

## Public Comment Proposal

# Appendix L Revisions

*OPTN/UNOS Membership and Professional Standards Committee*

*Prepared by: Chad Waller and Ann-Marie Leary  
UNOS Member Quality Department*

## Contents

Executive Summary	1
What problem will this proposal address?	2
Why should you support this proposal?	3
How was this proposal developed?	4
How well does this proposal address the problem statement?	16
Which populations are impacted by this proposal?	17
How does this proposal impact the OPTN Strategic Plan?	17
How will the OPTN implement this proposal?	18
How will members implement this proposal?	18
Transplant Hospitals	18
OPOs	18
Histocompatibility Laboratories	18
Will this proposal require members to submit additional data?	19
How will members be evaluated for compliance with this proposal?	19
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	19
Policy or Bylaws Language	20

# 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. However, given the volume of changes and the many changes to the 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.

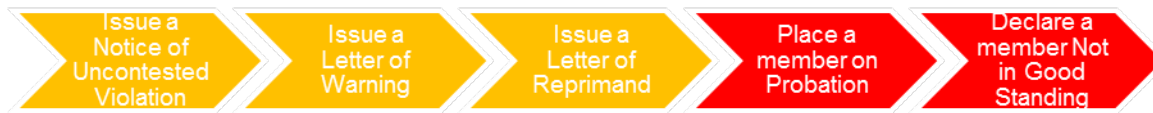
12. Require the MPSC to conduct all informal discussions, interviews, and hearings

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.

## **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>.

If public comment is favorable, 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 effectively 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 **Article I: Membership**

### 2 **1.1 Membership Requirements Guidelines**

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

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

6  
7 1. ~~All~~ Applicable provisions of the:

8 a. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*

9 b. OPTN Final Rule, 42 CFR Part 121

10 c. OPTN Bylaws

11 d. OPTN Policies

12 2. Acting to avoid risks to patient health or public safety

13 3. Fulfilling all requests for information

#### 14 15 **F. Member Reviews and Evaluations**

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

#### 23 24 **G. Reporting Potential Noncompliance with OPTN Obligations**

25 Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform  
26 the OPTN as soon as the member becomes aware of the issue, including potential  
27 noncompliance by the member itself.

28  
29 All incidences of potential noncompliance are referred for further review as outlined in these  
30 Bylaws. Any member who fails to comply with OPTN Obligations may be subject to actions as set  
31 forth in these Bylaws.

32  
33 ~~At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when~~  
34 ~~the Secretary has reason to believe that the member may be acting in a way that poses a risk to~~  
35 ~~patient health or public safety.~~

#### 36 37 **FH. Affiliated Organizations**

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

39  
40 1. Become a member of any organization that is a parent, sponsor, contractor, or affiliated  
41 organization of the OPTN.

- 42 2. Comply with bylaws of any parent, sponsor, contractor, or affiliated organization of the OPTN.  
43 3. Assume any corporate duties or obligations of any parent, sponsor, contractor, or affiliated  
44 organization of the OPTN.

45

## 46 **GI. Removal of Members**

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

50

51 All other OPTN members who no longer qualify for OPTN membership may be removed as  
52 members through any of the following procedures:

53

- 54 ■ The member itself may request to voluntarily withdraw from OPTN membership by forwarding  
55 a written request to the Executive Director.
- 56 ■ The OPTN may notify the member in writing that, unless the member demonstrates within  
57 sixty (60) days of notification that it continues to meet applicable membership criteria, the  
58 member's OPTN membership will be terminated, even if the member does not request  
59 removal.

60

61 If, within sixty (60) days of notification, the member demonstrates, to the satisfaction of the  
62 OPTN, that the member meets OPTN membership requirements, the OPTN will withdraw its  
63 notice of termination.

64

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

71

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

75

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

81

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

83

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

88  
89  
90  
91  
92  
93  
94  
95  
96  
97  
98  
99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134

## 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.~~

### A.13 Applying for Membership in the OPTN

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

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

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

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

135 **A. Conditions for Application**

136 By submitting a signed application for membership in the OPTN, each applicant and member  
137 agrees to *all* of the following:  
138

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

159 **Statement of Release and Immunity from Liability**

160 As used in this section, the following definitions apply:  
161

- 162 1. *OPTN Contractor and its representatives* means the corporation currently  
163 operating the OPTN under contract with HHS, its officers, its Board of Directors,  
164 its appointed representatives or employees, consultants, the Contractor's  
165 attorneys, assistants or designees, and all members, organizations or other  
166 persons who have any responsibility for obtaining or evaluating applicant or  
167 member qualifications or acting upon the application for membership or  
168 designated transplant program status. This includes any authorized  
169 representative of any of the entities or persons noted in this paragraph.  
170  
171 2. *A third party means* all individuals or government agencies, organizations,  
172 associations, partnerships and corporations, from whom information has been  
173 requested by the OPTN Contractor or its authorized representatives. This  
174 includes anyone who requests or receives information from the OPTN and its  
175 authorized representatives.  
176

177 The following are conditions that apply to any applicant or OPTN member. An applicant  
178 accepts the following conditions throughout the application process, whether or not the  
179 applicant is granted membership or approval as a designated transplant program:  
180

- 181 a. To the fullest extent permitted by law, the applicant or member gives absolute  
182 immunity to, and releases the OPTN Contractor, its representatives, and any



183 third party from any and all liability resulting from any acts, communications,  
184 reports, recommendations, or disclosures involving an applicant or member. This  
185 includes disclosures to, from, or by any third party, including other members,  
186 concerning activities within the scope of the OPTN Contract including but not  
187 limited to:

- 188
- 189 i. Applications for membership or designation as a transplant program;
- 190 ii. Proceedings regarding monitoring and enforcement of membership
- 191 requirements, change in membership or designated transplant program
- 192 status, termination of membership, or other policies of or regulations
- 193 concerning the OPTN
- 194 ~~iii. Hearings and appellate reviews~~
- 195 iviii. Other committee activities relating to the membership status or
- 196 designated transplant program status of an applicant or member. This
- 197 includes statements, investigations, materials provided, or inquiries, oral
- 198 or written, relating to an applicant's or member's qualifications, as well as
- 199 the review of all relevant records and documents
- 200
- 201 b. Any act, communication, report, recommendation or disclosure, with respect to
- 202 any applicant or member made in good faith and at the request of the OPTN
- 203 Contractor and its representatives, anywhere and at any time, for the purposes
- 204 described in (a) above are privileged to the fullest extent permitted by law as part
- 205 of the OPTN medical peer review. The medical peer review privilege extends to
- 206 any third parties who either supply or are supplied information and are authorized
- 207 to receive, release or act upon the same.
- 208 c. The immunity and release from liability provided in this section shall not apply to
- 209 acts of willful misconduct by the OPTN Contractor and its representatives.
- 210

## 211 **B. Initial Review of the Membership Application**

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

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

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

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

225 The Board of Directors makes all final decisions regarding membership and transplant program  
226 applications. Before being considered by the Board, the MPSC reviews all applications and  
227 submits a written report with recommendations regarding the application to the Board of  
228 Directors. The MPSC Chair, or a chosen representative, may appoint an MPSC subcommittee of  
229 at least four MPSC members to review the completed application and supporting documentation.  
230  
231  
232

233 The MPSC subcommittee may make recommendations regarding applications for membership or  
234 approval as a designated transplant program. The MPSC subcommittee's recommendations are  
235 advisory to the MPSC and the Board of Directors.

236  
237

### **MPSC Subcommittee Review and Recommendation**

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

243  
244  
245  
246  
247  
248

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**

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

253  
254  
255  
256  
257  
258  
259  
260

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**

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

264  
265

Interim approval will:

266  
267  
268  
269  
270

1. Grant the applicant OPTN membership or designated transplant program approval, as applicable.
2. Expire when and if the full Board rejects the interim action.

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

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

278  
279  
280  
281  
282  
283

~~Any applicant rejected for membership by the MPSC may request due process. For more information about the due process options available after a membership rejection, see of these Bylaws. If it is going to do so, the applicant must exercise its due process rights before the adverse recommendation is submitted to the Board of Directors by the MPSC.~~

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

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

287  
288 The Board of Directors will review the application and act on it during its next regular meeting if  
289 the following conditions are met:

- 290  
291 1. The Board of Directors receives the recommendation from the MPSC at least 10 business  
292 days before the meeting.  
293 2. A quorum is present at the meeting.

294  
295 Any application not received at least 10 business days before the meeting will not be considered  
296 until the next regular Board meeting at which a quorum is present. If the MPSC gave the  
297 application interim approval, a decision to defer the matter will continue the interim approval until  
298 the next regular meeting of the Board of Directors where a quorum is present.

299  
300 A majority vote of the Directors present at any meeting at which a quorum is present is required  
301 to approve a new member.

302  
303 ~~A recommendation for rejection by the Board of Directors entitles the applicant to due process as~~  
304 ~~specified in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws. The applicant may~~  
305 ~~also make a written appeal to the Secretary within 30 days of the final rejection of the application~~  
306 ~~by the Board of Directors.~~

307

308 **E. Appeals to the Secretary**

309 Applicants rejected for membership in the OPTN or for designation as a transplant program may  
310 appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the  
311 application. The Secretary may deny the appeal or direct the OPTN to take action consistent with  
312 the Secretary's response to the appeal.

313

314 **EF. Processing Time for Membership Applications**

315 The MPSC or an MPSC subcommittee will act on an application and provide a recommendation  
316 for interim approval or rejection within 90 days after the OPTN Contractor receives the completed  
317 application. Applications for membership and designated transplant program approval will be  
318 considered in a timely and good faith manner by the OPTN and the OPTN Contractor and, except  
319 for good cause, will be processed within the 90-day period.

320

321 **FG. Geographically Isolated Transplant Program Applicants**

322 The MPSC may recommend to the Board of Directors the approval of a designated transplant  
323 program if the prospective program cannot satisfy the current key personnel requirements due to  
324 its geographical isolation. Geographically isolated applicants must demonstrate to the MPSC that  
325 the proposed key personnel have both a satisfactory level of transplant experience and an  
326 established history of transplant success for the specific organ type indicated in the application for  
327 designated transplant program status.

328

329 MPSC recommendation of approval of a geographically isolated program that is not otherwise  
330 qualified does not give interim approval to the prospective program. The designated transplant  
331 program status of a geographically isolated program that is not otherwise qualified is effective  
332 only upon approval of the Board of Directors.

333

334 For purposes of this provision, “geographically isolated” is defined as a program located entirely  
335 within a state or commonwealth noncontiguous with the mainland United States. This includes

336 Alaska, Hawaii, and Puerto Rico.  
337

## 338 **Appendix B: Membership Requirements for Organ** 339 **Procurement Organizations (OPOs)**

340 An OPO member is any OPO that has been designated by the Secretary of the U.S. Department of  
341 Health and Human Services (HHS) under *Section 1138(b)* of the Social Security Act or any organization  
342 that meets all requirements under *Section 1138(b)*, except for OPTN membership.  
343

344 Only independent OPOs (IOPO) have voting privileges in the OPTN. An IOPO is defined as one that has  
345 a distinct governing body separate from any transplant hospital or commonly controlled group of  
346 transplant hospitals it serves.  
347

348 A hospital-based OPO is not independent from the transplant hospital it serves. Hospital-based OPOs are  
349 held to the same standards and requirements as OPO members, but do not have a vote on OPTN  
350 business separate from the vote granted the transplant hospital member that controls it.  
351

352 For more information on membership types, terms, voting privileges, and responsibilities, see *Article I:*  
353 *Membership* of these Bylaws.  
354

### 355 **B.1 OPO Compliance**

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

- 358 ~~1. National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
- 359 ~~2. OPTN Final Rule, 42 CFR Part 121~~
- 360 ~~3. OPTN Bylaws~~
- 361 ~~4. OPTN Policies~~

362 ~~The OPTN will conduct ongoing periodic reviews and on site evaluations of each OPO for compliance~~  
363 ~~with the OPTN Final Rule, OPTN Bylaws and OPTN Policies. OPOs must also fulfill all requests for~~  
364 ~~information from the OPTN Contractor as required to determine compliance. All compliance monitoring is~~  
365 ~~performed using procedures developed by the OPTN Contractor. Any OPO that no longer qualifies as an~~  
366 ~~OPTN member according to the requirements of these Bylaws will be dealt with according to *Appendix L:*~~  
367 ~~*Reviews, Actions, and Due Process* of these Bylaws.~~  
368

369 If any regulatory agency takes a final adverse action against an OPO, the OPO must notify the OPTN  
370 Contractor in writing within 10 business days. The OPO must also provide all documents relating to the  
371 final adverse action to the OPTN Contractor.  
372  
373

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

375 The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if  
376 the difference in observed and expected organ yield can be accounted for by some unique aspect of the  
377 Donation Service Area or OPO in question. ~~The evaluation may include a peer visit to the OPO at the~~  
378 ~~OPO's expense.~~  
379

380 Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified  
381 threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for  
382 different organs, and may be reviewed and modified by the MPSC after distribution to the transplant  
383 community and subsequent Board approval.  
384

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

- 387  
388 1. More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-  
389 Expected per 100 donors < -10).  
390 2. A ratio of observed to expected yield less than 0.90.  
391 3. A two-sided p-value is less than 0.05.

392  
393 All three criteria must be met for an OPO to be identified for MPSC review.  
394

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

401  
402 As part of this process, the MPSC may conduct a peer visit to the OPO at the member's expense. The  
403 MPSC may also require, at its discretion, that the member participate in an informal discussion. The  
404 informal discussion will be conducted according to Appendix L: Reviews and Actions.  
405

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

407 OPOs must have extensive facilities to be fully operational. OPOs must also provide a number of services  
408 as part of their daily operations. These required facilities and services are described in the sections that  
409 follow.  
410

### 411 **A. Transplant Hospital Relationship**

412 Each OPO must have written agreements with:

- 413  
414 1. All transplant hospitals within its Donation Service Area (DSA) to coordinate its procurement  
415 activities, according to the Code of Federal Regulations.  
416 2. Donor hospitals that include arrangements for the identification, referral, and maintenance of  
417 potential organ donors. This includes preservation and transportation of donated organs to  
418 transplant hospitals in its DSA.  
419

420 These agreements must be available to the OPTN Contractor on request.  
421

### 422 **B. Laboratory Testing Services**

423 Each OPO must have written agreements with:

- 424  
425 1. At least one Clinical Laboratory Improvement Amendment (CLIA) certified laboratory that  
426 meets OPTN standards to provide donor screening for transmissible disease, including  
427 Human Immunodeficiency Virus (HIV).  
428 2. An OPTN approved histocompatibility laboratory to perform the necessary tissue typing of  
429 donated organs.  
430

### 431 **C. Tissue Bank Services**

432 Each OPO must have written agreements with tissue banks for efficient and effective referral,  
433 recovery, processing, preservation, storage, and distribution of tissue from donors.  
434

435 **D. Education Plans**

436 Each OPO must submit written summaries of education plans that include:

- 437
- 438 1. Activities for public education about organ donation, including how donor families, transplant
  - 439 candidates, and recipients will participate.
  - 440 2. A plan to conduct or participate in professional education about organ and tissue
  - 441 procurement.

