 Bylaws, and the actions the OPTN may take in response. The Appendix also describes a member's rights  
2163 during OPTN reviews.

2164  
2165 **L.1. Methods for Correspondence**

2166 All correspondence between members and the OPTN required by this Appendix L must be sent by a  
2167 method that can be tracked and provides proof of receipt.

2168  
2169 **L.2. Representative Terminology Used throughout Appendix L**

2170 **A. References to the OPTN**

2171 Throughout this Appendix L, references to the OPTN include the Board of Directors, OPTN  
2172 committees and subcommittees, OPTN committee members, the OPTN Executive Director, and  
2173 the OPTN Contractor. Bylaws requirements that are specific to any of these groups or individuals  
2174 explicitly name the group or individual.

2175  
2176 **B. References to the MPSC Chair**

2177 References to the MPSC Chair in this Appendix L necessarily include the possibility of an MPSC  
2178 Chair designee. If the MPSC Chair cannot fulfill a duty as required in these Bylaws for any  
2179 reason, such as unavailability or potential conflicts of interest, then these duties will be delegated  
2180 to another individual. Selection of an MPSC Chair designee will proceed in the following order  
2181 until a designee is identified:

- 2182  
2183 1. MPSC Vice Chair  
2184 2. MPSC regional representatives, as selected by the OPTN President  
2185

2186 **L.3. Medical Peer Review**

2187 The OPTN will conduct all deliberations and take all actions according to applicable medical peer review  
2188 laws. Consistent with applicable laws, all inquiries, deliberations, recommendations, and actions during  
2189 member reviews by the OPTN will be kept confidential. All proceedings and records within the scope of  
2190 these OPTN quality review activities are confidential. Members of any OPTN Committee attending the  
2191 meeting in which a peer review is conducted, serving as a peer reviewer, working for or on behalf of the  
2192 OPTN, or providing information to the OPTN for peer review activities, are entitled to confidentiality.

2193  
2194 The OPTN will keep all materials, information, and correspondences to and from members and directly  
2195 related to the OPTN peer review process confidential to promote quality improvement and full disclosure  
2196 by OPTN members. Materials, information, and correspondences created by or for the peer review body  
2197 are considered "directly related."

2198  
2199 The OPTN will not disclose any materials provided to the OPTN by the member, except as required by  
2200 law. Materials prepared by members independent of the OPTN medical peer review process may be  
2201 shared by members in their discretion.  
2202

2203 **L.4. Conflicts of Interests**

2204 The OPTN's Conflict of Interest Policy applies to all OPTN inquiries, deliberations, recommendations and  
2205 actions during member reviews.

2207 **L.5. Investigation of Potential Noncompliance with OPTN Obligations**

2208 When the OPTN becomes aware of a member's potential noncompliance with OPTN Obligations, the  
2209 OPTN will conduct an investigation. This investigation will evaluate whether a potential noncompliance  
2210 exists. The investigation will also consider whether the potential noncompliance suggests a risk to patient  
2211 health or public safety, and the urgency and severity of the risk.

2213 Members must respond to all investigation requests within the specified period. A member may provide  
2214 any information that it believes is relevant to the investigation. The OPTN will notify the member of the  
2215 date by which the member must submit the requested or additional information.

2217 **L.6. Requests to Mitigate Risks**

2218 If an OPTN review suggests a potentially urgent or severe risk exists to patient health or public safety, the  
2219 OPTN may ask that the member take appropriate actions to mitigate the urgency and severity of the risk.  
2220 A member's failure to sufficiently mitigate the risk in the period requested will be considered a separate  
2221 potential noncompliance with OPTN Obligations.

2223 **L.7. Scheduling MPSC and Member Interactions**

2224 Members currently under MPSC review may be offered specific opportunities, in the form of informal  
2225 discussions, interviews, and hearings, to interact with the MPSC. The MPSC Chair will determine when  
2226 these interactions will be scheduled. Factors that will influence the scheduling of these MPSC and  
2227 member interactions include, but are not limited to, any of the following:

- 2229 • The urgency and severity of the issue
- 2230 • Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- 2231 • Adequate time for members to demonstrate the results and sustainability of their containment and  
2232 corrective action plans
- 2233 • The MPSC's meeting schedule

2234  
2235 The OPTN will notify the member when the MPSC is offering an informal discussion, interview, or  
2236 hearing. The OPTN's offer notice will include all of the following:

- 2238 1. The reasons the MPSC is offering the member an interaction
- 2239 2. The date by which the member must accept or decline the MPSC's offer
- 2240 3. A list of any information the OPTN would like the member to submit in advance of the interaction
- 2241 4. A summary of what the member should address during the interaction

2243 **L.8. Informal Discussions**

2244 An informal discussion is a direct conversation between a group of MPSC members and a member  
2245 currently under MPSC review. Informal discussions are intended to provide the MPSC and member an  
2246 opportunity to openly discuss the review and seek feedback. Informal discussions are information  
2247 gathering activities that may lead to a more efficient and effective review than written correspondence and  
2248 document reviews alone.

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**A. Member Informal Discussion Requests**

A member currently under review by the MPSC may request an informal discussion at any time. Members requesting an informal discussion must submit all of the following:

1. The reasons the member is requesting an informal discussion, including the applicable OPTN Policy or Bylaw
2. A summary of what the member would like to present to the MPSC, or what the member would like the MPSC to address during the informal discussion
3. Any information the member would like the MPSC to consider in advance of the informal discussion

The MPSC Chair will accept or decline a member’s request for an informal discussion with the MPSC within 14 days of receiving the member’s request. The OPTN will notify the member of the MPSC Chair’s decision.

**B. MPSC Informal Discussion Requests**

The MPSC or MPSC Chair may offer members currently under review one or more informal discussions at any time. A transplant program is entitled to an informal discussion before the MPSC recommends that the program inactivate or withdraw its designated transplant program status due to functional inactivity or transplant program performance reviews according to Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs.

**C. Waiving an Informal Discussion**

Members that decline the MPSC’s informal discussion request may submit additional written information for the MPSC’s review. The MPSC Chair will set a date by which the member must provide any additional written information.

Members that decline an MPSC informal discussion request do not waive their right to future interactions with the MPSC, including interviews and hearings.

**D. Informal Discussion Format**

Informal discussions will be conducted by teleconference and will include:

1. At least 10 minutes for the member to present information
2. At least 15 minutes for the member to respond to questions from the MPSC
3. At least 4 MPSC members

**E. Informal Discussion Outcome**

Within 21 days, the OPTN will provide the member with a written summary of the informal discussion.

The group that conducted the informal discussion may request that the member submit additional information for the MPSC’s review after the informal discussion, but will not take an action as outlined in Section L.12: OPTN Actions. The group will report its findings to the MPSC, along with any additional materials requested, no later than the MPSC’s next in-person meeting. Following this report, the MPSC will continue its review and will notify the member of any decisions or actions, including the reasons for the MPSC’s decision.

2298 **L.9. Interviews**

2299 An interview is an opportunity for the MPSC and member to discuss an ongoing review. During an  
2300 interview, the member has the opportunity to present information, including any steps the member has  
2301 taken to correct the issue and to address any concerns the MPSC shared with the member prior to the  
2302 interview. The MPSC will ask the member questions and will determine an appropriate action based on  
2303 the interview findings.

2304  
2305 **A. Right to an Interview**

2306 The MPSC or MPSC Chair may offer a member currently under MPSC review one or more  
2307 interviews at any time.

2308  
2309 The member has the right to an interview:

- 2310  
2311 1. Before the MPSC recommends that the Board of Directors places a member on Probation or  
2312 declares a member Not in Good Standing  
2313 2. If the MPSC rejects a member's request for release from Probation or Member Not in Good  
2314 Standing  
2315 3. If the MPSC recommends that the Board of Directors rejects a membership application as  
2316 outlined in *Appendix A: Membership Application and Review*  
2317 4. If the MPSC rejects a key personnel change application as outlined in *Appendix C:*  
2318 *Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership*  
2319 *Requirements for Transplant Hospitals and Transplant Programs*  
2320

2321 **B. Waiving an Interview**

2322 Members that do not respond to the interview offer by the specified date waive their right to an  
2323 interview.

2324  
2325 Members that waive their right to an interview with the MPSC also:

- 2326  
2327 • Waive their right to a hearing  
2328 • Waive their right to appear before the Board of Directors

2329  
2330 Members that waive their right to an interview must still respond to any MPSC requests for written  
2331 information and may provide additional written information for the MPSC to review. The MPSC  
2332 Chair will set a date by which the member must provide any additional written information.  
2333

2334 **C. Interview Format**

2335 Interviews may be conducted by teleconference or at an in-person MPSC meeting, as determined  
2336 by the MPSC Chair. Interviews will include:

- 2337  
2338 1. At least 15 minutes for the member to present information  
2339 2. At least 30 minutes for the member to respond to questions from the MPSC  
2340 3. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions  
2341 resulting from the interview.  
2342

2343 At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue  
2344 that is the subject of the review. If there are not at least 2 subject matter experts available from  
2345 the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN  
2346 committees. These individuals may participate in all aspects of the interview process, but they  
2347 serve in an advisory role and do not have a vote.  
2348

2349 **D. Possible Interview Outcomes**

2350 Following the interview, the MPSC will determine an appropriate action and notify the member of  
2351 the interview outcome. Within 21 days of the interview, the OPTN will provide the member with  
2352 documentation of the reasons for the MPSC's decision and a written summary of the interview.  
2353

2354 If the MPSC considers recommending an adverse action, then the member will be entitled to a  
2355 hearing with the MPSC before the MPSC forwards its recommendation to the Board of Directors.  
2356

2357 **L.10. Hearings**

2358 The MPSC will offer hearings to members when the MPSC is considering recommending that the Board  
2359 of Directors takes certain actions. Hearings are formal procedures during which the OPTN presents  
2360 information explaining the rationale for its recommendation. Hearings are the final opportunity for the  
2361 member to present information for the MPSC to consider before the MPSC makes its recommendation to  
2362 the Board of Directors.  
2363

2364 **A. Right to a Hearing**

2365 The member has the right to a hearing if the member participated in an interview and:  
2366

- 2367 1. Before the MPSC recommends that the Board of Directors places a member on Probation or  
2368 declares a member Not in Good Standing
- 2369 2. The MPSC rejects a member's request for release from Probation or Member Not in Good  
2370 Standing
- 2371 3. The MPSC recommends that the Board of Directors rejects a membership application as  
2372 outlined in *Appendix A: Membership Application and Review*
- 2373 4. The MPSC rejects a key personnel change application as outlined in *Appendix C:*  
2374 *Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership*  
2375 *Requirements for Transplant Hospitals and Transplant Programs*  
2376

2377 **B. Waiving a Hearing**

2378 Members that do not respond to the hearing offer by the specified date waive their right to a  
2379 hearing.  
2380

2381 Members that waive their right to a hearing with the MPSC also:  
2382

- 2383 • Accept the MPSC's recommendation
- 2384 • Waive their right to appear before the Board of Directors  
2385

2386 Members that waive their right to a hearing must still respond to any MPSC requests for written  
2387 information and may provide any additional written information for the MPSC to consider. The  
2388 MPSC Chair will set a date by which the member must provide any additional written information.  
2389

2390 **C. Hearing Format**

2391 Hearings will be conducted during an in-person MPSC meeting. The member and the OPTN have  
2392 the right to be represented by an attorney during a hearing.

2393  
2394 Hearings include all of the following:

- 2395  
2396 1. Equal time for the member and the OPTN to present information  
2397 2. At least 60 minutes for the member to present information  
2398 3. At least 60 minutes for the OPTN to present information  
2399 4. At least 60 minutes for the MPSC to question any member and OPTN representatives  
2400 present at the hearing  
2401 5. At least 10 MPSC members, which shall constitute a quorum for the purpose of any actions  
2402 resulting from the hearing.

2403  
2404 At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue  
2405 that is the subject of the review. If there are not at least 2 subject matter experts available from  
2406 the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN  
2407 committees. These individuals may participate in all aspects of the hearing process, but they  
2408 serve in an advisory role and do not have a vote.

2409  
2410 **D. Possible Hearing Outcomes**

2411 Following the hearing, the MPSC will determine an appropriate action and notify the member of  
2412 the hearing outcome. Within 21 days of the hearing, the OPTN will provide the member with  
2413 documentation of the reasons for the MPSC's decision and a transcript of the hearing.

2414  
2415 If the MPSC recommends an adverse action, then the member will be entitled to appear before  
2416 the Board of Directors.

2417  
2418 If the MPSC determines the matter represents a potentially urgent and severe risk to patient  
2419 health or public safety, the MPSC may recommend to the OPTN President that the OPTN  
2420 Executive Committee considers the MPSC's recommendation to allow for a more timely  
2421 resolution of the matter. The OPTN will notify the member following the hearing if the MPSC's  
2422 recommendation also includes a recommendation that the OPTN Executive Committee considers  
2423 the recommendation.

2424  
2425 **L.11. Appearances before the Board of Directors**

2426 Members and the MPSC Chair may appear before the Board of Directors prior to the Board of Directors  
2427 taking a final action on an MPSC recommendation. Appearances before the Board of Directors are formal  
2428 procedures that provide an opportunity for the MPSC Chair to explain the MPSC's recommendation and  
2429 for a member to present specific reasons as to why the Board of Directors should not support the MPSC's  
2430 recommendation.

2431  
2432 If the OPTN President determines that an urgent and severe risk to patient health or public safety exists  
2433 and that allowing the OPTN Executive Committee to consider the recommendation will allow for a more  
2434 timely resolution of the matter, the OPTN President may permit the appearance to take place before the  
2435 OPTN Executive Committee instead of the Board of Directors. In these instances, all requirements,  
2436 considerations, and actions described in the sections that follow that pertain to appearances before the  
2437 Board of Directors will apply to appearances before the OPTN Executive Committee.

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**A. Right to Appear before the Board of Directors**

A member has the right to appear before the Board of Directors if the member has participated in a hearing and afterwards one of the following conditions is met:

- The MPSC recommended that the Board of Directors places the member on Probation or declares a member Not in Good Standing
- The MPSC rejected a member’s request to be released from Probation or Member Not in Good Standing
- The MPSC recommended that the Board of Directors rejects a membership application as outlined in *Appendix A: Membership Application and Review*
- The MPSC rejected a key personnel change application as outlined in *Appendix C: Membership Requirements for Histocompatibility Laboratories* or *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*

**B. Accepting or Waiving a Board of Directors Appearance**

Members must accept or waive their right to appear before the Board of Directors within the period specified. Members that fail to respond to the offer of a Board of Directors appearance within the specified period waive their right to appear.

At the same time the member accepts its right to appear before the Board of Directors, the member must also provide its specific disagreements with the OPTN’s findings of fact, conclusions, or procedural issues that the member plans to contest before the Board of Directors.

Members that waive their right to appear accept the MPSC’s adverse action recommendation. Members that waive their right to appear may provide additional written information for the Board of Directors to consider. The OPTN President will set a date by which the member must provide any additional written information.

**C. Scheduling a Board of Directors Appearance**

The OPTN President will determine when a member’s appearance before the Board of Directors will occur. Factors that will influence the scheduling of a member’s Board of Directors appearance include, but are not limited to, any of the following:

- The urgency and severity of the issue
- Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk
- The Board of Directors’ meeting schedule

The OPTN will notify the member when the member is entitled to an appearance before the Board of Directors. The OPTN’s offer notice will include all of the following:

1. The reason the member is entitled to an appearance before the Board of Directors
2. The reasons for the MPSC’s recommendation to the Board of Directors
3. The date by which the member must accept or decline the offer
4. A summary of what the member should address during the interaction



2483 **D. Board of Directors Appearance Format**

2484 A member's appearance before the Board of Directors may be by teleconference or at an in-  
2485 person Board of Directors meeting, as determined by the OPTN President.

2486  
2487 The member and the OPTN have the right to be represented by an attorney during a Board of  
2488 Directors appearance.