442

443 If an OPO does not submit an education plan, the membership application will be considered

444 incomplete and not reviewed until the plan is submitted. The OPTN Board of Directors may also

445 notify the Secretary of the HHS if an OPO does not submit an education plan.

446

447 **E. Organ Allocation Plans**

448 Each OPO is responsible for equitable and efficient organ allocation within their DSAs that

449 adheres to OPTN obligations. To meet this requirement, each OPO must have the necessary

450 procedures and technology to communicate information to distribute organs to transplant

451 candidates at transplant hospitals within and beyond its service area.

452

453 Each OPO must have a plan to equitably allocate donated organs among transplant patients that

454 is consistent with the obligations of the OPTN. An OPO must demonstrate it has policies and

455 procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these

456 requirements will be considered a noncompliance with OPTN Obligations that may result in an

457 OPTN action according to Appendix L: Reviews and Actions. ~~Failure to comply with these~~

458 ~~requirements could result in corrective action as described in Appendix L: Reviews, Actions, and~~

459 ~~Due Process of these Bylaws, if applicable, or result in a recommendation to the Board of~~

460 ~~Directors to notify the Secretary of HHS.~~

461

462 **B.5 OPO Personnel**

463 Each OPO must have personnel who are qualified to effectively recover organs from all donors in its

464 DSA. Each OPO must have the necessary staff to recover and distribute organs according to OPTN

465 obligations, including an administrative director, a medical director, an organ donation coordinator, and an

466 organ procurement specialist.

467

468 **A. OPO Administrative Director**

469 Each OPO must identify an individual that serves as the administrative director. The

470 administrative director, together with other OPO staff, is responsible for effective organ recovery

471 and placement according to OPTN obligations.

472

473 **B. Medical Director**

474 The OPO medical director must be a physician licensed in at least one of the states within the

475 OPO's DSA. The OPO must submit the medical director's credentials to the OPTN Contractor.

476 The medical director is responsible for the medical and clinical activities of the OPO.

477

478 **C. Board of Directors**

479 Each OPO must have a board of directors or an advisory board with members selected according

480 to the Code of Federal Regulations. The board of directors or advisory board has the authority to

481 recommend policies that guide the donation, procurement, and equitable distribution of organs.

482

483 **D. Changes in Key Personnel**

484 When the OPO learns that the administrative or medical director plans to leave, it must notify the  
485 OPTN Contractor immediately, within 30 days of departure, if possible. The OPO must also  
486 submit to the OPTN Contractor at this time the replacement's name and curriculum vitae.  
487

488 **E. Failure to Report Changes in Key OPO Personnel**

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

492  
493 Failure to inform the OPTN Contractor of changes in the administrative director or medical  
494 director may result in corrective action as described in *Appendix L: Reviews, Actions, and Due*  
495 *Process* of these Bylaws, including adverse actions as defined in *L.15. OPTN Determinations and*  
496 *Actions.*

497  
498 The OPO must notify the MPSC if it has not filled a vacant administrative or medical director  
499 position within six months. The MPSC could then recommend that the OPTN Board of Directors  
500 notify the Secretary of HHS of the OPO's failure to fill the position.  
501

502 **Appendix C:**  
503 **Membership Requirements for Histocompatibility**  
504 **Laboratories**

505 **C.1 Histocompatibility Laboratory Compliance**

506 Each histocompatibility laboratory member must comply with all OPTN Obligations according to Article  
507 1.1.E: Member Compliance and both all of the following:

508  
509 ~~1. All application provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~

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

511 ~~3. The OPTN Charter~~

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

513 ~~5.~~ 1. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR §  
514 493.1278, unless exempt

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

521 If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory  
522 must notify the OPTN Contractor in writing within 10 business days. The histocompatibility laboratory  
523 must also provide all documents relating to the final adverse action to the OPTN Contractor.  
524

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

526 **A. Change in Laboratory Director, Technical Supervisor, General**  
527 **Supervisor, or Clinical Consultant**

528 When the histocompatibility laboratory is informed that the laboratory director, technical  
529 supervisor, general supervisor, or clinical consultant plans to leave or otherwise ends active  
530 participation in the laboratory, the laboratory must:

- 531
- 532 1. Notify the OPTN Contractor in writing within seven business days of when the laboratory  
533 becomes aware of the change in key personnel.
  - 534 2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30  
535 days before the end of the individual's active employment or change in status. The Personnel  
536 Change Application must document that the new or acting laboratory director, technical  
537 supervisor, general supervisor, and clinical consultant meet the requirements of these  
538 Bylaws.
  - 539 3. Submit an updated Laboratory Coverage Plan no less than 30 days before the date of  
540 departure that specifies how continuous coverage will be provided at the laboratory by all key  
541 personnel during and after the transition period to a new or acting laboratory director,  
542 technical supervisor, or clinical consultant.
  - 543 4. If the histocompatibility laboratory receives less than 60 days notice of the key personnel  
544 change, then the laboratory must submit a completed Personnel Change Application and  
545 updated Laboratory Coverage Plan to the OPTN Contractor within 30 days of the date of  
546 departure.

547  
548 A change in key personnel can be any of the following:

- 549
- 550 1. Departure of the director, technical supervisor, general supervisor, or clinical consultant.
  - 551 2. Any key personnel unavailable to perform responsibilities for more than 30 days.
  - 552 3. Reinstatement of the previously designated laboratory director, technical supervisor, general  
553 supervisor, or clinical consultant.
  - 554 4. Any key personnel that accepts additional responsibilities for more than 30 days at another  
555 histocompatibility laboratory.

556  
557 **B. Failure to Notify the OPTN Contractor of Key Personnel Changes**

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

563  
564 Any histocompatibility laboratory that fails to inform the OPTN Contractor of a change in the  
565 laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the  
566 required Personnel Change Application within the periods specified above will be reviewed by the  
567 MPSC. The MPSC may impose a sanction, including, but not limited to, any of the following:

- 568
- 569 1. ~~Notice of Uncontested Violation~~
  - 570 2. ~~Letter of Warning~~
  - 571 3. ~~Letter of Reprimand~~

572



573 Failure to inform the OPTN Contractor of changes in key personnel or to submit the required  
574 Personnel Change Application will result in a recommendation that the Board of Directors take  
575 appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of  
576 Health and Human Services (HHS) of the violation.  
577

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

579 The MPSC must offer the applicant an interview if the MPSC rejects a Key Personnel Change  
580 application. The applicant may also be entitled to a hearing with the MPSC and an appearance  
581 before the Board of Directors. Any interviews, hearings, or Board of Directors appearances, that  
582 occur as part of the Key Personnel Change application process will be conducted according to  
583 Appendix L: Reviews and Actions.  
584

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

### 586 **A. Criteria for Mandatory Performance Review a Histocompatibility** 587 **Laboratory**

588 The OPTN Contractor may review a histocompatibility laboratory if at any time it has *any* of the  
589 following performance indicators:  
590

- 591 ■ Failure to comply with the requirements and regulations according to *Section C.1:*  
592 *Histocompatibility Laboratory Compliance* of these Bylaws.
- 593 ■ Any of the following performance indicators on external proficiency testing:  
594 1. Less than 100% satisfactory performance in an ABO external proficiency testing  
595 program.  
596 2. For programs other than ABO, a less than 80% satisfactory performance on more than  
597 one external histocompatibility proficiency testing program within the previous twelve  
598 months.
- 599 ■ Accreditation revoked by any OPTN approved histocompatibility regulatory agency.
- 600 ■ A focused re-inspection by any OPTN approved histocompatibility regulatory agency.
- 601 ■ Restrictions imposed on the laboratory by any OPTN approved histocompatibility regulatory  
602 agency.
- 603 ■ One or more HLA typing or reporting errors on a deceased or living donor that results or  
604 could result in an incompatible transplant or the re-allocation of an organ to someone other  
605 than the intended recipient.
- 606 ■ Unresolved or repeat deficiencies identified during inspections conducted by OPTN approved  
607 regulatory agencies that are in violation of OPTN Contractor standards. When deficiencies  
608 are cited, laboratories must document that the deficiencies have been corrected.
- 609 ■ Complaints from transplant programs, OPOs, or other clients that have not been  
610 documented, investigated and resolved.
- 611 ■ Incomplete submission of all OPTN Contractor forms or forms not submitted within the 180  
612 day time limit.  
613

### 614 **B. Information Required from Laboratories with Unsatisfactory** 615 **Performance**

616 The OPTN Contractor may request at any time from a histocompatibility laboratory with  
617 unsatisfactory performance *any* of the following:

- 618
- 619       ▪ Letters from the affiliated transplant program or OPO staff describing the level of interaction
- 620       and involvement of the director, technical supervisor and clinical consultant.
- 621       ▪ Interviews with transplant program or OPO staff.
- 622       ▪ Laboratory complaint log and documentation of resolutions from other healthcare
- 623       professionals.
- 624       ▪ Samples of laboratory reports that demonstrate the review of patient history, notation of
- 625       unusual results, and recommendations for additional testing.
- 626       ▪ Documentation of any professional extracurricular commitments, including estimates of time
- 627       required, for laboratory director, technical supervisor, and clinical consultant outside of the
- 628       histocompatibility laboratory.
- 629       ▪ Quality Assessment and Performance Improvement records.
- 630       ▪ Other material as requested.

631

632       **C. ~~\_\_\_\_\_~~ Periodic Reviews**

633       ~~In order to determine compliance with the requirements and regulations according to C.1.~~

634       ~~Histocompatibility Laboratory Compliance, histocompatibility laboratory members will be~~

635       ~~reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN~~

636       ~~Contractor. Failure to comply with these rules and requirements will be cause for corrective action~~

637       ~~as described in Appendix L: Reviews, Actions, and Due Process of these Bylaws.~~

638

639       **D. ~~\_\_\_\_\_~~ Regulatory Agency Adverse Actions**

640       ~~If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the~~

641       ~~laboratory must notify the OPTN Contractor within 10 business days. The histocompatibility~~

642       ~~laboratory must also provide any documents relating to the final adverse action to the OPTN~~

643       ~~Contractor, along with the final determination of the regulatory agency.~~

644

645       **C.E. Inactive Status**

646       A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from

647       membership will be ineligible and may not provide histocompatibility testing to any OPTN

648       members.

649

650       ***Appendix D: Membership Requirements for***

651       ***Transplant Hospitals and Transplant Programs***

652       **D.1 Transplant Hospital Compliance**

653       By accepting membership in the OPTN, transplant hospitals agree to comply with all OPTN Obligations

654       according to Article 1.1.E: Member Compliance.

655

656       If any regulatory agency takes a final adverse action against a transplant hospital, the transplant hospital

657       must notify the OPTN Contractor in writing within 10 business days. The transplant hospital must also

658       provide all documents relating to the final adverse action to the OPTN Contractor.

659

660       Transplant hospital members agree to:

661

- 662 1. ~~Review and abide by the OPTN Final Rule, Bylaws, Policies and applicable provisions of the National~~  
663 ~~Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~  
664 2. ~~Comply with all obligations of OPTN membership.~~  
665 3. ~~Submit to reviews and on-site evaluations to monitor compliance with membership requirements.~~  
666 4. ~~Fulfill all requests for information.~~  
667 5. ~~Notify the OPTN Contractor within 10 business days if any regulatory agency takes a final adverse~~  
668 ~~action against the transplant hospital and then provide any documents relating to the final adverse~~  
669 ~~action to the OPTN Contractor.~~

670  
671 For more information, see ~~Article I: Membership~~ of these Bylaws.

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

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

676  
677 All transplant hospital operating rooms where transplants are performed must also meet at least *one* of  
678 these requirements:

- 679  
680 ▪ Are within a geographically contiguous campus  
681 ▪ Are within a one mile walking distance from the main hospital's physical address

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

- 687  
688 1. Maps that illustrate the transplant hospital campus and the location of each operating room facility  
689 2. Building name and address  
690 3. Floor number  
691 4. Unit identifier

692  
693 Transplant hospitals that do not meet these requirements will not be approved as a single transplant  
694 hospital and will require separate OPTN memberships, unless the transplant hospital is approved  
695 according to *D.2.A: Approval of Transplant Hospitals with Operating Rooms Beyond the Established*  
696 *Geographic Boundaries*. ~~Any application recommended for rejection by the MPSC or the Board of~~  
697 ~~Directors entitles the applicant to due process as specified in *Appendix L: Reviews, Actions, and Due*~~  
698 ~~*Process* of these Bylaws.~~

### 700 **A. Approval of Transplant Hospitals with Operating Rooms Beyond** 701 **the Established Geographic Boundaries**

702 As long as the hospital is able to fulfill all other requirements established in these Bylaws, the  
703 OPTN may approve transplant hospitals that have operating rooms used for transplantation  
704 beyond the geographical boundaries established above. The hospital may submit an application  
705 to the OPTN to consider its specific circumstances if *all* of the following conditions are met:

- 706  
707 1. The hospital provides a written explanation detailing the mitigating circumstances that  
708 necessitate designation of a single transplant hospital or preclude registration of a second  
709 transplant hospital. The written explanation must at least address the following:
- 710 a. Transplant patient safety  
711 b. Impact on patient access

712 c. Organ utilization

713

714 2. The hospital provides a written plan for transplant patient care, including evidence that all  
715 necessary services and support will be available to transplant recipients.

716 3. The hospital participates in an informal discussion with the MPSC.

717

718 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
719 Chair is authorized to conduct the informal discussion and grant interim approval, according to  
720 *Appendix A.3: Applying for Membership in the OPTN*. Interim approvals are:

721

722 ■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant  
723 approval of a transplant hospital.

724 ■ Effective temporarily, pending final decision by the MPSC or Board of Directors.

725

726 **B. Multiple Transplant Hospitals Citing the Same Campus**  
727 **Boundaries**

728 A transplant hospital campus may only be associated with one transplant hospital unless the  
729 other transplant hospital is *either* of the following:

730

731 ■ Has approval as a transplant hospital in a Department of Veterans Affairs, Department of  
732 Defense, or other Federal hospital.

733 ■ Primarily serves pediatric patients. Transplant hospitals that annually perform, or intend to  
734 perform, 50 percent or more of their total transplants in patients less than 18 years of age will  
735 be identified as primarily serving pediatric patients.

736

737 **C. Review of Pediatric Transplant Activity at Transplant Hospitals**  
738 **that Share a Campus**

739 Transplant hospitals that primarily serve pediatric patients, and that share a campus with another  
740 transplant hospital, will be reviewed periodically by the MPSC to verify that it performed 50  
741 percent or more of its transplants in patients less than 18 years of age during the previous 12  
742 months. Any transplant hospital that is identified as not meeting this 50 percent threshold in any  
743 12 month period will have the opportunity to explain its pediatric inactivity in a report to the  
744 MPSC.

745

746 As part of its review of pediatric transplantation activity at transplant hospitals that share a  
747 campus, the MPSC may require that the member participate in an informal discussion. ~~The~~  
748 ~~informal discussion will be conducted according to *Appendix L: Reviews and Actions*. The informal~~  
749 ~~discussion may be with the MPSC, a subcommittee, or a work group, as determined by the~~  
750 ~~MPSC. The informal discussion will be conducted according to the principles of confidential~~  
751 ~~medical peer review, as described in *Appendix L: Reviews, Actions, and Due Process* of these~~  
752 ~~Bylaws. The discussion is not an adverse action or an element of due process. A member who~~  
753 ~~participates in an informal discussion with the MPSC is entitled to receive a summary of the~~  
754 ~~discussion.~~

755

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

763

764  
765  
766  
767  
768  
769  
770  
771  
772  
773  
774  
775  
776  
777  
778  
779  
780  
781  
782  
783  
784  
785  
786  
787  
788  
789  
790  
791  
792  
793  
794  
795  
796  
797  
798  
799  
800  
801  
802  
803  
804  
805  
806  
807  
808  
809

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

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

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

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

- ~~A Notice of Uncontested Violation~~
- ~~Letter of Warning~~
- ~~Letter of Reprimand~~

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

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

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

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

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

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

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

**D.10 Investigation of Transplant Personnel**

The transplant hospital must investigate any personnel on staff at a designated transplant program if directed to do so by the MPSC. The MPSC will request an investigation to examine an individual's role in a matter reviewed or currently under review by the MPSC, and explain the reason for the investigation request to the transplant hospital. The transplant hospital must inform the MPSC when it has started the

814 investigation and when it completes the investigation. The transplant hospital must also provide  
 815 documentation that it conducted the investigation according to the requirements of these Bylaws.

816  
 817 The hospital's investigation must use the hospital's standard medical peer review process for conducting  
 818 inquiries of potential professional misconduct and conclude with appropriate action consistent with this  
 819 process.

820  
 821 A member's failure to investigate designated transplant program staff as directed will be considered a  
 822 noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L:  
 823 Reviews and Actions.

824  
 825 ~~Failure to comply with these requirements will result in a recommendation to the Board of Directors to~~  
 826 ~~notify the Secretary, or a recommendation to take appropriate action according to Appendix L: Reviews,~~  
 827 ~~Actions, and Due Process these Bylaws.~~

828  
 829 **D.11 Review of Transplant Program Functional Activity**

830  
 831 **A. Functional Inactivity**

832 Each transplant program must remain functionally active by performing a minimum number of  
 833 transplants. ~~Transplant program functional activity will be reviewed periodically by the MPSC. Any~~  
 834 ~~program identified as functionally inactive will have the opportunity to explain its inactivity in a~~  
 835 ~~report to the MPSC.~~ For purposes of these Bylaws, functional inactivity is defined as the failure to  
 836 perform a transplant during the periods defined in the table below:  
 837

<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>

838  
 839 Functional inactivity thresholds have not been established for pancreatic islet, intestinal, and VCA  
 840 transplant programs.

841  
 842 **B. Notification Requirements for Transplant Program Functional**  
 843 **Inactivity**

844 If a transplant program is notified by the MPSC that the program has been identified as  
 845 functionally inactive, the transplant program must provide written notice to *all* of the following:

- 846  
 847 1. Potential candidates  
 848 2. All candidates registered on the waiting list

849  
 850 Written notice must be provided within 30 days of the date of the MPSC notification to the  
 851 program and must include *all* of the following:

- 852  
 853 1. The dates identified in the MPSC notification during which no transplants were performed.  
 854 2. The reason no transplants were performed.  
 855 3. The options available to the candidates, including multiple listing or transfer of accrued  
 856 waiting time to another transplant hospital.  
 857 4. A copy of the OPTN Contractor's Patient Information Letter.

858  
 859 **C. Review of Member Functional Inactivity**

860 Transplant program functional inactivity will be reviewed periodically by the MPSC. Any program

861 identified as functionally inactive will have the opportunity to explain its inactivity in a report to the  
862 MPSC.

863  
864 As part of its review of a program's functional inactivity, the MPSC may require, that the member  
865 participate in an informal discussion. The informal discussion will be conducted according to  
866 Appendix L: Reviews and Actions.

867  
868 The MPSC may recommend that a program inactivate or withdraw its designated transplant  
869 program status due to the program's functional inactivity. The MPSC must offer the member an  
870 informal discussion before recommending that the program inactivate or withdraw its designated  
871 transplant program status. A program's failure to inactivate or withdraw its designated transplant  
872 program status when the MPSC recommends it do so will be considered a noncompliance with  
873 OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and  
874 Actions. ~~If the program fails to inactivate or withdraw its designated transplant program status~~  
875 ~~when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors~~  
876 ~~take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these~~  
877 ~~Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the program's~~  
878 ~~inactivity.~~

879

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

### 881 **A. Transplant Program Performance**

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

883

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

890

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

895

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

898

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

901

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

910

911 As part of this process, the MPSC may conduct a peer visit to the program at the member's  
912 expense. The MPSC may also require, at its discretion, that the member participate in an informal  
913 discussion. The informal discussion will be conducted according to Appendix L: Reviews and  
914 Actions. ~~The informal discussion may be with the MPSC, a subcommittee, or a work group, as~~

915 ~~determined by the MPSC. The informal discussion will be conducted according to the principles of~~  
916 ~~confidential medical peer review, as described in Appendix L of these Bylaws. The informal~~  
917 ~~discussion is not an adverse action or an element of due process. A member who participates in~~  
918 ~~an informal discussion with the MPSC is entitled to receive a summary of the discussion.~~

919  
920 The MPSC may recommend that a member inactivate a program, or a component of a program,  
921 or withdraw its designated transplant program status based on patient safety concerns arising  
922 from review of the program's graft and patient survival. The MPSC must offer the member an  
923 informal discussion before recommending that the program inactivate or withdraw its designated  
924 transplant program status. A program's failure to inactivate or withdraw its designated transplant  
925 program status when the MPSC recommends it do so will be considered a noncompliance with  
926 OPTN Obligations and may result in an OPTN action according to Appendix L: Reviews and  
927 Actions. ~~If the program fails to inactivate or withdraw its designated transplant program status~~  
928 ~~when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors~~  
929 ~~take appropriate action as defined in Appendix L: Reviews, Actions, and Due Process of these~~  
930 ~~Bylaws.~~

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

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

### 933 **Transplant Programs**

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

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

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

- 941 1. The surgeon's pancreas transplant training or experience is equivalent to the fellowship or  
942 clinical experience pathways as described in *Sections G.2.A or G.2.B* above.
- 943 2. The surgeon has maintained a current working knowledge of all aspects of pancreas  
944 transplantation and patient care, defined as direct involvement in pancreas transplant patient  
945 care within the last 2 years.
- 946 3. The surgeon submits a letter of recommendation from the training program's primary surgeon  
947 and director at the fellowship training program or transplant program last served by the  
948 surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon,  
949 as well as the surgeon's personal integrity, honesty, and familiarity with and experience in  
950 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may  
951 request additional recommendation letters from the primary physician, primary surgeon,  
952 director, or others affiliated with any transplant program previously served by the surgeon, at  
953 its discretion.
- 954 4. The hospital participates in an informal discussion with the MPSC.

955  
956 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
957 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
958 determinations are:

- 959  
960  
961 ■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant  
962 approval of a designated transplant program.



- 963 ■ Effective temporarily, pending final decision by the MPSC or Board.

964  
965 The MPSC must offer the applicant an interview if the MPSC recommends that the Board of  
966 Directors rejects a membership application. The applicant may also be entitled to a hearing with  
967 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
968 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
969 appearances that occur as a part of a membership application process will be held according to  
970 Appendix L: Reviews and Actions.

971  
972 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
973 ~~applicant to due process as specified in Appendix L: Reviews, Actions, and Due Process of these~~  
974 ~~Bylaws.~~  
975

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

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

978 If a physician does not meet the requirements for primary physician through the transplant  
979 fellowship or clinical experience pathways as described above, transplant programs that serve  
980 predominantly pediatric patients may petition the MPSC in writing to consider the physician for  
981 primary transplant physician if the program can demonstrate that the following conditions are met:  
982

- 983 1. That the physician's pancreas transplant training or experience is equivalent to the fellowship  
984 or clinical experience pathways as described in *Sections G.3.A and G.3.B* above.
- 985 2. The physician has maintained a current working knowledge of all aspects of pancreas  
986 transplantation, defined as direct involvement in pancreas transplant patient care within the  
987 last 2 years.
- 988 3. The physician submits a letter of recommendation from the primary physician and transplant  
989 program director at the fellowship program or transplant program last served by the physician  
990 outlining the physician's overall qualifications to act as a primary transplant physician, as well  
991 as the physician's personal integrity, honesty, and familiarity with and experience in adhering  
992 to OPTN obligations, and any other matters judged appropriate. The MPSC may request  
993 additional recommendation letters from the primary physician, primary surgeon, director, or  
994 others affiliated with any transplant program previously served by the physician, at its  
995 discretion.
- 996 4. The hospital participates in an informal discussion with the MPSC.

997  
998 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC  
999 Chair is authorized to conduct the informal discussion and make an interim determination. Interim  
1000 decisions are:

- 1001  
1002 ■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant  
1003 approval of a designated transplant program.
- 1004 ■ Effective temporarily, pending final decision by the MPSC or Board.

1005  
1006 The MPSC must offer the applicant an interview if the MPSC recommends that the Board of  
1007 Directors rejects a membership application. The applicant may also be entitled to a hearing with  
1008 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
1009 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
1010 appearances that occur as a part of a membership application process will be held according to  
1011 Appendix L: Reviews and Actions.  
1012

1013 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
1014 ~~applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these~~  
1015 ~~Bylaws.~~  
1016

## 1017 **Appendix I: Membership and Personnel Requirements** 1018 **for Lung Transplant Programs**

### 1019 **I.2 Primary Lung Transplant Surgeon Requirements**

#### 1020 **D. Alternative Pathway for Predominantly Pediatric Programs**

1021 If a surgeon does not meet the requirements for primary lung transplant surgeon through either the  
1022 training or clinical experience pathways described above, hospitals that serve predominantly pediatric  
1023 patients may petition the MPSC in writing to consider the surgeon for primary transplant surgeon if the  
1024 program can demonstrate that the following conditions are met:

- 1025
- 1026 1. The surgeon's lung transplant training or experience is equivalent to the residency,  
1027 fellowship, or clinical experience pathways as described in *Sections I.2.A* through *I.2.C*  
1028 above.
  - 1029 2. The surgeon has maintained a current working knowledge of all aspects of lung  
1030 transplantation and patient care, defined as direct involvement in lung transplant patient care  
1031 within the last 2 years.
  - 1032 3. The surgeon submits a letter of recommendation from the primary surgeon and transplant  
1033 program director of the fellowship training program or transplant program last served by the  
1034 surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon,  
1035 as well as the surgeon's personal integrity, honesty, and familiarity with and experience in  
1036 adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may  
1037 request additional recommendation letters from the primary physician, primary surgeon,  
1038 director, or others affiliated with any transplant program previously served by the surgeon, at  
1039 its discretion.
  - 1040 4. The hospital participates in an informal discussion with the MPSC.  
1041

1042 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is  
1043 authorized to conduct the informal discussion and make an interim determination. Interim determinations  
1044 are:

- 1045
- 1046 ■ Advisory to the MPSC, Board of Directors, or both, who have the final authority to grant  
1047 approval of a designated transplant program.
  - 1048 ■ Effective temporarily, pending final decision by the MPSC or Board.  
1049

1050 The MPSC must offer the applicant an interview if the MPSC recommends that the Board of  
1051 Directors rejects a membership application. The applicant may also be entitled to a hearing with  
1052 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
1053 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
1054 appearances that occur as a part of a membership application process will be held according to  
1055 *Appendix L: Reviews and Actions.*  
1056

1057 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~

1058 applicant to due process as specified in ~~Appendix L: Reviews, Actions, and Due Process~~ of these  
1059 Bylaws.

1060  
1061 **I.3 Primary Lung Transplant Physician Requirements**

1062 **C. Alternative Pathway for Predominantly Pediatric Programs**

1063 If a physician does not meet the requirements for primary physician through any of the transplant  
1064 fellowship or clinical experience pathways as described above, hospitals that serve predominantly  
1065 pediatric patients may petition the MPSC in writing to consider the physician for primary transplant  
1066 physician if the program can demonstrate that the following conditions are met:

- 1067
- 1068 1. That the physician's lung transplant training or experience is equivalent to the fellowship or  
1069 clinical experience pathways as described in *Sections 1.3.A* and *1.3.B* above.
  - 1070 2. The physician has maintained a current working knowledge of all aspects of lung  
1071 transplantation, defined as direct involvement in lung transplant patient care within the last 2  
1072 years.
  - 1073 3. The physician submits a letter of recommendation from the primary physician and transplant  
1074 program director of the fellowship training program or transplant program last served by the  
1075 physician outlining the physician's overall qualifications to act as a primary transplant  
1076 physician, as well as the physician's personal integrity, honesty, and familiarity with and  
1077 experience in adhering to OPTN obligations, and any other matters judged appropriate. The  
1078 MPSC may request additional recommendation letters from the primary physician, primary  
1079 surgeon, director, or others affiliated with any transplant program previously served by the  
1080 physician, at its discretion.
  - 1081 4. The hospital participates in an informal discussion with the MPSC.