2489  
2490 Board of Directors appearances include all of the following:

- 2491  
2492 1. Equal time for the member and the MPSC Chair to present  
2493 2. At least 10 minutes for the member to present information to the Board of Directors  
2494 3. At least 10 minutes for the MPSC Chair to present information to the Board of Directors  
2495 4. At least 15 minutes for the Board of Directors to ask questions of the member and MPSC  
2496 Chair

2497  
2498 A majority vote of the Directors present at any meeting at which a quorum is present is required  
2499 to approve an adverse action.

2500  
2501 **E. Burden of Proof**

2502 Appearances before the Board of Directors are to address specific disagreements with the  
2503 findings of fact, conclusions, or procedural issues raised at any step in the review process. The  
2504 member will have the burden of proving that the MPSC's recommendation lacks substantial basis  
2505 or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

2506  
2507 **F. Possible Board of Directors Appearance Outcomes**

2508 At the conclusion of the Board of Directors appearance, the Board of Directors will approve the  
2509 MPSC's recommendation or issue a lesser action and will notify the member of the outcome.  
2510 Within 21 days of the Board of Directors appearance, the OPTN will provide the member with a  
2511 written summary of the Board of Directors appearance.

2512  
2513 If the Board of Directors approves an adverse action, the OPTN will issue a public notice and the  
2514 member must provide additional notice within 30 days of receiving the Board of Directors  
2515 appearance summary as required according to Section L.12.D: OPTN Adverse Actions.

2516  
2517 **L.12. OPTN Actions**

2518 The OPTN may impose actions based on a member's failure to comply with OPTN Obligations. The  
2519 OPTN may impose a separate action for each noncompliance or may choose to impose a single action  
2520 for all related instances of noncompliance. The OPTN may also require a member to perform specific  
2521 activities to address a noncompliance. The OPTN will document all actions in the member's compliance  
2522 history.

2523  
2524 **A. Deferred Disposition**

2525 Deferred Disposition is a period to allow the member additional time to demonstrate improvement  
2526 and its ability and willingness to meet OPTN Obligations. Only the MPSC may offer a member a  
2527 Deferred Disposition period. The MPSC may offer a Deferred Disposition period at any time  
2528 before a hearing and may offer a member more than one Deferred Disposition period during a  
2529 review. Deferred Disposition does not apply to rejected membership applications.

2530  
2531 During this period, the member must demonstrate compliance with OPTN Obligations, including  
2532 implementation of and adherence to the member's corrective action plan or plan for quality  
2533 improvement. The MPSC will specify the length of the Deferred Disposition period, and may end  
2534 the Deferred Disposition period at any time if the MPSC determines, at its discretion, the member  
2535 is not demonstrating sufficient improvement or is not adhering to the member's corrective action  
2536 plan or plan for quality improvement. After the Deferred Disposition period, the MPSC will  
2537 evaluate whether the member has demonstrated improvement and implemented sustainable  
2538 corrective actions and will determine an appropriate action.

2539  
2540 The member is not entitled to an informal discussion, interview, hearing or Board of Directors  
2541 appearance to challenge the MPSC's decision not to offer, or to end, a Deferred Disposition  
2542 period.

2543  
2544 **B. Types of Actions**

2545 The OPTN may offer Deferred Disposition or take any of the following actions:

- 2546  
2547 • Close with No Action  
2548 • Issue a Notice of Noncompliance  
2549 • Issue a Letter of Warning  
2550 • Place a member on Probation  
2551 • Declare a member Not in Good Standing

2552  
2553 These actions represent a range, from Close with No Action to Member Not in Good Standing.  
2554 Close with No Action, Issuing a Notice of Noncompliance, and Issuing a Letter of Warning are  
2555 non-adverse actions. Non-adverse actions do not require approval by the Board of Directors and  
2556 are not made public. Probation and Member Not in Good Standing are adverse actions. Adverse  
2557 actions are further described in Section L.12.D: OPTN Adverse Actions.

2558  
2559 **C. Determining Appropriate Action**

2560 Factors considered when determining the appropriate action include, but are not limited to, the  
2561 extent to which:

- 2562  
2563 • The member has demonstrated an awareness of and accountability for the noncompliance,  
2564 including:  
2565     ○ whether the member self-reported the noncompliance  
2566     ○ whether the member took corrective action when learning of the noncompliance  
2567 • The noncompliance poses an urgent and severe risk to patient health or public safety  
2568 • The noncompliance poses or fails to avoid a substantial risk to the integrity of or trust in the  
2569 OPTN  
2570 • Patient medical records or other documentation provide sufficient detail to determine the  
2571 presence of mitigating factors at the time the noncompliance occurred  
2572 • The noncompliance demonstrates lack of stewardship of donated organs  
2573 • The noncompliance is likely to recur  
2574 • The member has demonstrated previous and ongoing compliance with OPTN Obligations  
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**D. OPTN Adverse Actions**

Probation and Member Not in Good Standing are the two OPTN adverse actions. Adverse actions are OPTN membership designations that must be approved by the Board of Directors and require public notice.

A member’s ongoing failure to comply with OPTN Obligations or a member’s failure to promptly address a potentially urgent and severe risk to patient health or public safety may result in the MPSC recommending that the Board of Directors takes an adverse action against the member.

Before the Board of Directors approves an adverse action, members have the right to an interview and a hearing with the MPSC and an appearance with the Board of Directors.

The Executive Committee will consider MPSC recommendations to release a member from an adverse action.

**1. Probation**

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**a. Loss of OPTN Privileges**

Members placed on Probation do not lose any OPTN membership privileges.

**b. Probation Notification Requirements**

When the Board of Directors places a member on Probation, the OPTN will provide notice to the public. This may include but is not limited to communication using the OPTN website. The OPTN may issue other public notices about the Probation as determined by the Board of Directors.

At its discretion, and based on the circumstances surrounding the noncompliance, the MPSC may recommend that the Board of Directors suspends, modifies, or adds to the requirements regarding the notice that members on Probation must provide. After the OPTN notifies the member that it has been placed on Probation, the member must provide notice within 30 days as instructed by the Board of Directors, if the Board of Directors acted on an MPSC recommendation regarding providing notice. If the MPSC did not provide, or the Board of Directors did not act on, recommendations for providing notice, then the member must provide notice within 30 days according to Table L-1 below.

**Table L-1: Probation Notification Requirements**

<b><u>If the member is a...</u></b>	<b><u>Then the member must provide notice to ...</u></b>
<u>Transplant hospital</u>	<u>All patients, as defined in these Bylaws, of the designated transplant program receiving Probation, including any new transplant program patients, during the entire Probation period. The notices must be provided in writing in each patient’s spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.</u>
<u>OPO</u>	<u>All hospitals that have a contractual agreement with the OPO in the OPO’s Donation Service Area (DSA).</u>
<u>Histocompatibility laboratory</u>	<u>All members that have a contractual agreement with the laboratory.</u>

2613

2614 These notices must communicate that the Board of Directors has placed the  
 2615 member on Probation and must also refer to the public notice about this action  
 2616 distributed by the OPTN.

2617  
 2618 The member must provide the OPTN Contractor a list of each patient and  
 2619 organization to whom it sent notice, along with an example of the notice it sent,  
 2620 by the date specified by the OPTN Contractor.

2621  
 2622 **c. Probation Monitoring Requirements**

2623 The MPSC will monitor members throughout the Probation period.  
 2624

2625 **2. Member Not in Good Standing**

2626 **a. Loss of OPTN Privileges**

2627 Members Not in Good Standing are prohibited from voting in OPTN matters and  
 2628 any personnel associated with the member are prohibited from serving on OPTN  
 2629 Committees and the Board of Directors. However, members designated  
 2630 Members Not in Good Standing must continue to comply with their OPTN  
 2631 member responsibilities.  
 2632

2633 **b. Member Not in Good Standing Notification Requirements**

2634 When the Board of Directors declares a member Not in Good Standing, the  
 2635 OPTN will provide notice to the public. This may include but is not limited to  
 2636 communication using the OPTN website. The OPTN may issue other public  
 2637 notices about the Member Not in Good Standing designation as determined by  
 2638 the Board of Directors.

2639  
 2640 After the OPTN notifies the member that it has been declared Not in Good  
 2641 Standing, the member must provide notice within 30 days according to Table L-2  
 2642 below.

2643 **Table L-2: Member Not in Good Standing Notification Requirements**  
 2644

<b><u>If the member is a...</u></b>	<b><u>Then the member must provide notice to ...</u></b>
<u>Transplant hospital</u>	<u>All transplant hospital patients as defined in these Bylaws, including any new transplant hospital patients, during the entire effective period of the Member Not in Good Standing designation. The notices must be provided in writing, in each patient's spoken language, and as specified by the Executive Committee or Board of Directors. The transplant program must retain a copy of the notification letter it provided to each individual patient.</u>
<u>OPO</u>	<u>All hospitals that have a contractual agreement with the OPO in the OPO's Donation Service Area (DSA).</u>
<u>Histocompatibility laboratory</u>	<u>All members that have a contractual agreement with the laboratory.</u>

2645  
 2646 These notices must communicate that the Board of Directors has declared the  
 2647 member Not in Good Standing and must also refer to the public notice about this  
 2648 action distributed by the OPTN.

2649  
 2650 The member must provide the OPTN Contractor a list of each patient and  
 2651 organization to whom it sent notice, along with an example of the notice it sent,  
 2652 by the date specified by the OPTN Contractor.  
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**c. Member Not in Good Standing Monitoring Requirements**

The MPSC will monitor members throughout the Member Not in Good Standing period, which will include the following:

- One or more unannounced on-site reviews
- One or more presentations by the member before the MPSC to provide an update on the member's corrective action plan and ongoing compliance with OPTN Obligations

**3. Release from Probation or Member Not in Good Standing**

**a. Request for Release**

A member on Probation or a Member Not in Good Standing must submit a written request to the OPTN requesting release from the adverse action. The MPSC will consider the member's request and will forward any recommendations to release a member from an adverse action to the Executive Committee for approval.

A member on Probation or a Member Not in Good Standing may request release from the adverse action when at least nine months have passed since *both* of the following occurred:

1. The MPSC approved the member's corrective action plan
2. The Board of Directors approved the adverse action

The MPSC may consider member requests to be released from an adverse action at any MPSC meeting where a quorum is present.

**b. Burden of Proof for Release**

When determining whether to release a member from Probation or a Member Not in Good Standing, the MPSC will consider whether the member can demonstrate *all* of the following:

1. It has implemented and adhered to its corrective action plan
2. Its corrective action plan is effective and sustainable
3. Its ongoing compliance with OPTN Obligations

The burden is on the member at all times to demonstrate that release from Probation or Member Not in Good Standing is appropriate.

**c. Possible MPSC Review Outcomes**

If the MPSC approves the member's request for release from Probation or Member Not in Good Standing, the MPSC will forward its recommendation to the OPTN Executive Committee. The OPTN President will determine the time and format for the OPTN Executive Committee to consider the MPSC's request.

If the MPSC rejects the member's request for release from Probation or Member Not in Good Standing, the MPSC must offer the member an interview.

**d. Possible OPTN Executive Committee Review Outcomes**

The OPTN President will determine the time and format, either in person or by teleconference, of the review. The OPTN Executive Committee will act on the MPSC's recommendation within 45 days of the date that the MPSC recommends the action.

2706  
2707 If the OPTN Executive Committee approves the MPSC’s recommendation and  
2708 releases the member from Probation or Member Not in Good Standing, the  
2709 OPTN will provide notice to the public. This may include, but is not limited to,  
2710 communication using the OPTN website. The MPSC may still require ongoing  
2711 monitoring of the member even after the OPTN Executive Committee has  
2712 released the member from Probation or Member Not in Good Standing.

2713  
2714 If the OPTN Executive Committee rejects the MPSC’s recommendation to  
2715 release the member from Probation or Member Not in Good Standing, the OPTN  
2716 will provide the member with a written summary of the reasons for declining the  
2717 MPSC’s recommendation. The member may submit another request to be  
2718 released from Probation or Member Not in Good Standing to the MPSC only after  
2719 it has addressed all of the reasons that the OPTN Executive Committee declined  
2720 the MPSC’s recommendation.

#### 4. Downgrading Member Not in Good Standing

2723 At its discretion, the MPSC may recommend that the Board of Directors downgrades  
2724 a Member Not in Good Standing designation to Probation. The OPTN President will  
2725 determine the time and format for the OPTN Board of Directors to consider the  
2726 MPSC’s request.

2727  
2728 The burden is on the member at all times to demonstrate that the lesser adverse  
2729 action is appropriate. The member is not entitled to an informal discussion, an  
2730 interview, a hearing or a Board of Directors appearance if the MPSC or the Board of  
2731 Directors does not support downgrading the Member Not in Good Standing to  
2732 Probation.

2733  
2734 If the Board of Directors downgrades a Member Not in Good Standing to Probation,  
2735 the OPTN will provide notice to the public. This may include, but is not limited to,  
2736 communication using the OPTN website. After the OPTN notifies the member that it  
2737 has been downgraded to Probation, the member:

- 2738  
2739 1. Will regain the ability to vote in OPTN matters  
2740 2. Will regain the ability for any personnel associated with the member to serve on  
2741 OPTN committees and the OPTN Board of Directors  
2742 3. Must comply with all Probation notification requirements  
2743 4. May request release from Probation when at least 3 months have passed since  
2744 the Board of Directors downgraded the member to Probation

### **L.13. Secretary of HHS Notice and Actions**

#### **A. Secretary’s Access to Information**

2747  
2748 The medical peer review privilege will not be extended to withhold any document from the  
2749 Secretary of HHS, or the Secretary’s designee. The OPTN Contractor is required to provide the  
2750 Secretary with any information acquired or produced under the OPTN Contract, including  
2751 information that would otherwise be protected by the medical peer review privilege. As specified  
2752 in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the  
2753 Secretary that the Secretary requests, in the format requested by the Secretary.

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**B. Health Resources and Services Administration (HRSA) Representation**

The Project Officer for the OPTN Contract and the Director of the Division of Transplantation within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*, non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting members of the Executive Committee and Board of Directors, they, or their designees, are granted full access to all deliberations, determinations, and actions. Representatives of HRSA are also *ex-officio*, non-voting members of the Membership and Professional Standards Committee (MPSC) and granted full access to all MPSC deliberations, determinations, and actions as well. Other designees of the Secretary may also attend OPTN meetings.

**C. Special Secretarial Reviews**

At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when the Secretary has reason to believe that the member may not be in compliance with the OPTN Final Rule or may be acting in a way that poses a risk to patient health or public safety. A Special Review is a review of the member in the manner and within the period specified by the Secretary. This may include, but is not limited to, requests for root cause analysis, corrective action, and due process proceedings completed in the period and as specified by the Secretary. Members must fully comply with all OPTN Contractor requests as part of a Special Review.

**D. OPTN Recommendations and Requests to the Secretary**

The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN Obligations or indicate a risk to the health of patients or to the public safety, and will provide any recommendations for appropriate action by the Secretary. Appropriate actions include, but are not limited to, those described in the OPTN Final Rule, as described in Section L.13.E Secretarial Actions that follows.

At any time, the Board of Directors may make recommendations to the Secretary for specific actions, on its own or after receiving a recommendation from the MPSC.

A member's failure to come into compliance with OPTN Obligations while designated as a Member Not in Good Standing may result in the Board of Directors recommending that the Secretary take action against the member.

If the Board of Directors finds, based on available evidence, that the member's potential violation poses a severe and urgent risk to patient health or public safety, the Board of Directors may recommend that a Secretarial action be made effective immediately, before completing any required interview or hearing.

**E. Secretarial Actions**

The Secretary may impose sanctions or take other appropriate action at any time when a member poses a risk to the health of patients or to the public safety.

Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

1. Violates the National Organ Transplant Act (NOTA).
2. Violates the OPTN Final Rule, 42 CFR Part 121.

- 2805 3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more  
2806 information on mandatory policies, see Section L.13.F: OPTN Policies Approved by the  
2807 Secretary as Mandatory.  
2808 4. Engages in behavior that poses a risk to patient health or public safety.  
2809

2810 Termination of membership requires Secretarial approval. Membership can only be terminated if  
2811 the OPTN member no longer meets the requirements for membership as described in the OPTN  
2812 Final Rule.

2813  
2814 In addition to termination of membership in the OPTN described above, the Secretary may take  
2815 appropriate actions, which include, but are not limited to:

- 2816  
2817 1. Removal of one or more of the member's designated transplant programs. After designated  
2818 transplant program status is removed, the program will no longer be eligible to receive organs  
2819 for transplantation within the OPTN.  
2820 2. Termination of the member's reimbursement under Medicare or Medicaid.  
2821 3. Termination of a transplant hospital's participation in Medicare or Medicaid.  
2822 4. Request for information from the OPTN.  
2823 5. Any other action that the Secretary considers necessary.  
2824

2825 If Secretarial action has been taken against a member, only the Secretary of HHS can restore its  
2826 unrestricted membership privileges. If Secretarial action has been taken against a member and  
2827 the member has presented evidence to the MPSC that it has fully complied with OPTN  
2828 Obligations, including completion of any actions prescribed as a result of the adverse action, the  
2829 MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges. If  
2830 a membership was suspended or terminated by the Secretary, the member must complete and  
2831 submit an application for OPTN membership.  
2832

2833 Actions recommended by the OPTN Board of Directors and taken by the Secretary for  
2834 noncompliance with mandatory policies will not become effective until the member has waived its  
2835 right to a hearing or the applicable hearing proceedings have been concluded.  
2836

## 2837 **F. OPTN Policies Approved by the Secretary as Mandatory**

2838 When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of  
2839 HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are  
2840 enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of  
2841 Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other  
2842 actions by the Secretary.  
2843

2844 Section 121.11(b)(2) of the OPTN Final Rule requires OPTN members that are OPOs and  
2845 transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the  
2846 Secretary certain information in the form required and in accordance with the schedule  
2847 prescribed.  
2848

2849 Data specified by the Secretary under this authority includes all data requested on forms  
2850 approved by the Office of Management and Budget (OMB), including all applications reviewed by  
2851 the OPTN. The Secretary may take an action described above for failure of a member to submit  
2852 accurate and complete data as required by the Secretary (including on OMB-approved forms).  
2853 Failure to submit accurate and complete data may also result in civil or criminal penalties.  
2854



2855 **L.14. Costs and Expenses**

2856 **A. Reimbursement of OPTN Contractor Costs and Expenses**

2857 Reasonable costs and expenses of conducting interviews and hearings as described in these  
2858 Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to all  
2859 of the following:

- 2860
- 2861 1. Travel and lodging expenses of member, volunteers, and OPTN Contractor representatives
  - 2862 2. Compensation of OPTN Contractor representatives
  - 2863 3. Court reporter fees
  - 2864 4. The costs of preparing copies of the hearing record
  - 2865 5. The member's costs of preparing for and attending the interview or hearing
  - 2866 6. The OPTN's costs of obtaining and compiling evidence and exhibits

2867

2868 OPTN Contractor representatives may include:

- 2869
- 2870 • OPTN Contractor staff
  - 2871 • Outside counsel
  - 2872 • Consultants
  - 2873 • Volunteers
  - 2874 • Expert witnesses

2875

2876 The OPTN will decide the nature and amount of expenses to be reimbursed. Reasonable costs  
2877 and expenses may be estimated and billed, wholly or partially, to the member in advance or may  
2878 be billed, wholly or partially, to the member as the matter is reviewed. If actual costs and  
2879 expenses otherwise reimbursable by the member for the entire matter before the MPSC are less  
2880 than \$500.00, or if member is not determined to be in violation of OPTN Obligations, no  
2881 reimbursement will be due from the member. In addition, any amounts previously reimbursed or  
2882 deposited will be returned. If the member has multiple matters before the MPSC within any 12-  
2883 month period, the \$500.00 amount will apply to all such matters cumulatively.

2884

2885 **B. Reasonable Costs and Expenses**

2886 Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be  
2887 reimbursed by the member, including any of the following:

- 2888
- 2889 1. Conducting other than routine on-site reviews
  - 2890 2. Reviewing and monitoring corrective action plans or plans for quality improvement
  - 2891 3. Conducting due process proceedings
  - 2892 4. Monitoring and conducting evaluations of transplant programs with lower than expected  
2893 survival rates as described in *Section D.12.A: Transplant Program Performance* of these  
2894 Bylaws, including on-site visits and monitoring plans for quality improvement

2895

2896 **C. Advanced Deposit for Reimbursable Costs and Expenses**

2897 The Executive Director may require that the member make and maintain a deposit with the OPTN  
2898 Contractor in an amount equal to the currently projected costs and expenses of any of the  
2899 following:

- 2900
- 2901 1. OPTN Contractor on-site reviews
  - 2902 2. OPTN member peer on-site reviews
  - 2903 3. The interview
  - 2904 4. The hearing

2905  
2906       The failure to make the required deposit within 10 days after the Executive Director requests an  
2907       advance deposit will be considered a waiver of the member's interview or hearing rights.  
2908       Following such a waiver, the MPSC and the Board of Directors may impose any actions, including  
2909       adverse actions.

2910  
2911       **D.     Default in Payment of Reimbursable Cost and Expenses**

2912       Any member who fails to reimburse costs and expenses within 30 days after receiving notice may  
2913       be referred to the Secretary for termination of OPTN membership.  
2914

2915       ***Appendix M: Definitions***

2916       **Informal Discussion**

2917       ~~An informal discussion is not an adverse action or an element of due process. An informal discussion is~~  
2918       ~~conducted according to the principles of confidential medical peer review, as described in *Appendix L* of~~  
2919       ~~these Bylaws. An informal discussion may be with the MPSC, a subcommittee, or a work group, as~~  
2920       ~~determined by the MPSC. An informal discussion may be held with a member regarding performance~~  
2921       ~~reviews, or when a transplant program is seeking approval for a transplant surgeon through the~~  
2922       ~~predominantly pediatric pathway.~~

2923       [Subsequent heading numbers, and any table captions and cross-references, affected by the re-  
2924       numbering of this policy will also be changed as necessary.]

#

## MEMBER GUIDE FOR INFORMAL DISCUSSIONS

### WHAT DO I NEED TO DO BEFORE THE DISCUSSION?

Informal discussions are offered when the MPSC feels that it needs more information about the circumstances of a review or the member's response to an issue. Review the relevant OPTN/UNOS Policies and Bylaws associated with your case.

Make sure you understand the requirements and the MPSC's concerns about the issue. Contact MPSC staff for clarification or additional information.

Decide who will participate in the discussion. Make sure you include anyone who is best suited to answer the MPSC's questions or address the MPSC's concerns.

Provide the information requested in the scheduling letter – including the names and titles of your participants, a contact number for at least one participant on the day of the meeting, and an electronic copy of your PowerPoint presentation – by the specified dates.

- We require that you submit a copy of your presentation in advance for technical reasons only; the Subcommittee will not receive or review your presentation prior to the meeting.

Determine what additional information you would like the MPSC to review before the informal discussion. What new information can you share to address the concerns outlined in your offer letter? If you have a significant amount of information to share or new information since your last submission, consider providing it to the Subcommittee in advance of the meeting. This will provide the Subcommittee with additional time to review the materials and will give you an opportunity to focus your presentation on key items.

Submit any new or relevant information to your staff contact by date specified in the scheduling letter, which will allow the MPSC to have sufficient time to review the materials before the informal discussion.

Prepare your presentation. The standard time for your presentation is 10 minutes. Remember the time constraints and plan accordingly for the most concise and relevant presentation possible. The informal discussion is an opportunity to provide the Subcommittee with additional information, including but not limited to, information regarding relevant quality improvement initiatives, or corrective actions that will positively impact the program.

- Based on the nature of your review consider whether you should include relevant facts about your organization; a timeline of events; details of your root cause analysis, corrective action plans, or plans for quality improvement; and/or updates to your policies or procedures.

## WHAT SHOULD I EXPECT?

Members of the MPSC, including ex-officio HRSA representatives, UNOS staff, and SRTR staff will be present on the call.

The Chair will read an introductory statement for the record, and staff will read a list of MPSC members on the phone.

The Chair will ask you to introduce your participants, after which you can begin your presentation.

You will be notified by the MPSC Chair when you have approximately two minutes remaining to present information. The Chair will open the floor for questions immediately following your presentation.

You will receive a formal letter and a summary of the informal discussion following the conference call. The names of all participants will be provided to you in the informal discussion summary.

## MEMBER GUIDE FOR INTERVIEWS WITH THE MPSC

### WHAT DO I NEED TO DO BEFORE THE INTERVIEW?

Interviews are offered when the MPSC feels that it needs more information to determine its level of response to a noncompliance with OPTN Obligations. Review the relevant OPTN/UNOS Policies and Bylaws associated with your case. Make sure you understand the requirements and your options.

Address the MPSC's concerns outlined in your interview offer letter. Contact MPSC staff for clarification or additional information.

Decide who will attend the interview. The MPSC encourages you to make sure you bring anyone who is the best suited to answer the MPSC's questions or address the MPSC's concerns. The MPSC may request that certain staff participate.

- For example, consider whether you should bring someone who can discuss your quality systems, metrics, staff training, and process improvements; a senior leader who can discuss the institution's commitment, resources and governance; a front line manager who can discuss day to day operations and oversight, or staff who were involved in a specific incident.
- Provide your attendee list, including names and titles of participants, to MPSC staff by the deadline in the attached letter.

Determine what additional information you would like the MPSC to review before the presentation. Consider what information you submitted to the MPSC before it's last review. What new information can you share to address the concerns outlined in your MPSC letter? What information about your organization do you want to share with the MPSC?

Examples of information submitted for the MPSC's review include:

- updated or expanded timeline of events
- revised corrective action plan
- assessed effectiveness of your corrective action plan(s)
- amended policies and procedures
- expanded details of your quality processes and/or training procedures
- established organizational chart, including new and open positions
- planned and ongoing recruitment efforts

Submit all information by the deadline in the attached letter, which will allow the MPSC to have sufficient time to review the materials before the interview. If you bring paper documents for the Committee on the day of the interview, the time required to distribute and collect the materials will be deducted from your presentation time. It is your responsibility to retrieve and properly dispose of paper documents.

Prepare your presentation. The standard time available for your presentation is 15 minutes. Remember the time constraints and plan accordingly for the most concise and relevant presentation possible. Some of the most valuable information is often shared during the question and answer session, and we allocate at least 30 minutes for that portion of the presentation. Provide a copy of the presentation to MPSC staff by the deadline in the attached letter.

Plan and book your travel arrangements. We make every effort to manage the day's agenda; however, we may begin your presentation up to an hour early or we may need to delay your start time by as much as 30-45 minutes. When organizing your departure, please make sure you allow sufficient time to check in and go through security at O'Hare Airport, a busy hub for the Midwest. Provide MPSC staff with your travel arrangements and contact information while traveling.

#### WHAT SHOULD I EXPECT AT THE INTERVIEW?

Please email your UNOS staff contact when you arrive at the hotel.

A UNOS staff member will meet you in the designated conference room and will escort you to the Grand Ballroom approximately 15 minutes before your presentation. Do not leave any items unattended while in this room, or leave anything in the room during the presentation. You will not have access to this room after your presentation.

The staff member will escort you into the meeting room. The MPSC Chair and Vice Chair will greet you and show you to your seats.

You will have a remote to advance your slides, water pitchers and glasses, pen and paper, and microphones at your seats. You may remain seated during the entire presentation. Please speak directly into a microphone at all times.

The MPSC Chair will read an introductory statement for the record and the MPSC Chair will ask you to introduce your participants, after which you can begin your presentation.

You will be notified by the MPSC Chair when you have approximately two minutes remaining to present information. The Chair will open the floor for questions immediately following your presentation.

At the conclusion of the question and answer session, UNOS staff will escort you out of the room. You may wait outside of the Grand Ballroom while the MPSC deliberates.

UNOS staff will notify you of the MPSC's decision at the conclusion of the deliberations. You should receive a formal letter and interview summary with additional details within two weeks of the interview, including details of the MPSC's concerns and next steps.

The attached list identifies all MPSC members who may be present on the day of the presentation, including ex-officio Committee members from the Health Resources Services Administration (HRSA). UNOS and SRTR staff will also be present in the room. The names of everyone present during the presentation will be provided to you in the interview summary after the interview.

## MEMBER GUIDE FOR HEARINGS WITH THE MPSC

### WHAT DO I NEED TO DO BEFORE THE HEARING?

The MPSC will offer hearings to members when the MPSC is considering recommending that the Board of Directors takes the actions of Probation or Member Not in Good Standing. Hearings are formal procedures during which the OPTN presents information explaining the rationale for its recommendation. Hearings are the final opportunity for the member to present information for the MPSC to consider before the MPSC makes its recommendation to the Board of Directors.

If your organization wishes to exercise its right to a hearing, you must submit written notification within the timeframe specified in your letter. Provide UNOS staff with the name and contact information for your counsel as soon as possible, but no later than the date specified in your hearing offer letter.

Review the relevant OPTN/UNOS Policies and Bylaws associated with your case. Make sure you understand the requirements and your options.

Address the MPSC's concerns outlined in your hearing offer letter, and review the questions included in your interview summary. Contact MPSC staff for clarification or additional information.

Each side is represented by counsel, presents opening statements and witness testimony, and has the opportunity to cross examine witnesses. During the question and answer portion of the hearing, the MPSC may ask questions of anyone present.

Decide who will attend the hearing. The MPSC encourages you to make sure you bring anyone who is the best suited to answer the MPSC's questions or address the MPSC's concerns. The MPSC may request that certain staff participate.

- For example, consider whether you should bring someone who can discuss your quality systems, metrics, staff training, and process improvements; a senior leader who can discuss the institution's commitment, resources and governance; a front line manager who can discuss day to day operations and oversight, or staff who were involved in a specific incident.
- Provide your attendee list, including names and titles of participants, to MPSC staff by the deadline provided in the hearing scheduling letter.
- Staff will notify you of a deadline to provide the names and titles of all witnesses participating at the hearing and a brief a summary of their anticipated testimony(s). The OPTN will provide your organization with the names of its witnesses and a summary of its witnesses' anticipated testimonies by the same day and time.

Staff will provide you with a complete file of all documents provided to the MPSC during their review of the issue. Determine what additional information you would like the MPSC to review before the presentation. Consider what information you submitted to the MPSC before its last review. What new information can you share to address the concerns outlined in your MPSC letter? What information about your organization do you want to share with the MPSC? If the MPSC has requested additional documentation prior to the hearing, make sure to submit the information by the requested date, so that the MPSC has time to review the documents prior to the hearing.

Examples of information submitted for the MPSC's review include:

- updated or expanded timeline of events
- revised corrective action plan
- assessed effectiveness of your corrective action plan(s)
- amended policies and procedures
- expanded details of your quality processes and/or training procedures
- established organizational chart, including new and open positions
- planned and ongoing recruitment efforts

*Submit* all information by the deadline in the attached letter, which will allow the MPSC to have sufficient time to review the materials before the hearing. You may provide a Powerpoint presentation to staff with your submission, or bring the presentation with you on a thumb drive to be uploaded to the presentation laptop right before your appearance. Please note that it is preferable to provide your presentation prior to the day of your hearing so that staff can ensure that it projects properly and allows ample time for adjustments to be made. Staff will not share your presentation with the committee prior to the hearing. If you bring paper documents for the Committee on the day of the hearing, staff will distribute them to the Committee members. However, the MPSC will likely not have time to review the information prior to the start of the hearing. It is your responsibility to ship, retrieve, and properly dispose of paper documents.