1082

1083 The MPSC or an Ad Hoc Subcommittee of at least 4 MPSC members appointed by the MPSC Chair is  
1084 authorized to conduct the informal discussion and make an interim determination. Interim decisions are:

- 1085
- 1086 ■ Advisory to the MPSC, Board of Directors, or both, which has the final authority to grant  
1087 approval of a designated transplant program.
  - 1088 ■ Effective temporarily, pending final decision by the MPSC or Board of Directors.
- 1089

1090 The MPSC must offer the applicant an interview if the MPSC recommends that the Board of  
1091 Directors rejects a membership application. The applicant may also be entitled to a hearing with  
1092 the MPSC and an appearance before the Board of Directors prior to the Board of Directors taking  
1093 a final action on any MPSC recommendation. Any interviews, hearings, or Board of Directors  
1094 appearances that occur as a part of a membership application process will be held according to  
1095 Appendix L: Reviews and Actions.

1096

1097 ~~Any application recommended for rejection by the MPSC or the Board of Directors may entitle the~~  
1098 ~~applicant to due process as specified in *Appendix L: Reviews, Actions, and Due Process* of these~~  
1099 ~~Bylaws.~~

1100

1101 **~~Appendix L: Reviews, Actions, and Due Process~~**

1102 **~~L.1. Member Compliance~~**

1103 Each OPTN member agrees to comply with OPTN Obligations, which include ~~all~~ of the following:

- 1104
- 1105 1. ~~National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.~~
  - 1106 2. ~~OPTN Final Rule, 42 CFR Part 121~~
  - 1107 3. ~~OPTN Bylaws~~
  - 1108 4. ~~OPTN Policies~~

1109

1110 At any time, the OPTN Board of Directors or the OPTN Executive Committee may recommend that the

1111 Secretary of the U.S. Department of Health and Human Services (HHS) take appropriate action as

1112 outlined in the OPTN Final Rule.

1113

1114 **~~A. Periodic Reviews~~**

1115 The OPTN will conduct ongoing periodic reviews and evaluations of each transplant hospital,

1116 histocompatibility laboratory member, and OPO member for compliance with OPTN Obligations.

1117 All compliance monitoring is performed using guidelines developed by the OPTN. Any member

1118 who fails to fulfill all the applicable OPTN Obligations may be subject to actions as set forth in

1119 these Bylaws.

1120

1121 **~~B. Failure to Pay OPTN Fees~~**

1122 The failure of an OPO, transplant hospital, or histocompatibility laboratory member to pay, within

1123 30 days, any OPTN fee, charge, or other monetary obligation to the OPTN Contractor will be

1124 considered a violation of OPTN Obligations.

1125

1126 **~~L.2. Compliance Monitoring~~**

1127 The OPTN Executive Director monitors compliance of members with OPTN Obligations, and refers all

1128 incidences of potential non-compliance for further review as outlined in these Bylaws.

1129

1130 The Executive Director may delegate these monitoring duties to any number of designees to ensure that

1131 the necessary actions are taken to meet the requirements of these Bylaws.

1132

1133 **~~L.3. Reporting Potential Violations and Non-compliance~~**

1134 Any member who becomes aware of a potential violation of or non-compliance with OPTN Obligations

1135 must inform the OPTN as soon as the member becomes aware of the issue, including potential violations

1136 or non-compliance by the member itself.

1137

1138 **~~L.4. Methods for Correspondence and Providing Notice~~**

1139 Unless otherwise noted, all correspondence between members and the OPTN required by this *Appendix*

1140 *L* must be sent by a method that can be tracked and that provides proof of receipt, such as:

1141

- 1142 ■ ~~Commercial overnight delivery service~~
- 1143 ■ ~~Secure electronic communication~~
- 1144 ■ ~~Registered or certified mail, return receipt requested~~

1145

1146 The Executive Director will send notice to members when they are required to respond to an OPTN action

1147 or request. When the member receives notice, the member must respond within the specified time, as

1148 defined in these Bylaws. Time limits specified for providing notice, including requests for interviews,  
1149 hearings, and to appear before the OPTN Board of Directors, begin on the date the notice is sent from the  
1150 Executive Director.

1151

## 1152 ~~L.5.—Medical Peer Review~~

1153 The OPTN will conduct all deliberations and take all actions according to applicable confidential medical  
1154 peer review laws. As appropriate and consistent with applicable laws, all of the following deliberations and  
1155 actions of any OPTN Committee, the OPTN Executive Committee, the OPTN Board of Directors, and the  
1156 OPTN Contractor will be kept confidential during the review of:

1157

- 1158 1. ~~Potential violations of or non-compliance with OPTN Obligations.~~
- 1159 2. ~~Matters relating to potential threats to patient health and public safety.~~
- 1160 3. ~~Applications for membership, designated transplant program status, or a change in Key~~  
1161 ~~Personnel.~~

1162

1163 Members must keep these records, review activity, and documents confidential to promote quality  
1164 improvement and full disclosure by OPTN members.

1165

## 1166 ~~A.—Secretary’s Access to Information~~

1167 The medical peer review privilege will not be extended to withhold any document from the  
1168 Secretary of HHS, or the Secretary’s designee. The OPTN Contractor is required to provide the  
1169 Secretary with any information acquired or produced under the OPTN Contract, including  
1170 information that would otherwise be protected by the medical peer review privilege. As specified  
1171 in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the  
1172 Secretary that the Secretary requests, in the format requested by the Secretary.

1173

## 1174 ~~B.—Health Resources and Services Administration (HRSA)~~ 1175 ~~Representation~~

1176 The Project Officer for the OPTN Contract and the Director of the Division of Transplantation  
1177 within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*,  
1178 non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting  
1179 members of the Executive Committee and Board, they, or their designees, are granted full access  
1180 to all deliberations, determinations and actions. Representatives of HRSA are also *ex-officio*, non-  
1181 voting members of the Membership and Professional Standards Committee (MPSC) and granted  
1182 full access to all MPSC deliberations, determinations, and actions as well. Other designees of the  
1183 Secretary may also attend OPTN meetings.

1184

## 1185 ~~L.6.—Requests for Root Cause Analysis and Corrective Action~~

1186 The OPTN Board of Directors, the MPSC, or any standing subcommittee of the MPSC or their designee  
1187 may require a member to take corrective action to address any potential violation or noncompliance.  
1188 Corrective action can include any of the following:

1189

- 1190 1. ~~Root cause analysis~~
- 1191 2. ~~Corrective action plan~~
- 1192 3. ~~Plan for quality improvement~~
- 1193 4. ~~On-site monitoring~~
- 1194 5. ~~Desk monitoring~~
- 1195 6. ~~Self-assessments~~
- 1196 7. ~~External expert consultants~~

1197  
1198

### **A. ~~Initiating Corrective Action~~**

1199 If it appears that an OPO, transplant hospital, or histocompatibility laboratory member may have  
1200 failed to meet OPTN Obligations, the MPSC or the Board of Directors may request that the  
1201 member performs a root cause analysis and then develops and implements a corrective action  
1202 plan or plan for quality improvement to address any potential violations or non-compliance.  
1203

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

1205 The Executive Director will promptly give notice to the member when requesting any corrective  
1206 action. The member must also submit any requested documentation to the Executive Director at  
1207 this time.  
1208

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

1210 The Secretary of HHS may request that the OPTN Contractor performs a Special Review under guidance  
1211 from the Secretary. A Special Review is a review of the member in the manner and within the period  
1212 specified by the Secretary. This may include, but is not limited to, requests for root cause analysis,  
1213 corrective action, and due process proceedings completed in the period and as specified by the  
1214 Secretary, and as defined *Sections L.6 and L.9 through L.14* in this Appendix L. Members must fully  
1215 comply with all OPTN Contractor requests as part of a Special Review.  
1216

1217 The Secretary may impose sanctions or take other appropriate action at any time when a member poses  
1218 a risk to the health of patients or to the public safety.  
1219

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

1221 The OPTN will review potential violations of and non-compliance with OPTN Obligations by one of three  
1222 pathways as defined below:  
1223

- 1224 1. An **Imminent Threat Review** will be conducted when the MPSC Chair determines that there is a  
1225 potential violation of or non-compliance with OPTN Obligations, which may pose an urgent and  
1226 severe risk to patient health or public safety. The MPSC Chair may choose this pathway when the  
1227 member is not taking action to mitigate the potential threat, or the Chair believes that the potential  
1228 threat may not be mitigated through routine procedures.
- 1229 2. An **Expedited Review** will be conducted when the MPSC Chair determines that a potential violation  
1230 of or non-compliance with OPTN Obligations may pose a potential risk to patient health or public  
1231 safety, which is not currently urgent but could become urgent or severe if not addressed using an  
1232 Expedited Review process. When a matter is reviewed using the Expedited Review pathway, a  
1233 hearing is offered to the member on an expedited schedule.
- 1234 3. A **Routine Review** will be conducted for any potential violation of or non-compliance with OPTN  
1235 Obligations when the MPSC Chair determines that an Expedited Review or an Imminent Threat  
1236 Review is not warranted.

1237  
1238 When investigating any potential violation or non-compliance and determining a review pathway, the  
1239 OPTN Contractor will take appropriate action as described in *Sections L.9 through L.14* that follow.  
1240

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

1242 When the OPTN learns of a possible failure of a member to comply with any aspect of applicable OPTN  
1243 Obligations, the Executive Director will conduct a preliminary investigation. This investigation will consider  
1244 whether the potential violation suggests a risk to patient health or public safety, and the urgency and  
1245 severity of the risk.

1246 If additional information is required in conducting the preliminary investigation of any potential violation,  
1247 the member must respond to requests from the OPTN. A member's documented history of violations and  
1248 non-compliance, or systemic problems and operational failures, could warrant review of the member  
1249 through the Imminent Threat or Expedited Review pathway.

1250

1251

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

1252 If the preliminary investigation concludes that the potential violation may pose an urgent and  
1253 severe risk to patient health or public safety, the matter will be referred to the MPSC Chair within  
1254 24 hours.

1255

1256 If the preliminary investigation concludes that the risk to patient health or public safety is not an  
1257 urgent and severe risk, but a substantial risk remains, the matter will be referred to the MPSC  
1258 Chair within 7 days.

1259

1260

#### **B. Notice to the Secretary after Preliminary Investigation**

1261 If the potential violation is referred to the MPSC Chair with a recommendation to follow the  
1262 Imminent Threat Review pathway, the Executive Director will provide notice to the Secretary  
1263 within 24 hours of the referral.

1264

1265 The OPTN will notify the Secretary within 7 days when a preliminary investigation determines that  
1266 the member has not violated OPTN Obligations but that a risk to patient health or public safety  
1267 exists.

1268

### **L.10. Determination of Review Pathway**

1270

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

1271 The OPTN will refer a potential violation to the MPSC Chair if the preliminary investigation  
1272 determines that the potential violation may pose an urgent and severe risk to patient health or  
1273 public safety. The MPSC Chair will consider the available information and determine the  
1274 appropriate review pathway. In making this determination, the MPSC Chair may consult with the  
1275 Executive Director, OPTN President, HRSA representatives, and any others, as determined by  
1276 the Chair. If the MPSC Chair is unavailable, the MPSC Vice Chair may make this determination.  
1277 The MPSC Chair must make this decision within 72 hours after the preliminary investigation is  
1278 completed.

1279

1280

#### **B. Requests to Take Action to Mitigate Imminent Threat**

1281 If the MPSC Chair determines that an urgent and severe risk appears to be present, the MPSC  
1282 Chair may request that the member voluntarily cease performing certain transplants or take a  
1283 specified action to mitigate the threat to patient health or public safety. If the member takes the  
1284 requested action to mitigate the threat within 24 hours, the matter may proceed through the  
1285 Expedited Review pathway.

1286

1287

#### **C. Notice of Chair's Determination**

1288 The MPSC Chair will provide notice to the Secretary of the Review pathway within 72 hours of the  
1289 determination.

1290

1291

#### **D. Changing Review Pathways**

1292 The MPSC Chair may change the review pathway of a potential violation at any time as  
1293 information is gathered and the assessment of the urgency and severity of the risk to patient  
1294 health or public safety changes.

1295  
1296  
1297  
1298  
1299  
1300  
1301  
1302  
1303  
1304  
1305  
1306  
1307  
1308  
1309  
1310  
1311  
1312  
1313  
1314  
1315  
1316  
1317  
1318  
1319  
1320  
1321  
1322  
1323  
1324  
1325  
1326  
1327  
1328  
1329  
1330  
1331  
1332  
1333  
1334  
1335  
1336  
1337  
1338  
1339  
1340

**L.11. OPTN Investigations**

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

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

**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:



- 1341 a. ~~Provide notice to the member of the Imminent Threat Review Committee's action~~  
1342 ~~within 24 hours by an approved method as described in Section L.4. Methods for~~  
1343 ~~Correspondence and Providing Notice. The member will have 24 hours after~~  
1344 ~~receiving notice to respond to the Executive Director regarding the Imminent Threat~~  
1345 ~~Review Committee's recommendations.~~  
1346 b. ~~Provide notice of the Imminent Threat Review Committee's recommendation to the~~  
1347 ~~Secretary within 24 hours.~~  
1348 c. ~~Refer the matter to the OPTN Executive Committee within 72 hours.~~  
1349 d. ~~Include a recommendation for an adverse action, and whether the matter should be~~  
1350 ~~referred to the Secretary for further action.~~  
1351

1352 **C. ~~Interviews in Imminent Threat Reviews~~**

1353 ~~When a potential violation proceeds through the Imminent Threat Review pathway, members are~~  
1354 ~~not entitled to an interview before the MPSC, even though the recommended action is an adverse~~  
1355 ~~action.~~

1357 **D. ~~OPTN Executive Committee Determination~~**

1358 ~~The Executive Committee of the OPTN will convene within 7 days of the Imminent Threat Review~~  
1359 ~~Committee's determination.~~

1361 ~~If the Executive Committee determines that an urgent and severe risk to patient health or public~~  
1362 ~~safety no longer exists, it will decide whether the matter should proceed through the Expedited~~  
1363 ~~Review or Routine Review pathway.~~

1364 ~~If the matter continues to proceed through the Imminent Threat Review pathway, the Executive~~  
1366 ~~Committee will make the following determinations:~~

- 1367
- 1368 ~~1. Whether to accept the recommendation of the Imminent Threat Review~~  
1369 ~~Committee, or take another action. An adverse action is effective immediately~~  
1370 ~~upon the determination by the Executive Committee, prior to any hearing.~~
  - 1371 ~~2. Whether the MPSC, Executive Committee, or Board of Directors will be the~~  
1372 ~~hearing body if the member requests a hearing. Members of the Imminent Threat~~  
1373 ~~Review Committee may also participate in the Imminent Threat Hearing Panel.~~

1374

1375 **E. ~~Notice after OPTN Executive Committee's Determination~~**

1376 ~~The OPTN Executive Director will provide notice of the Executive Committee's determinations:~~

- 1377
- 1378 ~~1. To the HHS Secretary within 24 hours.~~
  - 1379 ~~2. To the member within 24 hours.~~

1380

1381 ~~The Executive Committee will provide a written summary of this review to the Executive Director~~  
1382 ~~within 48 hours to be forwarded to the Secretary. The Executive Committee may determine when~~  
1383 ~~any notice to the membership or public required by Executive Committee actions will occur. The~~  
1384 ~~member may request a copy of the supporting documentation, which will be provided at the~~  
1385 ~~member's expense.~~

1386

1387 **F. ~~Requesting a Hearing in Imminent Threat Reviews~~**

1388 ~~The member has 7 days following notice of the Executive Committee's determination to request a~~

1389 hearing as described in ~~Section L.18.B: Requesting a Hearing~~. The hearing will occur not less  
1390 than 7 days or more than 30 days from the date of the Executive Director's receipt of the request  
1391 for a hearing.

1392 **~~G. Imminent Threat Hearing Process~~**

1393 If the member exercises its right to a hearing, the hearing will be conducted under the procedures  
1394 described in ~~Section L.18: Hearings~~ that follows, with these modifications:

- 1395
- 1396 1. The hearing will occur after the Executive Committee's review and determination of  
1397 the adverse action.
  - 1398 2. The Hearing Panel report will be issued within 14 days of the conclusion of the  
1399 hearing.
  - 1400 3. If the Imminent Threat Hearing Panel determines that no adverse action is warranted,  
1401 the Hearing Panel may immediately remove the designation of Member Not in Good  
1402 Standing or Probation and provide appropriate notice without Board of Directors'  
1403 approval.
- 1404

1405 **~~L.13. Expedited Reviews~~**

1406 Any potential violation of or non-compliance with OPTN Obligations that poses a potential risk to patient  
1407 health or public safety, which could become urgent or severe, will follow the Expedited Review pathway.

1408

1409 **~~A. Expedited Review Investigation~~**

1410 The OPTN must complete an investigation of the potential violation within 21 days of the initial  
1411 determination by the MPSC Chair that the potential violation will proceed through the Expedited  
1412 Review pathway.

1413

1414 **~~B. Expedited Review Committee~~**

1415 Within 42 days of the determination of the expedited review pathway, the Expedited Review  
1416 Committee will complete its review and forward its recommendations to the MPSC Chair.

1417

1418 **~~1. Composition of the Expedited Review Committee~~**

1419 The Expedited Review Committee may be the MPSC, any standing subcommittee of the  
1420 MPSC, or an ad hoc subcommittee of the MPSC, as appointed by the MPSC Chair. A  
1421 subcommittee must include at least 5 members of the MPSC and 2 of the members  
1422 should have expertise in the organ system or specific issue that is the subject of the  
1423 review.

1424 **~~2. Expedited Review Committee Recommendations~~**

1425 The Expedited Review Committee will consider instances of potential non-compliance  
1426 with OPTN Obligations. The Expedited Review Committee may determine that there was  
1427 no violation, issue a letter of warning, or issue a notice of uncontested violation. The  
1428 Expedited Review Committee may also recommend a Letter of Reprimand or an adverse  
1429 action.

1430

1431 If the Expedited Review Committee recommends a Letter of Reprimand or an adverse  
1432 action, then the member is entitled to an interview before the MPSC.

1433 **~~3. Notice after Expedited Review Committee's Recommendations~~**

1434 The MPSC Chair will provide notice of the Expedited Review Committee's determination  
1435 by an approved method as described in ~~Section L.4: Methods for Correspondence and~~

1436 ~~Providing Notice. If the recommendation is for an adverse action, then the OPTN~~  
1437 ~~Executive Director will provide notice of the Expedited Review Committee's determination~~  
1438 ~~to the Secretary within 24 hours.~~

1439 **C. Interviews in Expedited Reviews**

1440 The member will be entitled to an interview before the MPSC when the Expedited Review  
1441 Committee considers issuing a Letter of Reprimand or an adverse action. The member will have  
1442 the right to request an interview to be held at the next in-person meeting of the MPSC. If the next  
1443 in-person meeting of the MPSC is scheduled more than 60 days later, at the discretion of the  
1444 MPSC Chair, a special in-person meeting may be required or an interview may be conducted by  
1445 teleconference or electronic media.

1446  
1447 If the member exercises its right to an interview, the interview will be conducted as described in  
1448 *Section L.17: Interviews* that follows.

1449  
1450 **1. Requesting an Interview**

1451 The member has 14 days following notice of the Expedited Review Committee's  
1452 recommendation to request an interview before the MPSC as described in *Section*  
1453 *L.17.B: Requesting an Interview*.

1454  
1455 **D. Requesting a Hearing in Expedited Reviews**

1456 Following the interview before the MPSC, whether accepted by the member or not, the MPSC will  
1457 consider the Expedited Review Committee's recommendation and may recommend to the Board  
1458 of Directors to impose an adverse action on the member. The MPSC will provide Notice of the  
1459 recommended adverse action to the member. The member has 14 days following notice of the  
1460 MPSC's recommendation for an adverse action to request a hearing as described in *Section*  
1461 *L.18.B: Requesting a Hearing*.

1462  
1463 Hearings will be scheduled no fewer than 7 days or more than 60 days from the date that the  
1464 Executive Director receives the request for hearing. Hearings may be scheduled more than 60  
1465 days from the request date at the discretion of the MPSC Chair, and if the member and Chair  
1466 agree on the date.

1467  
1468 **E. Expedited Review Hearing Panel**

1469 The Expedited Review Hearing Panel will be appointed by the MPSC Chair and composed of at  
1470 least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc committee. Two of  
1471 the members must have expertise in the organ system or specific issue that is the subject of the  
1472 review.

1473  
1474 The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of the  
1475 Expedited Review Committee may also participate in the Expedited Review Hearing Panel.

1476  
1477 **F. Expedited Review Hearing Process**

1478 If the member exercises its right to a hearing, the hearing will be conducted under the procedures  
1479 described in *Section L.18: Hearings* that follows, with these modifications:

- 1480  
1481 1. The Hearing Panel report will be issued within 21 days of the conclusion of the hearing.  
1482 2. The Board will consider and act on the Hearing Panel report within 30 days of receiving the  
1483 report.

1484

1485 **L.14. Routine Reviews**

1486 A Routine Review will be conducted for any potential violation of OPTN Obligations when an Expedited  
1487 Review or an Imminent Threat Review is not warranted.

1488  
1489 **A. Routine Review Investigations**

1490 The OPTN will complete a routine review investigation of the matter and refer it to the Routine  
1491 Review Committee within 6 months.

1492  
1493 **B. Routine Review Committee**

1494 The Routine Review Committee will be composed of any standing subcommittee of the MPSC or,  
1495 at the discretion of the MPSC Chair, the entire MPSC. The Routine Review Committee may meet  
1496 by teleconference or electronic media, as needed, for the purpose of considering any new and  
1497 ongoing potential policy violations.

1498  
1499 **1. Notice after Routine Review Committee's Determinations**

1500 The Routine Review Committee will notify the member of its determination and any  
1501 recommendation for a specific action. If the Committee recommends an action that would  
1502 entitle the member to an interview, members will be notified of their right to an interview  
1503 at the time they are informed of the Committee's determination.

1504  
1505 **C. Interviews in Routine Reviews**

1506 The member will be entitled to an interview when the Routine Review Committee is considering  
1507 making a recommendation for a Letter of Reprimand or an adverse action. Interviews will be  
1508 scheduled at the next in-person meeting of the MPSC or standing subcommittee of the MPSC.

1509  
1510 **1. Requesting an Interview**

1511 The member has 14 days to request an interview as described in *Section L.17.B:*  
1512 *Requesting or Waiving the Right to an Interview* following notice of the Routine Review  
1513 Committee's determination.

1514  
1515 **D. Hearings in Routine Reviews**

1516 **1. Requesting a Hearing**

1517 The member has 14 days following notice of the Routine Review Committee's  
1518 recommendation for an adverse action to request a hearing as described in *Section*  
1519 *L.18.B: Requesting or Waiving the Right to a Hearing.*

1520  
1521 Hearings will be scheduled no fewer than 7 days or more than 60 days from the date the  
1522 OPTN Executive Director receives the request for hearing. Hearings may be scheduled  
1523 more than 60 days from the request date at the discretion of the MPSC Chair, and if the  
1524 member and MPSC Chair agree on the date.

1525  
1526 **2. Routine Review Hearing Panel**

1527 The Routine Review Hearing Panel will be appointed by the MPSC Chair and composed  
1528 of at least 15 MPSC members, 10 of which will constitute a quorum of the ad hoc  
1529 committee. Two of the members must have expertise in the organ system or specific  
1530 issue that is the subject of the review.

1531

1532 The Chair of the MPSC or the Chair's designee will be the presiding officer. Members of  
1533 the Routine Review Committee may also participate in the Routine Review Hearing  
1534 Panel.

1535  
1536 **3. ~~Routine Review Hearing Process~~**

1537 If the member exercises its right to a hearing, the hearing will be conducted using the  
1538 procedures described in *Section L.18: Hearings*, with the following additional notifications  
1539 to the member:

- 1540  
1541 a. ~~That all documentation about the member that was generated by or submitted to the~~  
1542 ~~MPSC, the OPTN Executive Committee, or the OPTN Board before the~~  
1543 ~~recommendation or action, will be made available to the member, upon request.~~  
1544 b. ~~The Hearing Panel report will be issued within 30 days of the conclusion of the~~  
1545 ~~hearing.~~  
1546 c. ~~The Board of Directors will consider and act on the Hearing Panel report at its next~~  
1547 ~~regularly scheduled meeting following receipt of the report.~~  
1548

1549 **L.15. ~~OPTN Determinations and Actions~~**

1550 OPTN actions may be imposed when a member:

- 1551  
1552 1. ~~Fails to comply with OPTN Obligations as described in L.1. Member Compliance.~~  
1553 2. ~~Fails to submit or follow a corrective action plan or plan for quality improvement.~~  
1554 3. ~~Fails to meet personnel requirements.~~  
1555 4. ~~Acts in a way that poses a risk to patient health or public safety.~~  
1556 5. ~~Fails to act as necessary to avoid risk to patient health or public safety.~~  
1557

1558 **A. ~~Determining Appropriate Action~~**

1559 Factors considered in reviewing potential violations and incidents of non-compliance include but  
1560 are not limited to:

- 1561  
1562 1. ~~Whether the potential violation poses an urgent and severe risk to patient health or public~~  
1563 ~~safety.~~  
1564 2. ~~Whether the potential violation poses a substantial risk to the integrity of or trust in the OPTN.~~  
1565 3. ~~Whether patient medical records or other documentation provide sufficient detail to determine~~  
1566 ~~the presence of mitigating factors at the time the potential violation occurred.~~  
1567 4. ~~Whether the member can show evidence of corrective action upon learning of the potential~~  
1568 ~~violation.~~  
1569 5. ~~The overall OPTN compliance history of the member, including but not limited to, MPSC~~  
1570 ~~reviews and actions in the member's history.~~

1571  
1572 The OPTN may impose a separate action for each violation or may choose to impose a single  
1573 action for all related violations that can be addressed by a single action.

1574  
1575 **B. ~~Corrective Action~~**

1576 The OPTN may require a member to take corrective action in addition to imposing an adverse  
1577 action, or instead of imposing an adverse action, including:

- 1578  
1579 1. ~~Root cause analysis~~

- 1580 2. ~~Corrective action plan~~
- 1581 3. ~~Plan for quality improvement~~
- 1582 4. ~~On-site monitoring~~
- 1583 5. ~~Desk monitoring~~
- 1584 6. ~~Self-assessments~~
- 1585 7. ~~External expert consultants~~

1586  
1587 If the MPSC or any standing subcommittee of the MPSC requires a member to take corrective  
1588 action to address any issues of noncompliance, the member must take corrective action as  
1589 specified and within the period provided. If the member fails to fulfill the corrective action  
1590 requirements, the OPTN may make any determination or take any action as outlined in this  
1591 *Appendix L*.

### 1593 **C. ~~Deferred Disposition with Monitoring Period~~**

1594 If the MPSC recommends an adverse action against a member, and the member has had an  
1595 interview before the MPSC, the MPSC may delay proceeding with the matter for a Deferred  
1596 Disposition period. Deferred Disposition will only be considered in cases where the member has  
1597 implemented a corrective action plan or plan for quality improvement within the 60 days prior to  
1598 the interview and where the potential violation or non-compliance under review is not egregious  
1599 or severe.

1600  
1601 Deferred Disposition is not an action, but rather a timeout period provided to the member to  
1602 demonstrate its ability and willingness to meet OPTN Obligations. If the MPSC chooses to  
1603 employ a Deferred Disposition, the recommendation for adverse action will not be communicated  
1604 to the Board of Directors until after Deferred Disposition. The MPSC is able to revise its  
1605 recommendation at the end of the Deferred Disposition before communicating it to the Board.