Prepare your testimony. Determine who will serve as your witnesses and the topics that you want them to cover. Please note that time limits are strictly enforced during the hearing. The standard time available for your presentation is 45 minutes, with an additional time for opening statement, rebuttal, and closing statement. Remember the time constraints and plan accordingly for the most concise and relevant presentation possible. The OPTN will have the same amount of time to present the reasons for the proposed action. Some of the most valuable information is often shared during the question and answer session, and we allocate at least 60 minutes for that portion of the presentation as well.

Plan and book your travel arrangements. While timelines are strictly enforced, the MPSC's deliberations may take a variable amount of time based on the information presented at the hearing. When organizing your departure, please make sure you allow sufficient time to check in and go through security at O'Hare Airport, a busy hub for the Midwest. Provide MPSC staff with your travel arrangements and contact information while traveling.

#### WHAT SHOULD I EXPECT AT THE HEARING?

Please email your UNOS staff contact when you arrive at the hotel.

A UNOS staff member will meet you outside the Grand Ballroom approximately 15 minutes before the hearing start time.

The staff member will escort you into the meeting room. The MPSC Chair and Vice Chair will greet you and show you to your seats.

You will have a remote to advance your slides, water pitchers and glasses, pen and paper, and microphones at your seats. You may remain seated during the entire hearing. Please speak directly into a microphone at all times.



The MPSC Chair will read an introductory statement for the record and the MPSC Chair will ask you to introduce your participants, after which the court reporter will swear in all witnesses. The OPTN representative will begin with their opening statement, after which your representative will do the same. The OPTN witnesses will then testify, followed by cross examination and any rebuttal.

After a break, your witnesses will testify. You will be notified by the MPSC Chair when you have approximately two minutes remaining in your witness testimony. Witness testimony will again be followed by cross examination and rebuttal.

After another break, the Chair will open the floor for questions from the MPSC.

At the conclusion of the question and answer session, each side will give their closing statements. UNOS staff will then escort you and the OPTN witnesses out of the room. You may wait outside of the Grand Ballroom while the MPSC preliminarily deliberates. Once the deliberations are over, UNOS staff will escort you back into the Grand Ballroom where the Chair will share the MPSC's overall concerns. You will then have five minutes to provide a response to address the concerns of the committee prior to their final deliberations.

UNOS staff will notify you of the MPSC's decision at the conclusion of the committee's final deliberations. You should receive an official hearing transcript and formal letter from the MPSC with additional details within two weeks of the hearing, including details of the MPSC's concerns and next steps.

The attached list identifies all MPSC members who may be present on the day of the presentation, including ex-officio Committee members from the Health Resources Services Administration (HRSA). UNOS and SRTR staff will also be present in the room. The names of everyone present during the presentation will be provided to you in the hearing transcript after the hearing.

## MEMBER GUIDE FOR APPEARANCES BEFORE THE BOARD OF DIRECTORS

### WHAT DO I NEED TO DO BEFORE THE BOARD APPEARANCE?

Members and the MPSC Chair may appear before the Board of Directors prior to the Board of Directors taking a final action on an MPSC recommendation of Probation or Member Not in Good Standing. Appearances before the Board of Directors are formal procedures that provide an opportunity for the MPSC Chair to explain the MPSC's recommendation and for a member to present specific reasons as to why the Board of Directors should not support the MPSC's recommendation.

If your organization wishes to exercise its right to appear before the Board of Directors, you must submit written notification within the timeframe specified in your letter. Along with your request to appear before the Board of Directors, you must also provide the specific disagreements with the OPTN's findings of fact, conclusions, or procedural issues that you plan to contest before the Board of Directors.

Address the MPSC's concerns outlined in your Board appearance offer letter, and review the transcript of the hearing and the concerns expressed by the MPSC after their deliberations. Contact MPSC staff for clarification or additional information.

Decide who will attend the Board appearance. Make sure you bring anyone who is the best suited to answer the Board's questions or address the disagreements with the OPTN's findings of fact, conclusions, or procedural issues.

- Provide your attendee list, including names and titles of participants, to MPSC staff by the deadline provided in the scheduling letter.
- Staff will notify you of a deadline to provide the names and titles of all participants.

Staff will provide the Board of Directors with a complete file of all documents provided to the MPSC during their review of the issue, as well as a hearing panel report and hearing transcript. Determine what additional information you would like the Board to review before the presentation. Consider what information you submitted to the MPSC before its last review. What new information can you share to address the concerns outlined in your MPSC letter?

Examples of information submitted for the Board's review include:

- detailed summary of disagreements with the OPTN's findings of fact, conclusions, or procedural issues
- revised corrective action plan
- assessed effectiveness of your corrective action plan(s)
- amended policies and procedures

Submit all information by the deadline in the offer letter, which will allow the Board to have sufficient time to review the materials before the Board appearance. You may provide a PowerPoint presentation to staff by the date requested. Staff will ensure that it projects properly. Staff will not share your presentation with the Board prior to the appearance.

Prepare your presentation. Determine who will speak before the Board and the topics that you want them to cover. Please note that time limits are strictly enforced during the Board appearance. The standard time available for your presentation is 10 minutes. Remember the time constraints

and plan accordingly for the most concise and relevant presentation possible. The MPSC Chair will also have 10 minutes to present information on the MPSC's recommendation. Some of the most valuable information is often shared during the question and answer session, and we allocate at least 15 minutes for that portion of the presentation.

Plan and book your travel arrangements. When organizing your departure, please make sure you allow sufficient time to check in and go through security at the airport. Provide MPSC staff with your travel arrangements and contact information while traveling.

#### WHAT SHOULD I EXPECT AT THE BOARD APPEARANCE?

Please email your UNOS staff contact when you arrive at the hotel.

A UNOS staff member will meet you outside the meeting room approximately 15 minutes before the Board appearance start time.

The staff member will escort you into the meeting room and show you to your seats.

You will have a remote to advance your slides, pen and paper, and microphones at your seats. You may remain seated during the entire presentation. Please speak directly into a microphone at all times.

The OPTN President will read an introductory statement for the record and ask you to introduce your participants, after which you can begin your presentation. After your presentation, the MPSC Chair will present information on the MPSC's decision. The President will then open the floor for questions from the Board.

At the conclusion of the question and answer session, UNOS staff will escort you out of the room. You may wait outside of the meeting room while the Board deliberates. UNOS staff will notify you of the Board's decision at the conclusion of the deliberations. You should receive a formal letter with additional details within two weeks of the Board appearance, including next steps.

## **Frequently Asked Questions MPSC Probation Recommendations**

The Membership and Professional Standards Committee's (MPSC) Probation recommendation entitles your organization to a hearing. This document gives you general information about what Probation entails and an overview of the hearing process. Probation and the member's procedural rights when the MPSC is considering an adverse action are defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at <https://optn.transplant.hrsa.gov/governance/bylaws/>. UNOS staff will provide you with a formal notification of the MPSC's decisions and more specific information regarding next steps within approximately two weeks.

### ***What is Probation?***

Probation is a public designation indicating that an OPTN member institution is undergoing extensive corrective action for compliance with OPTN obligations, or for a situation that, if left uncorrected, could pose a risk to the health and safety of transplant patients, living donors, or other members of the public. This could involve issues including a pattern of unresolved noncompliance with OPTN policies or bylaws, a sustained length of time where patient or graft survival is substantially below statistically expected outcomes, or a lengthy period of program inactivity.

The MPSC monitors any member on Probation for at least nine months. At a minimum, a member on Probation must submit detailed information regarding the implementation and effectiveness of its corrective actions for MPSC review at each of the MPSC's in person meetings. The MPSC may also require a member on Probation take additional actions, including but not limited to participating in peer visits or a site survey by UNOS staff (announced and unannounced), providing presentations to the MPSC, participating in informal discussions with the MPSC, obtaining external consultants, and visiting high performing OPTN members. The MPSC will only recommend that the Board of Directors release a member from Probation after the member has demonstrated compliance with OPTN obligations and has successfully implemented its corrective action plans.

Probation does not directly affect the ability of an OPTN member to continue to provide services. A transplant hospital may continue to provide transplant services; an organ procurement organization may continue to recover and allocate organs from deceased donors; and a laboratory may continue to provide transplant related services. The OPTN does not have the authority to close a member organization or remove it from the OPTN network – only the Secretary of HHS has that authority.

### ***What Are Our Options?***

#### **Request a Hearing**

If your organization wishes to exercise its right to hearing, you must submit written notification within the specified timeframe, typically within 7-14 days of receipt of the formal MPSC recommendation. UNOS staff will specify the amount of time in which you must make your request.

If your organization submits a hearing request within the prescribed time period, UNOS staff will notify you of the hearing date, time, and place. Hearings typically take place at the Hilton Hotel located at the Chicago O'Hare International Airport.

### **Decline the Hearing**

Your organization may decline the hearing. Your organization must acknowledge that it declines the hearing by submitting written notification to UNOS staff by the specified deadline, typically within 7-14 days of your formal notification. The MPSC may then recommend that the Board of Directors move forward with the adverse action of Probation. If you decline the hearing, your organization also declines its opportunity to appear before the Board of Directors.

### ***How Should We Prepare for the Hearing?***

- Staff will send you a letter, typically within 7-14 days, formally notifying you of the MPSC's recommendation. The letter will include information regarding the MPSC's observations and concerns. Ensure that you understand the MPSC's concerns. Ask UNOS staff if you have any questions or you require additional information.
- Review the OPTN Bylaws, Appendix L regarding hearings.
- Provide UNOS staff with the name and contact information for your counsel as soon as possible, but no later than the date specified in your hearing offer letter.
- Review the hearing record, which includes all documentation that was available to the MPSC. Staff will provide you with all documents shortly after receiving your request for a hearing.
- Identify who will come to the hearing. Members typically bring 5 – 10 representatives, based on the nature of their case. You should ensure the appropriate individuals are present to address the MPSC's concerns or answer questions, from senior leaders to staff who participated in specific cases. There is no limit on the number of representatives you may bring.
- Staff will notify you of a deadline to provide the names and titles of all witnesses participating at the hearing and a brief a summary of their anticipated testimony(s). The OPTN will provide your organization with the names of its witnesses and a summary of its witnesses' anticipated testimonies by the same day and time.
- Practice your witness testimony to ensure you do not exceed the allowable time. Time limits are strictly enforced during hearings.
- Submit any information you would like the MPSC to review in advance of the hearing by the specified date in your hearing offer letter, typically at least three weeks before the hearing. Submitting information in advance provides the MPSC with sufficient time to review the information.
- Book your travel. Hearings are held at the Chicago O'Hare Hilton Hotel and frequently begin as early as 7am. We strongly encourage you to arrive the night prior to the hearing and book your return flights no sooner than three hours from the estimated hearing end time.

### ***What Should We Expect at the Hearing?***

- Each side presents opening statements and witness testimony, and has the opportunity to cross examine witnesses. During the question and answer portion of the hearing, the MPSC may ask questions of anyone present. Please note that time limits are strictly enforced during the hearing. You may request to re-allocate the allocated rebuttal time for your witness testimony, but your total testimony time may not exceed the given time limit.

Any time not used will be reallocated at the Chair's discretion for the question and answer session and/or the Committee's deliberation period.

- A court reporter will be present and provide a transcript of the proceedings.
- A sample timeline of how the hearing may be conducted is included at the end of this document. Staff will provide a specific schedule in advance of the hearing.
- Staff will provide an area for you to wait while the Committee deliberates. Staff will notify you of the MPSC's decision at the conclusion of their deliberations.

### ***What Happens After the Hearing?***

After a hearing, the MPSC may issue a lesser action or continue to recommend Probation. If the MPSC recommends Probation, the MPSC will forward its recommendation to the Board of Directors for approval. Your organization will have the right to appear before the Board of Directors. Staff will send you a letter within approximately two weeks of the hearing formally notifying you of the MPSC's recommendations and your options to appear before the Board.

If the Board of Directors places your organization on Probation, the OPTN will release a statement notifying the public. The statement, including a high level summary of the events or concerns that prompted the action, is posted on the OPTN website. Additional details beyond the public summary remain part of the OPTN's confidential record of the institution and are not subject to public disclosure. Your organization would also be required to notify certain patients or other organizations as outlined in the OPTN Bylaws.

Alternatively, the MPSC may issue your organization a Letter of Warning, a Notice of Noncompliance or close the issue with no action. The MPSC may also request ongoing monitoring. These actions are immediate and do not require approval by the Board of Directors or require any public notification.

As specified in the Bylaws, the reasonable costs and expenses of conducting the hearing may be charged to your organization. Such costs and expenses include but are not limited to, the travel and lodging expenses of the OPTN Contractor representatives; the court reporter fees and the cost of preparation of the necessary number of copies of the hearing record; and the fees and expenses of the attorneys for the OPTN Contractor. If it is determined that your organization is in violation of OPTN obligations, the estimated costs associated with this hearing could be up to or exceed \$125,000, depending on overall legal fees. Please note this amount may vary significantly as costs are incurred. This amount is provided to give you a general estimate of the potential expense. A binding decision as to the nature and total amount of the chargeable costs and expenses of the hearing will be made by the Presiding Officer after consultation with the OPTN Executive Director.

**Sample Hearing Schedule**

15 minutes:	Opening remarks by Chair, serving as Hearing Officer Introduction of Committee Members, Participants Swearing in of witnesses by court reporter
10 minutes	OPTN Opening Statement
10 minutes	Member Opening Statement
45 minutes	OPTN witnesses testify
15 minutes	Member cross examination of OPTN witnesses
10 minutes	OPTN Rebuttal
15 minutes	Break
45 minutes	Member witnesses testify
15 minutes	OPTN cross examination of Member witnesses
10 minutes	Member Rebuttal
15 minutes	Break
60 minutes	Questions by Committee Members
5 minutes	Member closing statement
5 minutes	OPTN closing Statement
10 minutes	Break, Hearing participants leave room
60 minutes	Committee deliberations
15 minutes	Member hears decision and responds to Committee concerns
15 minutes	Final deliberations

## **FREQUENTLY ASKED QUESTIONS MPSC MEMBER NOT IN GOOD STANDING RECOMMENDATIONS**

The Membership and Professional Standards Committee's (MPSC) Member Not in Good Standing recommendation entitles your organization to a hearing. This document gives you general information about what being a Member Not in Good Standing entails and an overview of the hearing process. Member Not in Good Standing and the member's procedural rights when the MPSC is considering an adverse action are defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at <https://optn.transplant.hrsa.gov/governance/bylaws/>. UNOS staff will provide you with a formal notification of the MPSC's decisions and more specific information regarding next steps within approximately two weeks.

### ***What is Member Not in Good Standing?***

Member Not in Good Standing is a public designation of an OPTN organization that has failed to meet key expectations for compliance with OPTN obligations. It could also apply to an organization with a current situation that could pose a risk to the health and safety of transplant patients, living donors or other members of the public. This could involve a single adverse event or a pattern of unresolved behavior. Member Not in Good Standing is the strongest possible designation the OPTN may impose.

A Member Not in Good Standing is not allowed to vote on OPTN matters including approval of bylaws and election of the OPTN Board of Directors. Additionally, no representative from a Member Not in Good Standing is allowed to participate on the Board of Directors or any of the advisory committees that develop proposals for Board consideration as national transplant policy.

The MPSC monitors any member declared a Member Not in Good Standing for at least nine months. At a minimum, a Member Not in Good Standing must submit detailed information regarding the implementation and effectiveness of its corrective actions for MPSC review at each of the MPSC's in person meetings. The MPSC may also require a Member Not in Good Standing take additional actions, including but not limited to participating in peer visits or a site survey by UNOS staff (announced and unannounced), providing presentations to the MPSC, participating in informal discussions with the MPSC, obtaining external consultants, and visiting high performing OPTN members. The MPSC will only recommend that the Board of Directors restore a Member Not in Good Standing to full membership privileges after the member has demonstrated compliance with OPTN obligations and has successfully implemented its corrective action plans.