1606  
1607 Deferred Disposition is not appropriate if the member has received *either*:

- 1608
- 1609 1. ~~A Letter of Warning, Letter of Reprimand, or an MPSC recommendation for an adverse action~~  
1610 ~~in the previous 2 years from the date of the interview.~~
- 1611 2. ~~Two or more Notices of Uncontested Violation in the previous 2 years from the date of the~~  
1612 ~~interview.~~

#### 1613 1614 **1. ~~Additional Considerations for Deferred Disposition~~**

1615 The MPSC may also consider any of the following:

- 1616
- 1617 ■ ~~The overall performance and compliance history of the member, including its~~  
1618 ~~response to previous MPSC actions, and particularly requests for corrective action or~~  
1619 ~~plans for quality improvement.~~
- 1620 ■ ~~Any recent changes in the member's staffing, including changes in those responsible~~  
1621 ~~for oversight of the member.~~
- 1622 ■ ~~An MPSC assessment of the appropriateness or thoroughness of the corrective~~  
1623 ~~action plan or plan for quality improvement addressing the matter under review.~~

1624  
1625 The MPSC is not required to offer a Deferred Disposition after an interview with the  
1626 member and may proceed with its recommendation of the adverse action without a  
1627 Deferred Disposition. If the member declines the Deferred Disposition, the MPSC will  
1628 proceed with its recommendation of the adverse action.

1629

1630  
1631  
1632  
1633  
1634  
1635  
1636  
1637  
1638  
1639  
1640  
1641  
1642  
1643  
1644  
1645  
1646  
1647  
1648  
1649  
1650  
1651  
1652  
1653  
1654  
1655  
1656  
1657  
1658  
1659  
1660  
1661  
1662  
1663  
1664  
1665  
1666  
1667  
1668  
1669  
1670  
1671  
1672  
1673  
1674  
1675  
1676  
1677

**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~~**

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

**4. ~~Recommendation of an Adverse Action during or after Deferred Disposition~~**

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

**5. ~~Actions if Member Demonstrates Compliance after Deferred Disposition~~**

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

**D. ~~MPSC Actions without Board Referral~~**

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

- ~~■ Issue a Notice of Uncontested Violation~~
- ~~■ Issue a Letter of Warning~~
- ~~■ Consider Issuing a Letter of Reprimand~~

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

**1. ~~Notice of Uncontested Violation~~**

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

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

1678  
1679 The member is not entitled to an interview.

1680  
1681 **2. Letter of Warning**

1682 The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Warning for  
1683 a violation of OPTN Obligations when:

- 1684  
1685 a. Medical judgment is credibly put forth as a partial mitigating factor.  
1686 b. There is believed to be no likelihood of recurrence.

1687  
1688 Letters of Warning may also be issued in those cases where the compliance history of  
1689 the member warrants an action higher than Notice of Uncontested Violation. The member  
1690 is not entitled to an interview.

1691  
1692 **3. Letter of Reprimand**

1693 The MPSC, or any standing subcommittee of the MPSC, will issue a Letter of Reprimand  
1694 for a violation of OPTN Obligations when medical judgment does not appear to be a  
1695 credible mitigating factor. Letters of Reprimand may also be issued in those cases where  
1696 the compliance history of the member warrants an action higher than Notice of  
1697 Uncontested Violation or Letter of Warning. The member is entitled to an interview before  
1698 a Letter of Reprimand is issued.

1699  
1700 **E. Adverse Actions that Require Board Approval**

1701 The adverse actions of Probation and Member Not in Good Standing can only be imposed by the  
1702 Board of Directors. If a member receives an adverse action, the Executive Director will give notice  
1703 to the public of the adverse action as specified by the Board of Directors. This notice may include,  
1704 but is not limited to, communication using the OPTN website.

1705  
1706 **1. Probation**

1707 The MPSC may recommend that the Board of Directors place a member on Probation, or  
1708 the Board may do so on its own. Probation is an adverse action under these Bylaws, and  
1709 the OPTN Executive Director will give notice to all members when a member is placed on  
1710 Probation.

1711  
1712 **a. Corrective Action Requirements of Probation**

1713 The adverse action of Probation will require that the member adheres to corrective action  
1714 requirements as specified by the MPSC, which may include, but are not limited to:

- 1715  
1716 i. Required development and submission of a corrective action plan or plan for  
1717 quality improvement as specified by the MPSC, any standing subcommittee of  
1718 the MPSC, the Executive Committee, or the Board of Directors. The member  
1719 must demonstrate that it has adhered to the plan and that it has corrected any  
1720 noncompliant activity within the Probation effective period.  
1721 ii. Unscheduled on-site reviews by the OPTN Contractor staff or peer review  
1722 teams throughout the Probation period.  
1723 iii. Specified submission of reports, data, or other evidence to the OPTN that  
1724 documents correction of the non-compliant activity throughout the period of  
1725 Probation.



1726  
1727  
1728  
1729  
1730

**b. Notification Requirements of Probation**

The adverse action of Probation will require that the member 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 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.

1731  
1732  
1733  
1734  
1735  
1736

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.

1737  
1738  
1739  
1740

**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.

1741  
1742  
1743  
1744

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

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

1745  
1746  
1747  
1748  
1749  
1750  
1751  
1752  
1753  
1754  
1755  
1756  
1757  
1758

- 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.

1759  
1760  
1761  
1762  
1763

**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:

If the member is a...	Then notice must be provided to ...
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.
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.

1764  
 1765 Members must provide notices as described above within 30 days of receiving  
 1766 notification from the OPTN that it has been given the adverse action of Member Not in  
 1767 Good Standing.

1768  
 1769 The notice to transplant hospital patients must be provided in writing, in each patient's  
 1770 spoken language, and as specified by the Executive Committee or Board of Directors.  
 1771

1772 **F. Recommendations and Requests to the Secretary**

1773 The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic  
 1774 reviews and evaluations, or Secretarial directed reviews, of member OPOs and transplant  
 1775 hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN  
 1776 Obligations or indicate a risk to the health of patients or to the public safety, and will provide any  
 1777 recommendations for appropriate action by the Secretary. Appropriate actions, include, but are  
 1778 not limited to those described in the OPTN final rule, as described in *Section L.16*: that follows.

1779  
 1780 At any time, the Board may make recommendations to the Secretary for specific actions, on its  
 1781 own or after receiving a recommendation from the MPSC.  
 1782

1783 **L.16. Secretarial Actions**

1784 Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

- 1785 1. Violates the National Organ Transplant Act (NOTA).
- 1786 2. Violates the OPTN Final Rule, *42 CFR Part 121*.
- 1787 3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more  
 1788 information on mandatory policies, see *Section L.16.A: OPTN Policies Approved by the Secretary as*  
 1789 *Mandatory*.
- 1790 4. Engages in behavior that poses a risk to patient health or public safety.

1791  
 1792  
 1793 Termination of membership requires Secretarial approval. Membership can only be removed if the OPTN  
 1794 member no longer meets the requirements for membership as described in the OPTN Final Rule.  
 1795

1796 In addition to Termination of membership in the OPTN described above, the Secretary may take  
 1797 appropriate actions, which include, but are not limited to:

- 1798 a. Removal of one or more of the member's designated transplant programs. After designated  
 1799 transplant program status is removed, the Program will no longer be eligible to receive organs for  
 1800 transplantation within the OPTN.
- 1801 b. Termination of the member's reimbursement under Medicare or Medicaid.
- 1802 c. Termination of a transplant hospital's participation in Medicare or Medicaid.
- 1803 d. Request for information from the OPTN.

1805 e. ~~Any other action that the Secretary considers necessary.~~

1806

1807

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

1808 ~~When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of~~  
1809 ~~HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are~~  
1810 ~~enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of~~  
1811 ~~Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other~~  
1812 ~~actions by the Secretary.~~

1813

1814 ~~Section 121.11(b)(2) of the OPTN final rule requires OPTN members that are OPOs and~~  
1815 ~~transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the~~  
1816 ~~Secretary certain information in the form required and in accordance with the schedule~~  
1817 ~~prescribed.~~

1818

1819 ~~Data specified by the Secretary under this authority includes all data requested on forms~~  
1820 ~~approved by the Office of Management and Budget (OMB), including all applications reviewed by~~  
1821 ~~the OPTN. The Secretary may take an action described above for failure of a member to submit~~  
1822 ~~accurate and complete data as required by the Secretary (including on OMB-approved forms).~~  
1823 ~~Failure to submit accurate and complete data may also result in civil or criminal penalties.~~

1824

1825

**B. ~~Effective Date of Actions Recommended by the Board~~**

1826 ~~Actions recommended by the OPTN Board of Directors and taken by the Secretary for non-~~  
1827 ~~compliance with mandatory policies will not become effective until the member has waived its~~  
1828 ~~right to a hearing or the applicable hearing proceedings have been concluded.~~

1829

1830 ~~If the Board finds, based on available evidence, that the member's potential violation poses a~~  
1831 ~~severe and urgent risk to patient health or public safety, the Board may recommend that a~~  
1832 ~~Secretarial action be made effective immediately, before completing any required interview or~~  
1833 ~~hearing.~~

1834

1835

**L.17. ~~Interviews~~**

1836 ~~An interview is not a hearing, is preliminary in nature, and is not conducted according to the procedural~~  
1837 ~~rules followed for hearings. The member will be informed of the reasons for the interview and may~~  
1838 ~~present any information it considers useful and relevant.~~

1839

1840

**A. ~~Members' Right to an Interview~~**

1841 ~~The member will have the right to an interview when:~~

1842

1843 ~~1. A Letter of Reprimand is recommended.~~

1844 ~~2. An adverse action is recommended.~~

1845 ~~3. A membership application or application for designated transplant program status is~~  
1846 ~~rejected.~~

1847 ~~4. A pediatric membership exception request is rejected.~~

1848

1849 ~~However, a member has no right to an interview when a potential violation is being reviewed~~  
1850 ~~through the Imminent Threat Review pathway. After the interview is completed, the MPSC will~~  
1851 ~~promptly provide a summary of the interview to the member.~~

1852

1853

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

1854 ~~The member must submit its written interview request to the Executive Director using one of the~~  
1855 ~~approved methods described in L.4. *Methods for Correspondence and Providing Notice.*~~

1856  
1857 A member may waive its right to an interview in writing. In addition, a member who fails to request  
1858 an interview within the specified time waives any right to an interview. Waiver of the right to an  
1859 interview means that:

- 1860  
1861 1. ~~If the recommended action is a non-adverse action, the action will be issued.~~  
1862 2. ~~If the recommended action is an adverse action, the member is entitled to a~~  
1863 ~~hearing.~~

1864  
1865 **C. ~~Notice of Interview~~**

1866 When the Executive Director receives a request for an interview from the member within the time  
1867 and in the manner required, the interview will be conducted at the next in-person meeting of the  
1868 MPSC.

1870 **D. ~~Notice to Member after an Interview~~**

1871 The MPSC Chair will promptly provide notice to the member of the MPSC's recommendations or  
1872 actions resulting from the interview. The notice will:

- 1873  
1874 1. ~~Briefly advise the member of the nature of the action.~~  
1875 2. ~~Advise the member of the right to a hearing, if applicable, according to the provisions~~  
1876 ~~of these Bylaws.~~  
1877 3. ~~Specify the maximum number of days that the member has to submit a request for a~~  
1878 ~~hearing.~~

1879  
1880 **E. ~~Informal Discussion~~**

1881 The MPSC, or any subcommittee of the MPSC, may request that the member participate in an  
1882 informal discussion to provide additional details regarding a potential violation of or non-  
1883 compliance with OPTN Obligations or to gain additional information regarding member  
1884 performance. The discussion is informal, and may be conducted by teleconference or electronic  
1885 media. This informal discussion is intended to provide the member the opportunity to provide  
1886 clarification of the matter, and could lead to a more timely and effective assessment and  
1887 resolution of the matter.

1888  
1889 **L.18. ~~Hearings~~**

1890 If the MPSC makes a recommendation for an adverse action, or the Board of Directors takes an adverse  
1891 action without recommendation from the MPSC, the member is entitled to a hearing.

1892  
1893 **A. ~~Members' Right to a Hearing~~**

1894 The member has a right to a hearing when an adverse action is:

- 1895  
1896 1. ~~Recommended by the MPSC.~~  
1897 2. ~~Recommended by a subcommittee of the MPSC, if the action is the rejection of an~~  
1898 ~~initial membership application or application for designated transplant program~~  
1899 ~~status.~~  
1900 3. ~~A result of a determination regarding a potential violation undergoing an Imminent~~  
1901 ~~Threat Review.~~

- 1902 4. ~~Taken by the Board of Directors or the Executive Committee not withstanding a~~  
1903 ~~favorable recommendation by the MPSC or standing subcommittee of the MPSC~~  
1904 ~~under circumstances where no right to a hearing existed.~~  
1905 5. ~~Taken by the Board of Directors or the Executive Committee on its own without a~~  
1906 ~~prior recommendation by the MPSC.~~

1907  
1908 The member also has a right to a hearing when the MPSC or a subcommittee of the MPSC  
1909 rejects a pediatric membership exception request.

1910  
1911 If the Board of Directors determines, based on available evidence that a potential violation of  
1912 OPTN Obligations may pose an urgent and severe risk to patient health or public safety, the  
1913 Board may take action even if the member has not had the opportunity for a hearing.

1914  
1915 **B. ~~Requesting or Waiving the Right to a Hearing~~**

1916 The member must submit its written hearing request to the OPTN using one of the approved  
1917 methods described in *Section L.4: Methods for Correspondence and Providing Notice*.

1918  
1919 A member may waive its right to a hearing in writing. In addition, a member who fails to request a  
1920 hearing within the specified time waives any right to a hearing. Waiver of the right to a hearing  
1921 means that the member accepts the adverse action or recommendation and the following  
1922 outcomes will apply:

- 1923  
1924 1. ~~An adverse recommendation by the MPSC or the Executive Committee will~~  
1925 ~~become effective after the final decision of the Board of Directors.~~  
1926 2. ~~An adverse action by the Board of Directors will become effective and considered~~  
1927 ~~the final decision by the Board.~~

1928  
1929 If the member will be represented by an attorney at the hearing, the request for a hearing must  
1930 identify by name the attorney who will represent the member, and include the attorney's business  
1931 address and contact information.

1932  
1933 **C. ~~Notice of Hearing~~**

1934 When the Executive Director receives a request for a hearing within the period and in the required  
1935 manner, the Executive Director will send notification of the time, place, and date of the hearing to  
1936 the member at least 7 days before the hearing.