Member Not in Good Standing does not directly affect the ability of an OPTN member to continue to provide services. A transplant hospital may continue to evaluate, list, transplant and provide follow up care to patients; a laboratory may continue to provide transplant services, and an organ procurement organization may continue to recover and allocate organs from deceased donors. The OPTN does not have the authority to close a member organization or remove it from the OPTN network – only the Secretary of HHS has that authority.



## ***What Are Our Options?***

### **Request a Hearing**

If your organization wishes to exercise its right to hearing, you must submit written notification within the specified timeframe, typically within 7-14 days of receipt of the formal MPSC recommendation. UNOS staff will specify the amount of time in which you must make your request.

If your organization submits a hearing request within the prescribed time period, UNOS staff will notify you of the hearing date, time, and place. Hearings typically take place at the Hilton Hotel located at the Chicago O'Hare International Airport.

### **Decline the Hearing**

Your organization may decline the hearing. Your organization must acknowledge that it declines the hearing by submitting written notification to UNOS staff by the specified deadline, typically within 7-14 days of your formal notification. The MPSC may then recommend that the Board of Directors move forward with the adverse action of Member Not in Good Standing. Declining the hearing means that your organization also declines the opportunity to appear before the Board of Directors.

### ***How Should We Prepare for a Hearing?***

- Staff will send you a letter, typically within 7-14 days, formally notifying you of the MPSC's recommendation. The letter will include information regarding the MPSC's observations and concerns. Ensure that you understand the MPSC's concerns. Ask UNOS staff if you have any questions or you require additional information.
- Review the OPTN Bylaws, Appendix L regarding hearings.
- Provide UNOS staff with the name and contact information for your counsel as soon as possible, but no later than the date specified in your hearing offer letter.
- Review the hearing record, which includes all documentation that was available to the MPSC. Staff will provide you with all documents shortly after receiving your request for a hearing.
- Identify who will come to the hearing. Members typically bring 5 – 10 representatives, based on the nature of their case. You should ensure the appropriate individuals are present to address the MPSC's concerns or answer questions, from senior leaders to staff who participated in specific cases. There is no limit on the number of representatives you may bring.
- Staff will notify you of a deadline to provide the names and titles of all witnesses participating at the hearing and a brief a summary of their anticipated testimony(s). The OPTN will provide your organization with the names of its witnesses and a summary of its witnesses' anticipated testimonies by the same day and time.
- Practice your witness testimony to ensure you do not exceed the allowable time. Time limits are strictly enforced during hearings.
- Submit any information you would like the MPSC to review in advance of the hearing by the specified date in your hearing offer letter, typically at least three weeks before the hearing. Submitting information in advance provides the MPSC with sufficient time to review the information.

- Book your travel. Hearings are held at the Chicago O'Hare Hilton Hotel and frequently begin as early as 7am. We strongly encourage you to arrive the night prior to the hearing and book your return flights no sooner than three hours from the estimated hearing end time.

### ***What Should We Expect at the Hearing?***

- Each side presents opening statements and witness testimony, and has the opportunity to cross examine witnesses. During the question and answer portion of the hearing, the MPSC may ask questions of anyone present. Please note that time limits are strictly enforced during the hearing. You may request to re-allocate the allocated rebuttal time for your witness testimony, but your total testimony time may not exceed the time given. Any time not used will be reallocated at the Chair's discretion for the question and answer session and/or the Committee's deliberation period.
- A court reporter will be present and provide a transcript of the proceedings.
- A sample timeline of how the hearing may be conducted is included at the end of this document. Staff will provide a specific schedule in advance of the hearing.
- Staff will provide an area for you to wait while the Committee deliberates. Staff will notify you of the MPSC's decision at the conclusion of their deliberations.

### ***What Happens After the Hearing?***

After a hearing, the MPSC may issue a lesser action or continue to recommend Member Not in Good Standing. If the MPSC recommends an adverse action (either Member Not in Good Standing or Probation), the MPSC will forward its recommendation to the Board of Directors for approval. Your organization will have the right to appear before the Board of Directors.

If the Board of Directors declares your organization a Member Not in Good Standing or places your organization on Probation, the OPTN will release a statement notifying the public. The statement, including a high level summary of the events or concerns that prompted the action, is posted on the OPTN website. Additional details beyond the public summary remain part of the OPTN's confidential record of the institution and are not subject to public disclosure. Your organization would also be required to notify certain patients or other organizations as outlined in the OPTN Bylaws.

Alternatively, the MPSC may issue your organization a Letter of Warning, a Notice of Noncompliance or close the issue with no action. The MPSC may also request ongoing monitoring. These actions are immediate and do not require approval by the Board of Directors. These actions do not require any public notification.

As specified in the Bylaws, the reasonable costs and expenses of conducting the hearing may be charged to your organization. Such costs and expenses include but are not limited to, the travel and lodging expenses of the OPTN Contractor representatives; the court reporter fees and the cost of preparation of the necessary number of copies of the hearing record; and the fees and expenses of the attorneys for the OPTN Contractor. If it is determined that your organization is in violation of OPTN obligations, the estimated costs associated with this hearing could be up to or exceed \$125,000, depending on overall legal fees. Please note this amount may vary significantly as costs are incurred. This amount is provided to give you a general estimate of the potential expense. A binding decision as to the nature and total amount of the chargeable costs and expenses of the hearing will be made by the Presiding Officer after consultation with the OPTN Executive Director.

**Sample Hearing Schedule**

15 minutes:	Opening remarks by Chair, serving as Hearing Officer Introduction of Committee Members, Participants Swearing in of witnesses by court reporter
10 minutes	OPTN Opening Statement
10 minutes	Member Opening Statement
45 minutes	OPTN witnesses testify
15 minutes	Member cross examination of OPTN witnesses
10 minutes	OPTN Rebuttal
15 minutes	Break
45 minutes	Member witnesses testify
15 minutes	OPTN cross examination of Member witnesses
10 minutes	Member Rebuttal
15 minutes	Break
60 minutes	Questions by Committee Members
5 minutes	Member closing statement
5 minutes	OPTN closing Statement
10 minutes	Break, Hearing participants leave room
60 minutes	Committee deliberations
15 minutes	Member hears decision and responds to Committee concerns
15 minutes	Final deliberations

DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/OPO MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear NAME, NAME, and NAME:

At its meeting on MEETING DATE, the Membership and Professional Standards Committee (MPSC) reviewed a report that MEMBER NAME (XXXX) description of issue. The MPSC reviewed your submission, and decided that they required additional information on this event.

Continued description of issue, including information on the member's response and any documents submitted for the MPSC's review.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee requests that MEMBER NAME participate in an informal discussion with the committee.

The Committee voted XX For; X Against; and X Abstentions.

**MPSC Concerns**

The MPSC was particularly concerned by list specific committee concerns, including examples from discussion and member response documents. Include any additional information requested or any documentation to submit prior to discussion.

The MPSC requests that XXXX participate in an informal discussion prior to the MPSC meeting scheduled for MEETING DATE. This informal discussion will take place via conference call. If your institution wishes to participate in the informal discussion, please submit written notification to Betsy Warnick, Senior Compliance Operations Analyst, Member Quality Department no later than DATE, to [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org).

Please submit the additional requested information by **DATE**. The MPSC will review the documentation prior to the informal discussion.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Regional Review Committees must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact Betsy Warnick at **PHONE NUMBER** or [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org).

Sincerely,

MPSC Chair  
Chair, OPTN/UNOS Membership and Professional Standards Committee

XXX/xx

cc: **OPTN/UNOS REPRESENTATIVE (if not included earlier)**

DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear NAME, NAME, and NAME:

The Membership and Professional Standards Committee (MPSC) met on DATE, and reviewed a report that MEMBER NAME (XXXX) description of issue, including noncompliance with Policies NAME POLICIES.

Continue to summarize issue, include date of event and any corrective actions or policy/procedure changes.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee requests that MEMBER NAME participate in an interview with the committee.

The Committee voted XX For, X Against, and X Abstentions.

**MPSC Concerns**

The MPSC is concerned that list specific committee concerns, including examples from discussion and member response documents. The Committee reviewed this incident while also taking into account XXXX's compliance history, including two Notices of Uncontested Violation in 2013 for mislabeled blood tubes, a Letter of Warning in 2014 for mislabeling kidney laterality, a Notice of Uncontested Violation in 2014 for an incorrect hemodilution calculation, and a Letter of Warning in 2015 for improperly labeled vessels. The MPSC was concerned that the pattern of recurrent noncompliance led to the error in question.

## Options and Timelines

The interview process is described in Appendix L of the Bylaws, which can be accessed on the OPTN website at <http://optn.transplant.hrsa.gov>. The MPSC requests an interview with a member when it feels that additional information and a conversation with the member is necessary to determine the appropriate next step of a review.

XXXX has the following options:

1. Request an interview. If your institution wishes to exercise its right to an interview, please submit written notification to Betsy Warnick, Senior Compliance Operations Analyst, Member Quality Department no later than **5:00 pm EDT on DATE**, via secure email to [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org) or at the address in the letterhead using a method that can be tracked and provides proof of receipt. Should your institution exercise its right to an interview, the interview will be held at the MPSC's next meeting on **MEETING DATE**.

If XXXX chooses to appear before the MPSC, the Committee has requested that XXXX provide the following information prior to the interview:

- Bulleted list of documents
- Usually including RCA, CAP, QAPI monitoring, or additional explanations

Additionally, the MPSC has suggested that XXXX plan for the following staff to appear in-person before the committee:

- Chief Executive Officer
- Chief Medical Officer
- Director of Quality
- Director of Family Services
- Staff member directly involved in the issue
- An organizational trainer

After an interview, the MPSC may issue an action or recommend potential referral to Board of Directors for an adverse action. If the MPSC recommends these actions, your institution will be entitled to a hearing with the MPSC.

2. Decline the interview. Your institution must acknowledge that it declines this interview by submitting written notification to Betsy Warnick by **5:00 pm EDT on DATE**, using a method described in item one above. Should your institution decline the interview, the MPSC will review any additional information and take an action. Please note that if you decline your interview and the MPSC considers recommending an adverse action, your institution would have the right to submit additional written information. **As specified in the Bylaws, if your institution declines the interview, you also decline the opportunity to participate in a hearing or to appear before the Board of Directors.**

***Should your institution not request an interview in the manner described above, the institution is deemed to have waived its right to an interview and the MPSC may proceed to take an action.***

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations,

recommendations, and actions of the MPSC, Board of Directors, other committees, and Regional Review Committees must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact Betsy Warnick at **PHONE NUMBER** or [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org).

Sincerely,

MPSC Chair,  
Chair, OPTN/UNOS Membership and Professional Standards Committee

XXX/xx

cc: **OPTN/UNOS REPRESENTATIVE (if not already included)**

SAMPLE



DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear **NAME**, **NAME**, and **NAME**:

This letter is to confirm that **MEMBER NAME**'s (**XXXX**) interview with the OPTN/UNOS Membership and Professional Standards Committee (MPSC) has been scheduled for **DATE**, at **TIME**.

The interview will occur in Chicago, Illinois in the Grand Ballroom at the O'Hare Hilton Hotel. The interview schedule includes 15 minutes for **XXXX** to present information, followed by approximately 30 minutes for **XXXX** to respond to questions from the MPSC. We will notify you of the interview outcome immediately after the MPSC's deliberations.

I will provide you with the location of a conference room in the hotel where you can wait for your interview to start closer to the date of the meeting. The MPSC meeting agenda is fluid, and we may begin your interview early, if possible. Please make sure all of your interview participants are in the designated conference room at least 60 minutes before the scheduled interview time noted above. A UNOS staff member will escort you from the holding room to the Grand Ballroom when the MPSC is ready to begin your interview.

In preparation for the interview, please send me the following information by email to [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org) by **DATE**:

- A list of all personnel who will participate in the interview. Include their full name and title. This information will be included in the MPSC meeting agenda.
- Any additional documentation you would like the MPSC to review in advance of your interview. Because your presentation will be limited to 15 minutes, we strongly encourage you to provide information in advance. This can include, but is not limited to, narrative summaries or explanations of events, information regarding your institution's volume, updated corrective action plans, organizational charts, policies and procedures, etc.

In addition, please send me the following information by **DATE**:

- The name and telephone number for at least one interview participant who can be contacted on-site as needed for scheduling changes or other questions.
- A PowerPoint version of your presentation. Your presentation will not be shared with the MPSC prior to your interview. Staff need the presentation in advance to ensure it is properly loaded to the IT equipment during the meeting set up.

The O'Hare Hilton Hotel is located outside Terminals 1, 2, and 3, directly across from the B concourse, and can be accessed from the lower level of the B concourse or outside the baggage area of United Airlines (Terminal 1). The telephone number for the hotel is (773) 686-8000 and the fax number is (773) 601-2873.

The attached document, **Member Guide for Interviews with the MPSC**, will also help you prepare for your interview. If you have questions or concerns, or need any additional information, please contact me at **PHONE NUMBER**.

Sincerely,

NAME  
Compliance Operations Analyst

Enc.

cc: **OPTN/UNOS REPRESENTATIVE (if not included earlier)**

DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear NAME, NAME, and NAME:

On DATE, the Membership and Professional Standards Committee (MPSC) continued its review of MEMBER NAME (XXXX). Include brief description of issue. Based on its review, the MPSC requested that XXXX participated in an interview with the MPSC, which occurred on DATE.

Describe any information or documentation submitted by the member, which the MPSC reviewed in preparation for the interview. The MPSC considered your institution's file, statements by the representatives present at the interview, written records, and applicable provisions of the OPTN Final Rule, Bylaws and Policies. The MPSC also considered any supporting rationale and generally accepted technical or scientific information that was relevant to the interview. A summary of the interview is included with this letter.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee recommends that the Board of Directors place MEMBER NAME on Probation for noncompliance with Policies NAME POLICIES.

The Committee voted XX For, X Against, and X Abstentions.

**MPSC Concerns**

The MPSC is concerned that list specific committee concerns, including examples from discussion and member response documents. Also, acknowledge any strengths or improvements noted from the interview. The goal is to be clear why the MPSC decided to take the action, and provide the member with some specific reasons that the member can respond to, if necessary.

**Options and Timelines**

Probation and the member's procedural rights when the MPSC is considering an adverse action are specifically defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at <http://optn.transplant.hrsa.gov>.

XXXX has the following options:

1. Request a hearing. If your institution wishes to exercise its right to a hearing, you must submit written notification to Betsy Warnick by **5:00 pm EDT on DATE**, via secure email to [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org) or at the address in the letterhead using a method that can be tracked and provides proof of receipt.

The Bylaws describe the hearing process.

- During a hearing you would be entitled to present any information relevant to the general nature of the organization's ability to comply with Bylaws and Policies.
- All materials about the institution that were considered by the MPSC, consisting of supplemental information furnished by the institution and copies of correspondence, will be made available to you.
- If your institution submits a hearing request within the prescribed time period, UNOS staff will notify you of the hearing date, time, and place. Your institution's representatives must be present to participate in the hearing, which may also include legal counsel.
- Please specify whether the institution will be represented by counsel at the hearing and identify that counsel in the request for a hearing.

After a hearing, the MPSC may issue a lesser action or continue to recommend Probation. If the MPSC continues to recommend Probation, your institution will have the right to appear before the Board of Directors.

As specified in the Bylaws, the reasonable costs and expenses of conducting the hearing will be charged to your institution. Such costs and expenses will include, but not be limited to, the travel and lodging expenses of the OPTN Contractor representatives; the court reporter fees and the cost of preparation of the necessary number of copies of the hearing record; the costs of obtaining and compiling evidence and exhibits; and the fees and expenses of the attorneys for the OPTN Contractor in preparing for and attending the hearing. A binding decision as to the nature and total amount of the chargeable costs and expenses of the hearing will be made by the Presiding Officer after consultation with the Executive Director.