1937  
1938 The hearing notice will include a concise statement of the adverse recommendation or action that  
1939 is the subject of the hearing, and be delivered to the member using an approved method as  
1940 described in *Section L.4: Methods for Correspondence and Providing Notice*.

1941  
1942 At this time, all documentation about the member that was available to the MPSC, the Executive  
1943 Committee, or the Board at the time of deliberation, will be provided to the member, upon request  
1944 and at the member's expense.

1945  
1946 **D. ~~Appointment of Hearing Panels~~**

1947 Hearing Panels will be appointed according to the review pathway of the potential violation as  
1948 described in:

- 1949  
1950 ■ ~~Section L.12: Imminent Threat Reviews~~  
1951 ■ ~~Section L.13: Expedited Reviews~~

1952 ~~■—Section L.14: Routine Reviews~~

1953  
1954 Alternatively, at the discretion of the President, those Board members who are in attendance at a  
1955 regular or special meeting of the Board may conduct the hearing, provided that the members  
1956 comprise a quorum of the full Board. One of the members will be designated as Chair of the  
1957 Hearing Panel.  
1958

1959 **E.——Hearing Participants**

1960 Hearing participants will be:

- 1961  
1962 1. ~~The Hearing Panel.~~  
1963 2. ~~The member being reviewed for the adverse recommendation or action.~~

1964  
1965 **F.——Service on Hearing Panels**

1966 Hearing Panel members must avoid conflicts of interest according to *Article 2.7: Conflicts of*  
1967 *Interest* of these Bylaws, and will be disqualified from serving on a Hearing Panel if the member  
1968 has been directly involved in compiling evidence or providing expert consultation to the OPTN on  
1969 the matter being reviewed.  
1970

1971 **G.——Appearance and Representation at Hearings**

1972 The member who requested the hearing must appear in person at the hearing. A member who  
1973 fails without good cause to appear at a requested hearing will waive its rights to a hearing. The  
1974 member, the body whose recommendation resulted in the hearing, and the Hearing Panel may be  
1975 represented by an attorney.  
1976

1977 **H.——Presiding Officer**

1978 The Chair of the MPSC or the Chair's designee will be the presiding officer. The presiding officer  
1979 will manage the hearing to ensure that all participants in the hearing have the opportunity to  
1980 present relevant evidence and to conduct any necessary cross-examination required for a full  
1981 disclosure of the facts.

1982 The presiding officer will determine the order of procedure during the hearing and make all rulings  
1983 on interpretation or construction of the OPTN Obligations, relevant documents, OPTN  
1984 requirements on procedure, and on the admissibility of evidence. The presiding officer makes all  
1985 decisions regarding the exclusion of irrelevant, immaterial, redundant, or repetitive evidence.  
1986

1987  
1988 **I.——Rights of Hearing Participants**

1989 During a hearing, the member and the Hearing Panel will have the right, subject to the presiding  
1990 officer's rulings, to:

- 1991  
1992 ■ ~~Call and examine witnesses.~~  
1993 ■ ~~Introduce exhibits.~~  
1994 ■ ~~Cross-examine any witness on any matter relevant to the issue.~~  
1995 ■ ~~Impeach any witness.~~  
1996 ■ ~~Refute any evidence.~~

1997 The Hearing Panel may call and question any member representatives who are present at the  
1998

1999 hearing, even if they do not testify as witnesses for the member or the member chooses not to  
2000 testify on its own behalf.

2001

2002 **J. Procedure and Evidence**

2003 The hearing need not be conducted strictly according to rules of law relating to the examination of  
2004 witnesses or presentation of evidence. The presiding officer may permit admission of any relevant  
2005 information, regardless of whether such evidence would be admitted in a court of law.

2006 Each party will, before or during the hearing, be entitled to submit documents concerning any  
2007 relevant issue, and these documents will become part of the hearing record. The presiding officer  
2008 may, but is not required to, order that oral evidence is taken only on oath or affirmation. The oath  
2009 or affirmation may be administered by any person designated by the presiding officer and who is  
2010 authorized to notarize documents in the state where the hearing is held.

2011

2012 **K. Official Notice**

2013 In reaching a decision, the Hearing Panel may take official notice at any time during the hearing  
2014 of any generally accepted technical, scientific, or medical information relating to the issues under  
2015 consideration.

2016

2017 When the Hearing Panel takes official notice of any information, participants will be informed of  
2018 the information considered and that information will be noted in the hearing record. Any  
2019 participant may request that information be given official notice. Hearing participants may  
2020 challenge any information given official notice, either by providing evidence or expert witness  
2021 testimony.

2022

2023 **L. Burden of Proof**

2024 The body whose adverse recommendation or action resulted in the hearing must present  
2025 evidence to support the adverse recommendation or action, including an explanation of the action  
2026 or recommendation, and the reason it was taken. The member will then have the burden of  
2027 proving and persuading, by clear and convincing evidence, that the adverse recommendation or  
2028 action lacks substantial basis or that such basis or the conclusions drawn are arbitrary,  
2029 unreasonable, or capricious.

2030

2031 **M. Hearing Record**

2032 The Hearing Panel will keep a record of the hearing that includes a hearing transcript and any  
2033 documents reviewed during the hearing. A court reporter will prepare the written transcript. All  
2034 exhibits admitted into evidence at the hearing and all documents submitted to the Hearing Panel  
2035 will be incorporated in the record until the hearing is declared adjourned.

2036

2037 **N. Postponement**

2038 Request for postponement of a hearing will be granted by the MPSC Chair only for good cause  
2039 and only if the request is made as soon as is reasonably possible.

2040

2041 **O. Presence of Hearing Panel**

2042 The Hearing Panel must be present throughout the hearing and deliberations. If a Panel member  
2043 is absent from any part of the proceedings, the Panel member will not be permitted to participate  
2044 in the Panel's deliberations or the decision.

2045

2046

2047 **P. ~~Recesses and Adjournment~~**

2048 The Chair of the Hearing Panel may recess the hearing and reconvene within 60 days or when  
2049 reasonably practical for the convenience of the participants, to obtain material new or additional  
2050 information, or to consult with experts.

2051 When the presentation of oral and written evidence is concluded, the hearing will be closed. The  
2052 Hearing Panel will then, at a time convenient to the Panel, conduct its deliberations away from the  
2053 parties. When the Hearing Panel completes its deliberations, the hearing will be declared finally  
2054 adjourned.  
2055

2056 **Q. ~~Action after Hearing~~**

2057 At the conclusion of their deliberations, the Hearing Panel will do *one* of the following:

- 2058 ~~■ Issue a recommendation for an adverse action.~~
- 2059 ~~■ Issue a lesser action.~~
- 2060 ~~■ Recommend that the MPSC close the review of the potential violation without issuing any~~  
2061 ~~action.~~

2062 A hearing cannot remain open or be re-opened after the hearing panel has taken an action.  
2063

2064 **R. ~~Hearing Panel Report~~**

2065 Following preparation of the hearing record, the Hearing Panel will make a written report of its  
2066 findings and recommendations and will forward it, together with the hearing record, to the Board  
2067 of Directors. At the same time, a copy of the Hearing Panel report will be forwarded to the  
2068 member. The Hearing Panel report will be approved by the presiding officer before it is provided  
2069 to the Board of Directors and member.

2070 All findings and recommendations by the Hearing Panel will be supported by references to the  
2071 hearing record. The presiding officer may extend the time for making the Hearing Panel's written  
2072 report at his or her discretion by giving written notice to the participants.  
2073

2074 **S. ~~Notice after Hearing~~**

2075 The Executive Director will promptly send a copy of the result of the Hearing to the member by an  
2076 approved method as described in *Section L.4: Methods for Correspondence and Providing*  
2077 *Notice*. A copy of the result also will be provided to the Board of Directors.  
2078

2079 **T. ~~Effect of Favorable Result~~**

2080 If the Hearing Panel closes the matter without recommending an adverse action, then no further  
2081 due process is required.  
2082

2083 **U. ~~Effect of Adverse Result~~**

2084 If the result of the hearing continues to be adverse to the member, the adverse recommendation  
2085 will be forwarded to the Board of Directors to make a final decision. The member will have the  
2086 right to request to appear before the Board of Directors before a final action is taken by the  
2087 Board.  
2088  
2089  
2090  
2091  
2092



2093 **L.19. Final Decision of the Board of Directors**

2094 **A. Right to Appear before the Board**

2095 Before the Board of Directors takes final action regarding any recommendation for adverse  
2096 action, the member has the right to appear before the Board and submit a written statement and  
2097 provide oral statement that details any disagreement with the findings of fact, conclusions, or  
2098 procedural issues raised at any step in the review process.

2099  
2100 The member requesting to appear before the Board must submit a written request to the OPTN  
2101 Executive Director using one of the approved methods as described in *Section L.4: Methods for*  
2102 *Correspondence and Providing Notice*. Members must provide to the Executive Director any  
2103 written statements that will be submitted to the Board at least 15 days before the scheduled  
2104 appearance.

2105  
2106 At least 25 days before the member is scheduled to appear before the Board, the Executive  
2107 Director will provide notice to the member of the time, place, and date.

2108  
2109 **B. Board of Directors Action**

2110 After the conclusion of appropriate due process proceedings and after the MPSC forwards a  
2111 recommendation to the Board of Directors, the Board will make its final decision in the matter. At  
2112 this time, the Board will send written notice of its decision to the member and to the Secretary of  
2113 HHS within 3 business days of the final decision. Written notice will be sent by an approved  
2114 method as described in *Section L.4: Methods for Correspondence and Providing Notice*.

2115  
2116 The Board may take longer than 3 days to provide notice of its decision for good reason, as  
2117 determined by the Secretary. A majority vote by a quorum is required for the Board to take any  
2118 action permitted by these Bylaws.

2119  
2120 **1. Terms of Probation**

2121 A Board action placing a member on Probation will be effective only after hearing  
2122 proceedings have been concluded, or the member has waived its right to a hearing, and  
2123 final Board action is taken.

2124  
2125 Probation may also be made effective at any time the Board finds, based on available  
2126 information, that the potential violation of OPTN Obligations may pose an urgent and  
2127 severe risk to patient health or public safety.

2128  
2129 **2. Terms of Member Not in Good Standing**

2130 When the Board takes the adverse action of Member Not in Good Standing, the action  
2131 will be effective only after hearing proceedings have been concluded, or the member has  
2132 waived its right to a hearing, and final Board action is taken.

2133  
2134 Member Not in Good Standing may also be made effective at any time the Board finds,  
2135 based on available information, that the potential violation of OPTN Obligations may pose  
2136 an urgent and severe risk to patient health or public safety.

2137  
2138 **3. Board Recommendations to the Secretary**

2139 A Board of Directors' recommendation that the Secretary take action against a member  
2140 will not become effective until after applicable hearing proceedings have been concluded  
2141 or the member has waived its right to a hearing, unless the Board finds, at any time,  
2142 based on available information, that the potential violation of OPTN Obligations may pose  
2143 an urgent and severe risk to patient health or public safety.

2144

2145                   The action that the Board recommends the Secretary take will not become effective until  
2146                   the Secretary of HHS accepts the Board's recommendation, or takes other action that the  
2147                   Secretary determines is appropriate.

2148  
2149

**C. Notice**

2150                   Notice of a final decision by the Board of Directors that the member has been placed on  
2151                   Probation or declared a Member Not in Good Standing will be circulated to all members as  
2152                   described in *Section L.15: OPTN Determinations and Actions*. OPTN membership will be notified  
2153                   of final decisions by the Board to recommend to the Secretary of HHS Suspension or Termination  
2154                   of membership only after the Secretary approves the recommendation.

2155  
2156

**L.20. Restoration of Unrestricted Membership Privileges**

2157                   If a member that is given Probation or declared a Member Not in Good Standing has presented evidence  
2158                   to the MPSC that it has fully complied with OPTN Obligations, including completion of any actions  
2159                   prescribed as a result of the adverse action, the MPSC may recommend that the Board of Directors  
2160                   restore unrestricted membership privileges.

2161

2162                   If Secretarial Action has been taken against a member as described in *Section L.16: Secretarial Actions*,  
2163                   only the Secretary of HHS can restore its unrestricted membership privileges. The MPSC may  
2164                   recommend that the Secretary of HHS restore unrestricted membership privileges if Secretarial Action  
2165                   has been taken against a member if the member has presented evidence to the MPSC that it has fully  
2166                   complied with OPTN Obligations, including completion of any actions prescribed as a result of the  
2167                   adverse action.

2168

2169                   If a membership was suspended or terminated by the Secretary, the member must complete and submit  
2170                   an application for OPTN membership, as described in *Appendix A: Membership Application and Review*.

2171

2172

**A. Request for Restoration of Membership Privileges**

2173                   A member may request restoration of membership privileges after it demonstrates to the  
2174                   satisfaction of the MPSC that:

2175

- 2176                   1. The member is in compliance with OPTN Obligations.
- 2177                   2. The member has fully implemented any corrective action plan or a plan for quality  
2178                   improvement previously required by the MPSC.
- 2179                   3. The member has demonstrated that the underlying cause for the adverse action has  
2180                   been corrected, or eliminated.
- 2181                   4. The type of violation that resulted in the adverse action is not likely to recur.
- 2182                   5. There are no pending compliance issues that may lead to a potential violation or non-  
2183                   compliance that would require an Imminent Threat Review.

2184

2185                   The burden is on the member at all times to demonstrate that restoration of membership  
2186                   privileges is appropriate.

2187

2188

**B. Minimum Requirements to Request Restoration of Membership Privileges**

2189

2190                   The MPSC will only consider requests for restoration of membership privileges during its regularly  
2191                   scheduled meetings and the member may not request restoration of membership privileges until  
2192                   both occur:

2193

2194

- 2194                   1. At least twelve months have passed since the approval and implementation of the MPSC

2195 ~~prescribed corrective action plan.~~  
2196 2. ~~At least twelve months have passed since the approval of the final action by the Board of~~  
2197 ~~Directors or the Secretary of HHS.~~

2198  
2199 If the MPSC denies the member's request for restoration of membership privileges, the member  
2200 may renew its request 6 months from the date the MPSC denied the request.