2. Decline the hearing, and accept the adverse action of Probation. Your institution must acknowledge that it accepts this action by submitting written notification to Betsy Warnick by **5:00 pm EDT on DATE**, using a method described in item one above. The MPSC may then recommend that the Board move forward with the adverse action of Probation. **As specified in the Bylaws, if your institution declines the hearing, you also decline the opportunity to appear before the Board of Directors.**

***Should your institution not request a hearing or accept the adverse action in the manner described above, the institution is deemed to have waived its right to a hearing and the MPSC may continue to recommend that the Board of Directors place **XXXX** on Probation.***

You are reminded that this letter and all related documents comprise confidential medical peer review materials, which must be kept confidential by members during the review process and after the matter is closed. If you have any questions or concerns, or need any additional information regarding this resolution, please contact Betsy Warnick at phone number or [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org).

Sincerely,

MPSC Chair  
Chair, Membership and Professional Standards Committee

XXX/xx

Enc

cc: OPTN/UNOS REPRESENTATIVE (if not included earlier)  
MEMBER COUNSEL (if member has provided name)

DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear NAME, NAME, and NAME:

The Membership and Professional Standards Committee (MPSC) received on DATE, a letter from MEMBER NAME (XXXX) requesting a hearing pursuant to the Bylaws Appendix L. The hearing has been scheduled for DATE, at START TIME a.m. CDT, in Chicago at the O'Hare Hilton Hotel.

The hearing will be conducted to consider the MPSC's DATE recommendation that the Board of Directors place XXXX on Probation based on violations of NAME POLICIES.

During the hearing your institution may present information, including any information that was previously submitted to the MPSC. XXXX is entitled to all materials generated by or submitted to the MPSC regarding the institution. All materials that will be provided to the MPSC for consideration during XXXX's hearing will be sent to you via secure email, and will be incorporated in to the hearing record.

XXXX may be represented by an attorney at the hearing. XXXX has advised UNOS that it will be represented by COUNSEL NAME AND FIRM. The OPTN will be represented by COUNSEL NAME AND FIRM.

During a hearing, XXXX has the right to call and examine witnesses, introduce exhibits, cross-examine witnesses, impeach witnesses and rebut any evidence. Please identify who XXXX will call as its witnesses, along with their titles or area of expertise and a summary of the witnesses' anticipated testimonies no later than 5:00 p.m. EDT on DATE. This information should be submitted via email to Betsy Warnick at [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org). The OPTN will provide XXXX with a summary of its witnesses and the witnesses' anticipated testimonies by the same day and time.

The total time for the presentation of evidence and Committee deliberation at the hearing is 6 hours and 15 minutes. Enclosed is a timeline of how the hearing will be conducted.

The attached document, **Member Guide for Hearings with the MPSC**, will also help you prepare for your hearing. If you have any further questions or concerns regarding this resolution or need any additional information, please contact me at **PHONE NUMBER** or UNOS General Counsel at **PHONE NUMBER**.

Sincerely,

NAME  
Compliance Operations Analyst, UNOS

**XXX/**

Enc.

cc: **OPTN/UNOS REPRESENTATIVE (if not already included)**  
**MEMBER COUNSEL**

**MEMBER NAME**  
**Hearing Timeline**  
**DATE**  
**Chicago O'Hare Hilton**  
**Chicago, Illinois**

- 7:30 – 7:45 Opening remarks by Chair, serving as Hearing Officer.  
Introduction of Committee Members, Participants  
Swearing in of witnesses by court reporter
- 7:45 – 7:55 Opening Statement by OPTN Counsel
- 7:55 – 8:05 Opening Statement by XXXX Counsel
- 8:05 – 8:50 OPTN witnesses testify
- 8:50 – 9:05 Cross examination of OPTN witnesses
- 9:05 – 9:15 Rebuttal (Any portion of this time may be allocated to the OPTN presentation  
provided that aggregate time may not exceed :55)
- 9:15 – 9:30 Break
- 9:30 – 10:15 XXXX witnesses testify
- 10:15 – 10:30 Cross examination of XXXX witnesses
- 10:30 – 10:40 Rebuttal (Any portion of this time may be allocated to the XXXX presentation  
provided that aggregate time may not exceed :55)
- 10:40 – 10:55 Break
- 10:55 – 11:55 Questions by Committee Members
- 11:55 – 12:00 Closing statement by XXXX
- 12:00 – 12:05 Closing Statement by OPTN
- 12:05 – 12:15 Break, Hearing participants leave room
- 12:15 – 1:15 Committee deliberations
- 1:15 – 1:30 Member hears decision and responds to Committee concerns
- 1:30 – 1:45 Final deliberations

(Notes: These time frames are an example for each step in the process. If the issue is extremely long or controversial, times for testimony, cross examination, or committee member questions may need to be extended.)



DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR  
TITLE  
MEMBER NAME  
ADDRESS  
ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR  
TITLE  
MEMBER NAME  
ADDRESS  
ADDRESS

PRIMARY PROGRAM ADMINISTRATOR  
TITLE  
MEMBER NAME  
ADDRESS  
ADDRESS

Dear NAME, NAME, and NAME:

On DATE, the Membership and Professional Standards Committee (MPSC) met and continued its review of MEMBER NAME (XXXX). For reference, this letter summarizes the relevant procedural history of the MPSC's review.

**Review Process**

At its meeting on DATE, the MPSC reviewed a summary of events, and other information that showed a violation of OPTN Policies. Based on its review, the MPSC, considered recommending that the Board of Directors declare XXXX a Member Not in Good Standing.

This consideration entitled XXXX to an interview with the MPSC, which occurred on DATE. Your institution submitted a plan for quality improvement in response to the issue, which the MPSC reviewed in preparation for the interview. Based on its review and deliberations, the MPSC recommended that the Board of Directors place XXXX on Probation for violations of NAME POLICIES. In addition, the MPSC expressed concerns about include other concerns about member response and this particular issue. After conducting the interview with your institution, the MPSC noted that the plan and presentation lacked a thorough analysis of the underlying issues, particularly the risk to patient safety, and did not include specific dates, responsible parties, data for measuring success, or timelines for follow up.

The MPSC notified XXXX of this resolution and of its right to a hearing by letter on DATE, and provided an interview summary. XXXX requested a hearing on DATE. On DATE, UNOS staff provided XXXX with copies of all materials generated by or submitted to the MPSC regarding the issue.

XXXX participated in a hearing with the MPSC on DATE. A copy of the hearing transcript is enclosed. Based on your institution's file, the testimony and written evidence, and the applicable provisions of the Bylaws and Policies, the MPSC approved the following at the conclusion of its deliberations following the hearing:

RESOLVED, that the Membership and Professional Standards Committee recommends that the Board of Directors place MEMBER NAME on Probation for violations of NAME POLICIES.

The MPSC approved this resolution by a vote of XX For, X Against and X Abstentions.

The MPSC did not approve XXXX's corrective action plan at this time. The MPSC will review the corrective action plan and approve or request modifications on an upcoming conference call.

### MPSC Concerns

The MPSC acknowledges and appreciates that XXXX has recently taken many steps to address the MPSC's concerns. The MPSC also recognizes that XXXX is committed to changing the culture and to addressing the issue. However, the MPSC believes XXXX has not sufficiently demonstrated that it has implemented sustainable and effective changes, and the MPSC is concerned that XXXX's corrective action plan may not be effective. Moreover, the MPSC believes that XXXX has not yet addressed a number of its concerns. For example, specify the reasons that the MPSC has not approved the corrective action plan and the ongoing issues.

### Options and Timelines

Probation and the member's procedural rights when the MPSC is recommending an adverse action are specifically defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at <http://optn.transplant.hrsa.gov>.

According to Appendix L, XXXX has the right to appear before the Board of Directors. Specifically, XXXX has the right to submit a written statement and provide an oral statement that details any disagreement with the findings of fact, conclusions or procedural issues raised at any step in the review process.

XXXX should submit its request to appear before the Board of Directors by **5:00 pm EDT on DATE**. If requested, the appearance will take place at the regular Board of Directors meeting currently scheduled for DATE, at the Omni Richmond Hotel in Richmond, Virginia. If XXXX wishes to appear, the Board of Directors will review the issue on DATE, starting at TIME EDT.

If XXXX wishes to submit a written statement for the Board of Directors' review, we ask that XXXX submit any written statement by **5:00 pm EDT on DATE**.

XXXX should submit all of the information requested above to Betsy Warnick via secure email at [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org) or at the address in the letterhead using a method that can be tracked and that provides proof of receipt.

You are reminded that this letter and all related documents comprise confidential medical peer review materials, which must be kept confidential by members during the review process and after the matter is closed. If you have any further questions or concerns regarding this issue or

need any additional information, please contact Betsy Warnick at **PHONE NUMBER** or UNOS General Counsel at **PHONE NUMBER**.

Sincerely,

MPSC Chair  
Chair, OPTN/UNOS Membership and Professional Standards Committee

**XXX/xx**

Enc.

cc: **OPTN/UNOS REPRESENTATIVE (if not included earlier)**  
**MEMBER COUNSEL**

SAMPLE

DATE

**VIA SECURE EMAIL**

PROGRAM DIRECTOR/OPO ADMINISTRATIVE DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PROGRAM DIRECTOR/MEDICAL DIRECTOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

PRIMARY PROGRAM ADMINISTRATOR

TITLE

MEMBER NAME

ADDRESS

ADDRESS

Dear NAME, NAME and NAME:

On DATE, the Membership and Professional Standards Committee (MPSC) continued its review of MEMBER NAME (XXXX) regarding a violation of NAME POLICIES. XXXX participated in a hearing with the MPSC. At the conclusion of the hearing, the MPSC recommended that the Board of Directors place XXXX on Probation.

According to the Bylaws, XXXX has the right to appear before the Board of Directors. XXXX has the right to submit a written statement and to provide an oral statement that details any disagreement with the findings of fact, conclusions, or procedural issues raised at any step in the review process. On DATE, XXXX notified UNOS of its intent to appear before the Board of Directors.

This letter confirms that XXXX's appearance before the OPTN/UNOS Board of Directors has been scheduled for DATE, at TIME. The appearance will occur at the Omni Richmond Hotel located at 100 South 12th Street, Richmond, Virginia 23219. The hotel's telephone number is (804) 344-7000.

XXXX will have 10 minutes to provide an oral statement and then the Chair of the MPSC will have 10 minutes to provide the MPSC's report. The Board of Directors will have the opportunity to ask both participants questions. UNOS staff will notify you of the Board of Directors' decision following their review.

Please make sure you are available in the Ballroom lobby at least 15 minutes before your appearance. A UNOS staff member will meet you in the lobby and escort you into the Ballroom at the appropriate time.

If you plan to have a PowerPoint presentation, please provide it to me via email at [betsy.warnick@unos.org](mailto:betsy.warnick@unos.org) no later than TIME on DATE, so that UNOS staff can ensure the

presentation projects on the screen properly and is ready at the start of your appearance. Staff will provide you with a remote to advance the slides. Please also send me a complete list of the hospital representatives who will appear before the Board of Directors and the contact number of a representative who will be in attendance no later than **DATE**.

The attached document, **Member Guide for Board Appearances**, will also help you prepare for your appearance. If you have questions or concerns regarding your scheduled appearance before the Board of Directors, or need any additional information, please contact me at **PHONE NUMBER** or UNOS General Counsel at **PHONE NUMBER**.

Sincerely,

NAME  
Compliance Operations Analyst

cc: **OPTN/UNOS REPRESENTATIVE (if not included earlier)**  
**MEMBER COUNSEL**

SAMPLE

## Appendix L: Reviews, Actions, and Due Process

<i>Current Bylaws Section</i>			<i>Modifications for Public Comment</i>
L.1.		<b>Member Compliance</b>	Deleted section from Appendix L. Very similar language is already included in <b>Article 1.1.E (Member Compliance)</b> . Not necessary to duplicate in Appendix L.
	A.	<b>Periodic Reviews</b>	Deleted section from Appendix L. Now included in <b>Article 1.1.F (Member Reviews and Evaluations)</b> .
	B.	<b>Failure to Pay OPTN Fees</b>	Deleted section from Appendix L. Very similar language is already included in <b>Article 1.1.D (Expenses)</b> . Not necessary to duplicate in Appendix L.
L.2.		<b>Compliance Monitoring</b>	Deleted section from Appendix L. Content combined with similar language in <b>Article 1.1.F</b> .
L.3.		<b>Reporting Potential Violations and Non-compliance</b>	Deleted section from Appendix L. Now included in <b>Article 1.1.G</b> .
L.4.		<b>Methods for Correspondence and Providing Notice</b>	<b>Now L.1.</b> Deleted bulleted list of examples, moved second paragraph to L.5
L.5.		<b>Medical Peer Review</b>	<b>Now L.3.</b> Edited to clarify OPTN and member responsibilities
	A.	<b>Secretary's Access to Information</b>	<b>Now L.13.A.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
	B.	<b>Health Resources and Services Administration (HRSA) Representation</b>	<b>Now L.13.B.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
L.6.		<b>Requests for Root Cause Analysis and Corrective Action</b>	Deleted section. Investigation and requests to mitigate risks are now covered in L.5 and L.6, but detailed examples deleted
	A.	<b>Initiating Corrective Action</b>	Deleted section. Remaining content thought to be duplicative or understood per other Bylaws requirements
	B.	<b>Fulfilling Requests for Root Cause Analysis and Corrective Action</b>	Deleted section. Content thought to be understood per other Bylaws requirements
L.7.		<b>Special Secretarial Reviews</b>	<b>Now L.13.C and L.13.E.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
L.8.		<b>Review Pathways for Potential Violations</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
L.9.		<b>Preliminary Investigation of Potential Violations</b>	Investigations <b>now covered in L.5</b> , references to Imminent Threat and Expedited Review deleted.
	A.	<b>Referral of Potential Violations to the MPSC Chair</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	B.	<b>Notice to the Secretary after Preliminary Investigation</b>	Deleted, no longer applicable once review pathways are eliminated. Secretary's access to information (now L.13.A) also addresses the need to notify the Secretary of any MPSC actions.
L.10.		<b>Determination of Review Pathway</b>	<i>Section Title Deleted</i>
	A.	<b>MPSC Chair's Determination of Urgency and Severity</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary

## Appendix L: Reviews, Actions, and Due Process

<i><b>Current Bylaws Section</b></i>			<i><b>Modifications for Public Comment</b></i>
	<b>B.</b>	<b>Requests to Take Action to Mitigate Imminent Threat</b>	Deleted section. Requests to mitigate <b>now covered in L.6</b> without the reference to Imminent Threat
	<b>C.</b>	<b>Notice of Chair's Determination</b>	Deleted section. No longer applicable. Secretary's access to information (now L.13.A) also addresses the need to notify the Secretary of any MPSC actions
	<b>D.</b>	<b>Changing Review Pathways</b>	Deleted section. No longer applicable.
<b>L.11.</b>		<b>OPTN Investigations</b>	Deleted section. Investigations <b>covered in L.5</b> , additional detail on preliminary versus additional investigation no longer needed. Deleted "including but not limited to" lists throughout proposal.
<b>L.12.</b>		<b>Imminent Threat Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>A.</b>	<b>Imminent Threat Review Investigation</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>B.</b>	<b>Imminent Threat Review Committee</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
		<b>1. Composition of the Imminent Threat Review Committee</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
		<b>2. Imminent Threat Review Committee Recommendation</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
		<b>3. Notice after Imminent Threat Review Committee Recommendation</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>C.</b>	<b>Interviews in Imminent Threat Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>D.</b>	<b>OPTN Executive Committee Determination</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>E.</b>	<b>Notice after OPTN Executive Committee's Determination</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>F.</b>	<b>Requesting a Hearing in Imminent Threat Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>G.</b>	<b>Imminent Threat Hearing Process</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
<b>L.13.</b>		<b>Expedited Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>A.</b>	<b>Expedited Review Investigation</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>B.</b>	<b>Expedited Review Committee</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary

## Appendix L: Reviews, Actions, and Due Process

<i>Current Bylaws Section</i>			<i>Modifications for Public Comment</i>
	<b>C.</b>	<b>Interviews in Expedited Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>D.</b>	<b>Requesting a Hearing in Expedited Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>E.</b>	<b>Expedited Review Hearing Panel</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>F.</b>	<b>Expedited Review Hearing Process</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
<b>L.14.</b>		<b>Routine Reviews</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>A.</b>	<b>Routine Review Investigations</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>B.</b>	<b>Routine Review Committee</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
		<b>1. Notice after Routine Review Committee's Determinations</b>	Deleted section. Rewrite of review process no longer includes specified pathways, but all investigations can include requests to mitigate and can move as fast as necessary
	<b>C.</b>	<b>Interviews in Routine Reviews</b>	<b>Now L.9 Interviews.</b> Updated to describe an interview and reflect changes in the interview process. Specific action will not be determined at this point, MPSC will just decide if it would like to offer the member an interview to discuss the potential noncompliance further. Content details the member's right, interview format, and possible outcomes. Also describes a new approach to prevent members from waiving steps of due process only to more quickly advance to later steps of due process.
		<b>1. Requesting an Interview</b>	<b>Now L.9.A Right to an Interview.</b> Specifies when the MPSC must offer an interview. Scheduling and notice also referenced in L.7.
	<b>D.</b>	<b>Hearings in Routine Reviews</b>	<b>Now L.10 Hearings.</b> Updated to describe a hearing and reflect changes in the hearing process. Content details the member's right, hearing format, and possible outcomes. Also describes a new approach to prevent members from waiving steps of due process only to more quickly advance to later steps of due process.
		<b>1. Requesting a Hearing</b>	<b>Now L.10.A Right to a Hearing.</b> Specifies when the MPSC must offer a hearing. Scheduling and notice also referenced in L.7.
		<b>2. Routine Review Hearing Panel</b>	<b>Now covered by L.10.C Hearing Format.</b> Describes hearing panel as well as process of hearing.
		<b>3. Routine Review Hearing Process</b>	<b>Now covered in L.10.D Possible Hearing Outcomes.</b> Removed reference to Routine Review.
<b>L.15.</b>		<b>OPTN Determinations and Actions</b>	<b>Now L.12 OPTN Actions.</b> List deleted as it is duplicative of other Bylaws. Sentence from L.15.A regarding separate actions added.



## Appendix L: Reviews, Actions, and Due Process

<i>Current Bylaws Section</i>			<i>Modifications for Public Comment</i>
	<b>A.</b>	<b>Determining Appropriate Action</b>	<b>Now L.12.C.</b> List expanded and clarified
	<b>B.</b>	<b>Corrective Action</b>	<b>Now covered by L.5 and L.6;</b> Remaining content thought to be duplicative or understood per other Bylaws requirements
	<b>C.</b>	<b>Deferred Disposition with Monitoring Period</b>	<b>Now L.12.A.</b> Updated to provide MPSC more flexibility to offer deferred disposition, and in hopes of member addressing issue without proceeding further through due process
		<b>1. Additional Considerations for Deferred Disposition</b>	Deleted section to make deferred disposition more flexible and useful.
		<b>2. Notice of Deferred Disposition</b>	<b>Now covered in L.12.A</b>
		<b>3. Monitoring during Deferred Disposition</b>	<b>Now covered in L.12.A</b>
		<b>4. Recommendation of an Adverse Action during or after Deferred Disposition</b>	<b>Now covered in L.12.A</b>
		<b>5. Actions if Member Demonstrates Compliance after Deferred Disposition</b>	<b>Now covered in L.12.A</b>
	<b>D.</b>	<b>MPSC Actions without Board Referral</b>	<b>Complete list of actions now in L.12.B.</b> Modified to explain that actions are a range, include close with no action as an option, and remove Letter of Reprimand.
		<b>1. Notice of Uncontested Violation</b>	Deleted specific section to shift away from describing the type of noncompliance that warrants this action.
		<b>2. Letter of Warning</b>	Deleted specific section to shift away from describing the type of noncompliance that warrants this action.
		<b>3. Letter of Reprimand</b>	Deleted section and removed as an option
	<b>E.</b>	<b>Adverse Actions that Require Board Approval</b>	<b>Now L.12.D.</b> Intent is to make the description of these actions more meaningful as a resource for members and more clearly explain the differences between these determinations
		<b>1. Probation</b>	<b>Now L.12.D.1.</b> Rewritten to explain more clearly what probation is and the consequences of the Board taking this action.
		<b>2. Member Not in Good Standing</b>	<b>Now L.12.D.2.</b> Rewritten to explain more clearly what Member Not in Good Standing is and the consequences of the Board taking this action.
	<b>F.</b>	<b>Recommendations and Requests to the Secretary</b>	<b>Now L.13.D OPTN Recommendations and Requests to the Secretary.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
<b>L.16.</b>		<b>Secretarial Actions</b>	<b>Now L.13.E.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
	<b>A.</b>	<b>OPTN Policies Approved by the Secretary as Mandatory</b>	<b>Now L.13.F.</b> All Secretary information consolidated into a single section. No language changes except references to other Bylaws sections or as directed by HRSA.
<b>L.17.</b>		<b>Interviews</b>	<b>Now L.9 Interviews</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.

## Appendix L: Reviews, Actions, and Due Process

<i>Current Bylaws Section</i>			<i>Modifications for Public Comment</i>
	A.	Members' Right to an Interview	<b>Now L.9 Interviews</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	B.	Requesting or Waiving the Right to an Interview	<b>Now L.9 Interviews</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	C.	Notice of Interview	<b>Now L.9 Interviews</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	D.	Notice to Member after an Interview	<b>Now L.9 Interviews</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	E.	Informal Discussion	<b>Now L.8 Informal Discussions.</b> Description now provides additional information on scheduling and potential outcomes
L.18.		Hearings	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	A.	Members' Right to a Hearing	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	B.	Requesting or Waiving the Right to a Hearing	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	C.	Notice of Hearing	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	D.	Appointment of Hearing Panels	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	E.	Hearing Participants	<b>Now L.10 Hearings</b> New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	F.	Service on Hearing Panels	<b>Now covered by L.4 Conflicts of Interest</b>
	G.	Appearance and Representation at Hearings	<b>Now L.10 Hearings.</b> All hearing information has been written at a higher level to allow for additional flexibility in the hearing process
	H.	Presiding Officer	Deleted section
	I.	Rights of Hearing Participants	Deleted section
	J.	Procedure and Evidence	Deleted section
	K.	Official Notice	Deleted section
	L.	Burden of Proof	Deleted section
	M.	Hearing Record	<b>Now in L.10 Hearings</b>
	N.	Postponement	Deleted section
	O.	Presence of Hearing Panel	Deleted section
	P.	Recesses and Adjournment	Deleted section
	Q.	Action after Hearing	<b>Now L.10.D Possible Hearing Outcomes</b>

## Appendix L: Reviews, Actions, and Due Process

<i>Current Bylaws Section</i>			<i>Modifications for Public Comment</i>
	R.	Hearing Panel Report	Now L.10.D Possible Hearing Outcomes
	S.	Notice after Hearing	Now L.10.D Possible Hearing Outcomes
	T.	Effect of Favorable Result	Now L.10.D Possible Hearing Outcomes
	U.	Effect of Adverse Result	Now L.10.D Possible Hearing Outcomes
L.19.		Final Decision of the Board of Directors	Now L.11 Appearances before the Board of Directors. New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing.
	A.	Right to Appear before the Board	Now L.11.A, B, and C. Additional detail added regarding a member's right to appear before the Board and the purpose of the appearance. New language added to reiterate that the member waives their right to appear before the Board if they waive their right to an interview or hearing. Additional information provided about scheduling.
	B.	Board of Directors Action	Now L.11.F Possible Board Appearance Outcomes
	C.	Notice	Now covered in L.12.D
L.20.		Restoration of Unrestricted Membership Privileges	Now L.12.D.3 Provides additional detail on specific requirements of restoration. Changes the minimum required timeframe to nine months. Paragraph that discusses Secretarial actions moved to L.13.E.
	A.	Request for Restoration of Membership Privileges	Now L.12.D.3.a
	B.	Minimum Requirements to Request Restoration of Membership Privileges	Combined into L.12.D.3.a
	C.	Additional Requirements	Now in L.12.D.1 or 2 as part of requirements for Probation or Member Not in Good Standing
	D.	Hearing	Now L.12.D.3.c. Modified to eliminate the possibility of hearing to streamline and reduce costs of this process. If MPSC rejects restoration request, member has the right to an interview.
	E.	Restoration of Privileges after Violation of Mandatory Policies under Section 121.10(c) of the OPTN Final Rule	Included in Section L.13 with other Secretary actions
L.21.		Lesser Adverse Actions	Now L.12.D.4. Updated to focus on the possibility of downgrading a member from Member Not in Good Standing to Probation. Eliminated possibility of "trial restoration period" as this option has not been historically used or considered. Clarifies that member is not entitled to informal discussion, interview, hearing, or Board appearance if the MPSC does not support the request
	A.	Requesting a Lesser Adverse Action	Now in L.12.D.4
	B.	Considering Requests for Lesser Adverse Actions	Now in L.12.D.4
L.22.		Rejected Membership Applications	Now in Appendix A.1.C, A.5, C.5.C, D.8.F, G.2.C, G.3.C, I.2.D, I.3.C. Also listed in L.9 Interviews, L.10 Hearings, and L.11 Appearances before the Board

## Appendix L: Reviews, Actions, and Due Process

<b><i>Current Bylaws Section</i></b>			<b><i>Modifications for Public Comment</i></b>
L.23.		Costs and Expenses	Now L.14, no language changes
	A.	Reimbursement of OPTN Contractor Costs and Expenses	Now L.14.A
	B.	Reasonable Costs and Expenses	Now L.14.B
	C.	Advanced Deposit for Reimbursable Costs and Expenses	Now L.14.C
	D.	Default in Payment of Reimbursable Cost and Expenses	Now L.14.D
<b><i>New Bylaws Section</i></b>			<b><i>Additions for Public Comment</i></b>
L.2 (new)		Representative Terminology Used Throughout Appendix L	New section intended to capture standard language appearing in Appendix L.
L.4 (new)		Conflicts of Interest	New section intended to capture that all reviews in Appendix L are subject to conflict of interest considerations.
L.6 (new)		Requests to Mitigate Risks	New section intended to clarify that -- even though the "Imminent Threat Review" process has been removed -- the MPSC Chair may ask a member to take specific action to mitigate the urgency and severity of a risk to patient health or public safety.
L.7 (new)		Scheduling MPSC and Member Interactions	New section intended to combine all mentions of notice and when interactions may occur. Also provides additional details of what the member can expect from an offer notice.

# Appendix L “Evaluation Plan”

<b>Appendix L Section</b>	<b>Language</b>
Throughout	“OPTN Obligations” are defined in Article I: Membership of the OPTN Bylaws.
L.1 (Methods for Correspondence)	Tracked and provides proof of receipt includes but is not limited to: <ul style="list-style-type: none"> <li>• Commercial overnight delivery service</li> <li>• Secure electronic communication</li> <li>• Registered or certified mail, return receipt requested</li> </ul>
L.3 (Medical Peer Review)	<p>Members may not share copies or details of directly related materials. Examples of materials considered “directly related” include but are not limited to:</p> <ul style="list-style-type: none"> <li>• site survey reports</li> <li>• peer visit reports</li> <li>• inquiry letters</li> <li>• informal discussion and interview summaries</li> <li>• hearing transcripts</li> <li>• member presentations or responses prepared for the MPSC</li> <li>• copies of any completed templates or documents provided by the OPTN for members to use in response to a review, such as a completed site survey corrective action plan template or a completed peer visit plan for quality improvement template.</li> </ul> <p>Materials that are not considered directly related are things that the member may create or produce on their own, regardless of whether the member is under review by the OPTN. This information is protected by confidential medical peer review when shared with the OPTN, and the OPTN will keep the information confidential. Members may choose to share this information with other parties at their own risk, as it may not be protected by confidential medical peer review if shared with other parties.</p> <ul style="list-style-type: none"> <li>• Root cause analyses</li> <li>• Corrective action plans</li> <li>• Policies and procedures</li> </ul>
L.4 (Conflicts of Interest)	The OPTN Conflicts of Interest Policy is available on the OPTN website. <a href="https://www.unoslabs.org/redcap/surveys/?s=XP39XPX3DA">https://www.unoslabs.org/redcap/surveys/?s=XP39XPX3DA</a>
L.5 (OPTN Investigations)	OPTN investigations may include but are not limited to any of the following: <ul style="list-style-type: none"> <li>• Data review</li> <li>• Document review</li> <li>• Informal discussions between the member and MPSC</li> <li>• On-site visits by OPTN Contractor staff</li> <li>• On-site visits by peer review teams</li> </ul>
L.6 (Request to Mitigate Risk)	<p>The MPSC may take an action, including recommending that the Board of Directors place a member on Probation or declare a member Not in Good Standing, if a member fails to mitigate a risk as requested. See L.12 for additional information about OPTN Actions.</p> <p>Members have the right to an interview and hearing with the MPSC before the MPSC could forward such a recommendation to the Board of Directors. See L.9 for information about interviews, L.10 for information about hearings and L.11 for information about Board appearances.</p>

# Appendix L “Evaluation Plan”

<b>Appendix L Section</b>	<b>Language</b>
L.7 (Scheduling MPSC and Member Interactions)	<p>The OPTN conducts ongoing and periodic reviews for member compliance with OPTN obligations. See Article I: Membership for more information. However, not all OPTN members are actively under MPSC review.</p> <p>Examples of members who are actively under MPSC review are:</p> <ul style="list-style-type: none"> <li>• responding to an OPTN investigation regarding a potential noncompliance with OPTN Obligations</li> <li>• participating in a deferred disposition period</li> <li>• under review for receiving an adverse action</li> <li>• under review for lower than expected outcomes</li> <li>• under review for lower than expected organ yield</li> <li>• under review for functional inactivity</li> <li>• have submitted a membership application to the MPSC</li> </ul> <p>The MPSC Chair will make every reasonable effort to provide sufficient notice to members in order to allow them to prepare for an interaction with the MPSC. In situations where a member is not taking requested action to mitigate the urgency and severity of a risk to patient health or public safety, the MPSC Chair will schedule the interactions as quickly as possible.</p> <p>In most situations, staff make every effort to provide notice to the member 6-8 weeks before the date and time of any in-person interactions, and at least 4 weeks notice before any conference calls.</p> <p><b>Refer to the Sample Informal Discussion Offer, Interview Offer, Interview Schedule, Hearing Offer, Hearing Schedule, Board Appearance Offer, and Board Appearance Schedule Letters for more information.</b></p>
L.8 (Informal Discussions)	<p><b>Refer to the “What to Expect – Informal Discussions” document.</b> This document is sent to members in advance of an informal discussion.</p>

# Appendix L “Evaluation Plan”

<i><b>Appendix L Section</b></i>	<i><b>Language</b></i>
L.8. D (Possible Informal Discussion Outcomes)	<p>Immediately after the informal discussion, the informal discussion group may ask the member to submit additional information. In most situations, the informal discussion group will not take an action without first discussing the information obtained during the informal discussion with the MPSC, unless the Bylaws allow the informal discussion group to grant interim approval to an application. See Appendices A.1.C, D.2.A, G.2.C, G.3.C, 1.2.D, 1.3.C for more information about interim approval.</p> <p>Based on its review of the informal discussion and all other information available, the MPSC may take an action. The type of action may vary based on the nature of the review.</p> <p>If the informal discussion is regarding an application, the informal discussion group may recommend</p> <ul style="list-style-type: none"> <li>• approving the application</li> <li>• rejecting the application</li> </ul> <p>If the informal discussion is regarding transplant program outcomes, transplant program functional inactivity or OPO organ yield, the MPSC may</p> <ul style="list-style-type: none"> <li>• release the program or OPO from active review</li> <li>• continue to monitor and request that additional information be provided or actions be taken by the member</li> <li>• request that the member participate in a peer visit</li> <li>• ask the transplant hospital to inactivate or cease a component of a transplant program (not an option for OPO)</li> </ul> <p>If the informal discussion is regarding a complaint, site survey, allocation deviation, or other noncompliance with OPTN Obligations, the MPSC may</p> <ul style="list-style-type: none"> <li>• Close the review with no action</li> <li>• Issue a notice of noncompliance</li> <li>• Issue a letter of warning</li> <li>• Offer the member deferred disposition</li> <li>• Offer the member an interview</li> <li>• Ask the member to inactivate or cease a component of the transplant program (not an option for OPO)</li> </ul>
L.9 (Interviews)	<p><b>Refer to the “What to Expect – Interviews” document.</b> This document is sent to members in advance of an interview.</p>

# Appendix L “Evaluation Plan”

<b>Appendix L Section</b>	<b>Language</b>
L.9.D (Possible Interview Outcomes)	<p>At the conclusion of the interview, the MPSC will determine an appropriate action. As with informal discussions, the type of action may vary based on the nature of the review.</p> <p>If the interview is regarding an application, the MPSC group may recommend</p> <ul style="list-style-type: none"> <li>• approving the application</li> <li>• rejecting the application</li> </ul> <p>If the interview is regarding a member’s failure to inactivate when requested, a complaint, site survey, allocation deviation, or other noncompliance with OPTN Obligations, the MPSC may</p> <ul style="list-style-type: none"> <li>• Close the review with no action</li> <li>• Issue a notice of noncompliance</li> <li>• Issue a letter of warning</li> <li>• Offer the member deferred disposition</li> <li>• Offer the member a hearing</li> <li>• Ask the member to inactivate or cease a component of the transplant program</li> </ul>
L.10 (Hearings)	<b>Refer to the “What to Expect – Hearings” document.</b> This document is sent to members in advance of a hearing.
L.10.D (Possible Hearing Outcomes)	<p>At the conclusion of the hearing, the MPSC will determine an appropriate action.</p> <p>If the hearing is regarding an application, the MPSC group may recommend</p> <ul style="list-style-type: none"> <li>• approving the application</li> <li>• rejecting the application</li> </ul> <p>If the hearing is regarding a recommendation for Probation or Member Not in Good Standing in response to a noncompliance with OPTN Obligations, the MPSC may</p> <ul style="list-style-type: none"> <li>• Close the review with no action</li> <li>• Issue a notice of noncompliance</li> <li>• Issue a letter of warning</li> <li>• Offer the member deferred disposition</li> <li>• Continue to recommend Probation or Member Not in Good Standing and offer a Board appearance</li> </ul>
L.11 (Board Appearance Format)	<p><b>Refer to the “What to Expect – Board Appearances” document.</b> This document is sent to members in advance of a Board appearance.</p> <p>The MPSC will provide the Board of Directors and the member with all of the following:</p> <ol style="list-style-type: none"> <li>1. Copies of all documents available to the MPSC prior to and during the hearing</li> <li>2. A copy of the hearing transcript</li> <li>3. A report outlining the reasons the MPSC is recommending an adverse action.</li> </ol>



# Appendix L “Evaluation Plan”

<b>Appendix L Section</b>	<b>Language</b>
L.11.F (Possible Board Appearance Outcomes)	<p>At the conclusion of the Board appearance, the Board will determine an appropriate action. The Board may:</p> <ul style="list-style-type: none"> <li>• approve the MPSC's recommendation</li> <li>• issue a lesser action</li> </ul>
L.12.A (Deferred Disposition)	<p>Members must implement any required activities within the period provided. Required activities during a deferred disposition period may include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Submit, edit, or provide updates on a containment plan</li> <li>• Submit, edit, or provide updates on root cause analysis</li> <li>• Submit, edit, or provide updates on corrective action plan</li> <li>• Submit, edit, or provide updates on quality improvement plan</li> <li>• On-site monitoring by the OPTN</li> <li>• Desk monitoring by the OPTN through documentation submissions</li> <li>• Self-assessments</li> <li>• Engage external expert consultants</li> <li>• Participate in informal discussions with the MPSC</li> </ul>
L.12.B (Types of Actions)	<p>Close with No Action: The MPSC may close a review if there is no confirmed noncompliance with OPTN Obligations.</p> <p>Notice of Noncompliance: The MPSC may issue a Notice of Noncompliance to document a confirmed noncompliance with OPTN Obligations. Typically when the MPSC issues a Notice of Noncompliance, the MPSC expects the member to follow any corrective action plans in place but does not have ongoing concerns, provided the issue does not recur.</p> <p>Letter of Warning: The MPSC may issue a Letter of Warning when the MPSC has concerns that the member is not sufficiently addressing. When issuing a Letter of Warning, the MPSC will specify the steps the MPSC believes the member should take in order to avoid future problems. This is a non-adverse action that is not made public. No further action is needed, provided the issue does not recur.</p> <p>Probation: (See L.12.D.1 for more information.) This is the less severe of the two OPTN adverse actions. The MPSC may recommend Probation if a member has failed to take action necessary to demonstrate improvement.</p> <p>Member Not in Good Standing: (See L.12.D.2 for more information.) This is the most severe OPTN action and is typically reserved for instances where a member has had significant, ongoing issues and has failed to adequately address the issues or when the member has failed to mitigate an urgent and severe risk to patient health or public safety. A member's failure to improve while on Probation may also result in the MPSC recommending that the Board declare the member Not in Good Standing.</p> <p>Only the Board of Directors or the Executive Committee can place a member on Probation or declare a member Not in Good Standing. See Appendix L.11 for information about the Board of Directors review of MPSC adverse action recommendations.</p>

# Appendix L “Evaluation Plan”

<b>Appendix L Section</b>	<b>Language</b>
L.12.C (Determining Appropriate Action)	The MPSC considers a number of factors when determining which action is appropriate to take. The MPSC is always mindful of the need to protect patient health and public safety. Provided an issue does not present a potentially urgent and severe risk to patient health or public safety, the MPSC’s primary objective is to help members improve and avoid future issues. The MPSC also considers whether the member has demonstrated an awareness of and accountability for the noncompliance.
L.12.D (OPTN Adverse Actions)	<i>[Include sample OPTN notices of adverse action.]</i>
L.12.D.1	<b>See Probation FAQ</b>
L.12.D.2.C (Probation Monitoring Requirements)	<p>The MPSC will request specific monitoring activities based on the nature of the review. The MPSC will assign 3-4 members to participate on a work group to conduct the reviews and present their findings to the MPSC.</p> <p>Members on Probation should expect to submit at least one document submission that includes an update on the progress of the member’s corrective action plan in advance of each MPSC in-person meeting. Submissions are typically due in late January, early June, and mid-August. MPSC staff will notify you of the submission deadlines and will share any feedback or requests after the MPSC’s meeting.</p> <p>In addition, the MPSC may request that you participate in one or more informal discussions, present information to the MPSC during a conference call or in-person meeting, hire external consultants, participate in a peer visit, and/or visit other members to learn effective practices, etc.</p>
L.12.D.2	<b>See Member Not in Good Standing FAQ</b>
L.12.D.2.C (Member Not in Good Standing Monitoring Requirements)	<p>The MPSC will request specific monitoring activities based on the nature of the review. The MPSC will assign 3-4 members to participate on a work group to conduct the reviews and present their findings to the MPSC.</p> <p>A Member Not in Good Standing should expect to submit at least one document submission that includes an update on the progress of the member’s corrective action plan in advance of each MPSC in-person meeting. Submissions are typically due in late January, early June, and mid-August. MPSC staff will notify you of the submission deadlines and will share any feedback or requests after the MPSC’s meeting.</p> <p>In addition, Members Not in Good Standing will receive at least one unannounced on-site review and must present information to the MPSC on the status of the member’s corrective actions during at least one in-person MPSC meeting. The MPSC may also request the member participate in one or more informal discussions, hire external consultants, participate in a peer visit, and/or visit other members to learn effective practices, etc.</p>
L.12.D.3. (Release from Probation or Member Not in Good Standing)	<p>After nine months has passed from the date that the MPSC approved the member’s corrective action plan and the date that the Board of Directors approved the adverse action, the member can request to be released from Probation or Member Not in Good Standing.</p> <p>The MPSC may, prior to nine months, recommend that the Board of Directors downgrade a Member Not in Good Standing to Probation. The member must demonstrate that the lesser adverse action is appropriate, and must then wait at least three months before requesting release from Probation.</p>

	Informal Discussion	Interview	Hearing	Board Appearance
Structure	At least 10 min member presentation At least 15 min Q&A	At least 15 min member presentation At least 30 min Q&A	At least 60 min member presentation At least 60 min OPTN presentation At least 60 min Q&A	At least 10 min member presentation At least 10 min MPSC presentation At least 15 min Q&A
Format	Teleconference	In person or teleconference	In-person	In person or teleconference
Approximate Timing	Determined by MPSC Chair; member will be notified at least 14 days in advance	Determined by MPSC Chair; member will be notified at least 7 days in advance of a teleconference interview, 21 days in advance of an in-person interview	Determined by MPSC Chair; member will be notified at least 30 days in advance	Determined by OPTN President; member will be notified at least 7 days in advance of a teleconference interview, 21 days in advance of an in-person interview
Review Panel	MPSC	MPSC	MPSC	Board of Directors; OPTN President may delegate to Executive Committee if urgent/severe risk exists.
Quorum	At least 4 MPSC members	At least 10 MPSC members, including at least 2 with SME in issue under review, or Chair will appoint advisors from other OPTN committee	At least 10 MPSC members, including at least 2 with SME in issue under review, or Chair will appoint advisors from other OPTN committee.	Quorum of Board of Directors
Right to	Members under review may request, subject to Chair approval.  MPSC may request at any time.  MPSC must offer before asking a member to inactivate due to outcomes or inactivity.	MPSC may request at any time. MPSC does not need to specify what action is being considered before the interview.  MPSC must offer an interview <ul style="list-style-type: none"> <li>• before considering an adverse action.</li> <li>• after rejecting a membership application</li> <li>• after rejecting a members request for release from an adverse action</li> </ul>	MPSC must offer if member participated in an interview and after the interview the MPSC: <ul style="list-style-type: none"> <li>• considered recommending adverse action</li> <li>• rejected a membership application</li> <li>• rejected a members request for release from an adverse action.</li> </ul>	Member and the MPSC both have the right to appear if the member participated in a hearing and after the hearing, the MPSC: <ul style="list-style-type: none"> <li>• recommended an adverse action.</li> <li>• rejected a membership application</li> <li>• rejected a members request for release from an adverse action</li> </ul>
Accepting or Waiving	Waiving an informal discussion does not waive any future interactions, including additional informal discussions, interviews, hearings or Board appearances. Members who waive the informal discussion may submit additional written information or documentation for the MPSC to review and must submit any other information requested by the MPSC.	Members who waive their interview waive their right to a hearing and Board appearance. Members who waive the interview may submit additional written information or documentation for the MPSC to review and must submit any other information requested by the MPSC.	Members who waive their right to a hearing waive their right to a Board appearance. Members who waive the hearing may submit additional written information or documentation for the MPSC to review and must submit any other information requested by the MPSC.	Members who waive the Board appearance may submit additional written information or documentation for the Board to review and must submit any other information requested by the MPSC or the Board.
Outcome	Subcommittee discusses with MPSC, MPSC makes decision.	MPSC may take an action or may offer member deferred disposition period.	MPSC must make decision either to recommend adverse action or issue lesser action at conclusion of hearing. No further opportunity for deferred disposition.	Board must make a final action, either approving MPSC recommendation or issuing a lesser action. The OPTN will issue public notice for all adverse actions.

*\*For each interaction, the OPTN will provide members with an offer notice that will include the reason the interaction is being offered, the concerns that led to the interaction being offered or what the MPSC would like to discuss, any information the MPSC would like the member to submit in advance of the interaction, and the date by which the member must accept or waive the offer. The OPTN will provide members with summaries of each interaction within 21 days.*

## Post-Public Comment Changes

- *Line 71*: Reference to “sixty (60) days” updated to “60 days”
- *Line 75*: Reference to “sixty (60) days” updated to “60 days”
- *Line 411*: typo corrected
- *Lines 627, 628*: Replaced “applicant” with “member”
  - Clarification suggested in response to common misunderstandings about key personnel applications.
- *Lines 660, 662*: Title added to table, and reference to table included in preceding paragraph
- *Lines 773, 774*: Replaced “applicant” with “member”
  - Clarification suggested in response to common misunderstandings about key personnel applications
- *Lines 814, 815*: Replaced “applicant” with “member”
  - Clarification suggested in response to common misunderstandings about key personnel applications
- *Lines 858, 859*: Replaced “applicant” with “member”
  - Clarification suggested in response to common misunderstandings about key personnel applications.
- *Lines 899, 900*: Replaced “applicant” with “member”
  - Clarification suggested in response to common misunderstandings about key personnel applications.
- *Line 2265*: Added “MPSC Chair”
  - Clarification to specify that the MPSC Chair may request an informal discussion at any time, in addition to the MPSC
- *Lines 2266-2267*: Modified beginning of sentence to read “A transplant program is entitled to an informal discussion before the MPSC recommends...”
  - Clarified to avoid voting questions/concerns regarding operationalizing the previous language which stated, “The MPSC must offer a transplant program...”
- *Lines 2292, 2294*: Replaced “present” and “presentation” with “report”
  - Changed terms to simplify operationalizing this requirement.
- *Line 2305*: Added “MPSC Chair”
  - Clarification to specify that the MPSC Chair may request an informal discussion at any time, in addition to the MPSC
- *Line 2308*: Modified to read, “The member has the right to an interview:”
  - Clarified to avoid voting questions/concerns regarding operationalizing the previous language which stated, “The MPSC must offer an interview:”
- *Lines 2310-2318*: Periods deleted at the end of each list item per UNOS Style Guide
- *Lines 2339-2340*: Added “...which shall constitute a quorum for the purpose of any actions resulting from the interview.”

- Added so that decisions following an interview are actionable, in case the interview is conducted by a number of members that is less than the traditional quorum.
- *Lines 2349:* Deleted “Immediately” to align with L.10.D (Possible Hearing Outcomes), and considering this action can’t technically occur *immediately*.
- *Lines 2364-2367:* Language changed so that it reads more similarly to same content in interview section (L.9.A)
- *Lines 2366-2374:* Periods deleted at the end of each list item per UNOS Style Guide
- *Line 2382:* Deleted “adverse action”
  - Changes to more broadly reflect that the member will accept the MPSC’s recommendation, be that an adverse action or something lesser. It is unlikely, but the member may waive a hearing and submit information that convinces the MPSC to take a non-adverse action (as provided in the last paragraph of this section).
- *Lines 2400-2401:* Added “...which shall constitute a quorum for the purpose of any actions resulting from the hearing.”
  - Added so that decisions following a hearing are actionable, in case the hearing is conducted by a number of members that is less than the traditional quorum.
- *Lines 2442-2450:* Numbered list changed to bulleted list per UNOS Style Guide
- *Line 2528:* Content added to clarify that Deferred Dispositions are not applicable in response to rejected membership applications.
- *Line 25371:* Added a period at the end of sentence
- *Line 2540:* Sentence structure modified
- *Lines 2608- 2611:* Title added to table, and reference to table included in preceding paragraph
- *Lines 2640 - 2643:* Title added to table, and reference to table included in preceding paragraph
- *Lines 2657 - 2660* Periods deleted from list per UNOS Policy Editor
- *Lines 2703 - 2704:* Language added to clarify the timeline of the Executive Committee’s action
- *Line 2760:* Comma added
- *Line 2812:* Changed “Termination” to “termination”
- *Line 3842:* Changed “final rule” to “Final Rule”
- *Lines 2859- 2864:* Periods deleted from list per UNOS Style Guide
- *Line 2891:* Updated to reflect correct Bylaws reference
- *Lines 2887- 2892:* Periods deleted from list per UNOS Policy Editor
- *Line 2900:* Changed “Peer” to “peer”