2201  
2202 **C. ~~Additional Requirements~~**

2203 At its discretion, the MPSC may require any of the following before it considers a request for  
2204 restoration of privileges:

- 2205  
2206 1. ~~An unannounced OPTN Contractor on-site review.~~  
2207 2. ~~An unannounced peer on-site review.~~  
2208 3. ~~Data and document review.~~  
2209 4. ~~A presentation to the MPSC by the member.~~

2210  
2211 **D. ~~Hearing~~**

2212 If the MPSC denies the member's request for restoration of privileges and the member has met  
2213 the conditions identified above, then the member will be entitled to a hearing at the next regularly  
2214 scheduled MPSC meeting. The member must submit a written hearing request using one of the  
2215 approved methods described in *Section L.4: Methods for Correspondence and Providing Notice*.  
2216 The hearing will be held at the member's expense, as outlined in *Section L.23: Costs and*  
2217 *Expenses*.

2218  
2219 **E. ~~Restoration of Privileges after Violation of Mandatory Policies under~~**  
2220 **~~Section 121.10(c) of the OPTN Final Rule~~**

2221 If the member presents evidence to the MPSC's satisfaction that a member found to be in  
2222 violation of a mandatory policy under Section 121.10(c) of the OPTN Final Rule has fully  
2223 complied with OPTN Obligations, including completing any corrective actions prescribed, the  
2224 MPSC will recommend to the Board of Directors that full membership privileges be restored.

2225  
2226 **L.21. ~~Lesser Adverse Actions~~**

2227 The MPSC may consider a lesser adverse action if a member requests either restoration of unrestricted  
2228 membership or a lesser adverse action. The MPSC may recommend to the Board of Directors the lesser  
2229 adverse actions of Probation or, if the existing action is Probation, a trial restoration period.

2230  
2231 The MPSC may consider the recommendation if the member has demonstrated to the MPSC's  
2232 satisfaction all of the following:

- 2233  
2234 1. ~~The member is now in compliance with OPTN Obligations.~~  
2235 2. ~~The underlying cause for the adverse action is corrected.~~  
2236 3. ~~The corrective action plan or plan for quality improvement has been implemented.~~  
2237 4. ~~The type of violation that resulted in the adverse action is not likely to recur.~~  
2238 5. ~~There are no pending compliance issues that may lead to a potential violation or non-compliance~~  
2239 ~~that would require an Imminent Threat Review.~~

2240  
2241 The burden is on the member at all times to demonstrate that a lesser adverse action is appropriate.  
2242

2243 **A. Requesting a Lesser Adverse Action**

2244 The burden is on the member at all times to demonstrate that a lesser adverse action is  
2245 appropriate. However, the MPSC will only consider requests during its regularly scheduled  
2246 meetings.

2247 The member may not request a lesser adverse action until *both* occur:

- 2248
- 2249 1. At least twelve months have passed since the approval and implementation of
  - 2250 the MPSC prescribed corrective action plan.
  - 2251
  - 2252 2. At least twelve months have passed since the approval of the final action by the
  - 2253 Board of Directors or the Secretary of HHS.

2254

2255 In its discretion, the MPSC may require an unannounced on-site review or peer on-site review  
2256 before considering the request.

2257

2258 **B. Considering Requests for Lesser Adverse Actions**

2259 The consideration of lesser adverse actions does not entitle the member to an interview or  
2260 hearing under these Bylaws. If the MPSC denies the request by the member and the member  
2261 believes that the MPSC acted arbitrarily and capriciously, the member will be entitled to a hearing  
2262 regarding the recommendation for the action of Probation or trial reinstatement period at the next  
2263 regularly scheduled meeting of the MPSC. The hearing will be held at the member's expense.

2264

2265 If the MPSC denies the member's request for a lesser adverse action, the member may renew its  
2266 request 6 months after the MPSC denies the request.

2267

2268 **L.22. Rejected Membership Applications**

2269 If an application for membership, designated transplant program status, or a Change in Key Personnel is  
2270 rejected the applicant has the same due process rights given to a member as outlined in this *Appendix L*.

2271

2272 An applicant for membership or designated transplant program status has the right to appeal to the  
2273 Secretary of HHS decisions of the MPSC, MPSC subcommittees, or the Board of Directors regarding  
2274 these applications according to Section 121.10(c) of the OPTN Final Rule.

2275

2276 If an applicant exercises this right of appeal before exhausting the procedural rights granted in these  
2277 Bylaws, the applicant will provide written notice to the Executive Director by an approved method as  
2278 described in *Section L.4: Methods for Correspondence and Providing Notice*. When the Executive  
2279 Director receives notice, it will notify the Secretary of the appeal within 3 business days, or a longer  
2280 period if necessary, as determined by the Secretary. Pending a decision on the appeal, due process  
2281 procedures will continue unless the Secretary directs otherwise.

2282

2283 If the appeal to the Secretary is denied, the rejection process may continue, according to *Appendix A:*  
2284 *Membership Application and Review* of these Bylaws. Any other decision by the Secretary on the appeal  
2285 will be submitted to the MPSC or Board for action consistent with the Secretary's decision.

2286

2287 **L.23. Costs and Expenses**

2288 **A. Reimbursement of OPTN Contractor Costs and Expenses**

2289 Reasonable costs and expenses of conducting interviews and hearings as described in these  
2290 Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to:

2291

- 2292 1. ~~Travel and lodging expenses of member, volunteers, and OPTN Contractor~~  
2293 ~~representatives.~~  
2294 2. ~~Compensation of OPTN Contractor representatives.~~  
2295 3. ~~Court reporter fees.~~  
2296 4. ~~The costs of preparing copies of the hearing record.~~  
2297 5. ~~The member's costs of preparing for and attending the interview or hearing.~~  
2298 6. ~~The OPTN's costs of obtaining and compiling evidence and exhibits.~~

2299  
2300 OPTN Contractor representatives may include:

- 2301  
2302 ~~▪ OPTN Contractor staff~~  
2303 ~~▪ Outside counsel~~  
2304 ~~▪ Consultants~~  
2305 ~~▪ Volunteers~~  
2306 ~~▪ Expert witnesses~~

2307  
2308 The presiding officer, after consultation with the Executive Director, will decide the nature and  
2309 amount of expenses to be reimbursed. Reasonable costs and expenses may be estimated and  
2310 billed, wholly or partially, to the member in advance or may be billed, wholly or partially, to the  
2311 member as the matter is reviewed. If actual costs and expenses otherwise reimbursable by the  
2312 member for the entire matter before the MPSC are less than \$500.00, or if member is not  
2313 determined to be in violation of OPTN Obligations, no reimbursement will be due from the  
2314 member. In addition, any amounts previously reimbursed or deposited will be returned. If the  
2315 member has multiple matters before the MPSC within any 12-month period, the \$500.00 amount  
2316 will apply to all such matters cumulatively.  
2317

2318 **~~B. Reasonable Costs and Expenses~~**

2319 Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be  
2320 reimbursed by the member, including any of the following:

- 2321  
2322 1. ~~Conducting other than routine on-site reviews.~~  
2323 2. ~~Reviewing and monitoring corrective action plans or plans for quality improvement.~~  
2324 3. ~~Conducting due process proceedings.~~  
2325 4. ~~Monitoring and conducting evaluations of transplant programs with lower than~~  
2326 ~~expected survival rates as described in Section D.12.A: Transplant Program Survival~~  
2327 ~~Rates of these Bylaws, including on-site visits and monitoring plans for quality~~  
2328 ~~improvement.~~

2329  
2330 **~~C. Advanced Deposit for Reimbursable Costs and Expenses~~**

2331 The Executive Director may require that the member make and maintain a deposit with the OPTN  
2332 Contractor in an amount equal to the currently projected costs and expenses of any of the  
2333 following:

- 2334  
2335 1. ~~OPTN Contractor on-site reviews~~  
2336 2. ~~OPTN member Peer on-site reviews~~  
2337 3. ~~The interview~~  
2338 4. ~~The hearing~~

2339  
2340 The failure to make the required deposit within 10 days after the Executive Director requests an

2341 ~~advance deposit will be considered a waiver of the member's interview or hearing rights.~~  
2342 ~~Following such a waiver, the MPSC and the Board of Directors may impose any actions, including~~  
2343 ~~adverse actions.~~

2344  
2345 **~~D. Default in Payment of Reimbursable Cost and Expenses~~**  
2346 ~~Any member who fails to reimburse costs and expenses within 30 days after receiving notice may~~  
2347 ~~be referred to the Secretary for Termination of OPTN membership.~~  
2348  
2349

## 2350 **Appendix L: Reviews and Actions**

2351 By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations  
2352 according to Article 1.1: Member Requirements. This Appendix outlines how the OPTN reviews potential  
2353 noncompliance with OPTN Obligations, the process for other reviews as specified in OPTN Policies and  
2354 Bylaws, and the actions the OPTN may take in response. The Appendix also describes a member's rights  
2355 during OPTN reviews.  
2356

### 2357 **L.1. Methods for Correspondence**

2358 All correspondence between members and the OPTN required by this Appendix L must be sent by a  
2359 method that can be tracked and provides proof of receipt.  
2360

### 2361 **L.2. Representative Terminology Used throughout Appendix L**

#### 2362 **A. References to the OPTN**

2363 Throughout this Appendix L, references to the OPTN include the Board of Directors, OPTN  
2364 committees and subcommittees, OPTN committee members, the OPTN Executive Director, and  
2365 the OPTN Contractor. Bylaws requirements that are specific to any of these groups or individuals  
2366 explicitly name the group or individual.  
2367

#### 2368 **B. References to the MPSC Chair**

2369 References to the MPSC Chair in this Appendix L necessarily include the possibility of an MPSC  
2370 Chair designee. If the MPSC Chair cannot fulfill a duty as required in these Bylaws for any  
2371 reason, such as unavailability or potential conflicts of interest, then these duties will be delegated  
2372 to another individual. Selection of an MPSC Chair designee will proceed in the following order  
2373 until a designee is identified:  
2374

- 2375 1. MPSC Vice Chair
  - 2376 2. MPSC regional representatives, as selected by the OPTN President
- 2377

#### 2378 **L.3. Medical Peer Review**

2379  
2380 The OPTN will conduct all deliberations and take all actions according to applicable medical peer review  
2381 laws. Consistent with applicable laws, all inquiries, deliberations, recommendations, and actions during  
2382 member reviews by the OPTN will be kept confidential. All proceedings and records within the scope of  
2383 these OPTN quality review activities are confidential. Members of any OPTN Committee attending the  
2384 meeting in which a peer review is conducted, serving as a peer reviewer, working for or on behalf of the  
2385 OPTN, or providing information to the OPTN for peer review activities, are entitled to confidentiality.  
2386

2387 The OPTN will keep all materials, information, and correspondences to and from members and directly  
2388 related to the OPTN peer review process confidential to promote quality improvement and full disclosure  
2389 by OPTN members. Materials, information, and correspondences created by or for the peer review body  
2390 are considered “directly related.”

2391  
2392 The OPTN will not disclose any materials provided to the OPTN by the member, except as required by  
2393 law. Materials prepared by members independent of the OPTN medical peer review process may be  
2394 shared by members in their discretion.

#### 2395 **L.4. Conflicts of Interests**

2397 The OPTN’s Conflict of Interest Policy applies to all OPTN inquiries, deliberations, recommendations and  
2398 actions during member reviews.

#### 2399 **L.5. Investigation of Potential Noncompliance with OPTN Obligations**

2401 When the OPTN becomes aware of a member’s potential noncompliance with OPTN Obligations, the  
2402 OPTN will conduct an investigation. This investigation will evaluate whether a potential noncompliance  
2403 exists. The investigation will also consider whether the potential noncompliance suggests a risk to patient  
2404 health or public safety, and the urgency and severity of the risk.

2405  
2406 Members must respond to all investigation requests within the specified period. A member may provide  
2407 any information that it believes is relevant to the investigation. The OPTN will notify the member of the  
2408 date by which the member must submit the requested or additional information.

#### 2409 **L.6. Requests to Mitigate Risks**

2410  
2411 If an OPTN review suggests a potentially urgent or severe risk exists to patient health or public safety, the  
2412 OPTN may ask that the member take appropriate actions to mitigate the urgency and severity of the risk.  
2413 A member’s failure to sufficiently mitigate the risk in the period requested will be considered a separate  
2414 potential noncompliance with OPTN Obligations.

#### 2415 **L.7. Scheduling MPSC and Member Interactions**

2416  
2417 Members currently under MPSC review may be offered specific opportunities, in the form of informal  
2418 discussions, interviews, and hearings, to interact with the MPSC. The MPSC Chair will determine when  
2419 these interactions will be scheduled. Factors that will influence the scheduling of these MPSC and  
2420 member interactions include, but are not limited to, any of the following:

- 2421  
2422 • The urgency and severity of the issue  
2423 • Whether the member has taken appropriate actions that mitigate the urgency and severity of the risk  
2424 • Adequate time for members to demonstrate the results and sustainability of their containment and  
2425 corrective action plans  
2426 • The MPSC’s meeting schedule

2427  
2428 The OPTN will notify the member when the MPSC is offering an informal discussion, interview, or  
2429 hearing. The OPTN’s offer notice will include all of the following:

- 2430  
2431 1. The reasons the MPSC is offering the member an interaction  
2432 2. The date by which the member must accept or decline the MPSC’s offer  
2433 3. A list of any information the OPTN would like the member to submit in advance of the interaction  
2434 4. A summary of what the member should address during the interaction

2435

2436 **L.8. Informal Discussions**

2437 An informal discussion is a direct conversation between a group of MPSC members and a member  
2438 currently under MPSC review. Informal discussions are intended to provide the MPSC and member an  
2439 opportunity to openly discuss the review and seek feedback. Informal discussions are information-  
2440 gathering activities that may lead to a more efficient and effective review than written correspondence and  
2441 document reviews alone.

2442

2443 **A. Member Informal Discussion Requests**

2444 A member currently under review by the MPSC may request an informal discussion at any time.  
2445 Members requesting an informal discussion must submit all of the following:

2446

- 2447 1. The reasons the member is requesting an informal discussion, including the applicable OPTN  
2448 Policy or Bylaw
- 2449 2. A summary of what the member would like to present to the MPSC, or what the member  
2450 would like the MPSC to address during the informal discussion
- 2451 3. Any information the member would like the MPSC to consider in advance of the informal  
2452 discussion

2453

2454 The MPSC Chair will accept or decline a member's request for an informal discussion with the  
2455 MPSC within 14 days of receiving the member's request. The OPTN will notify the member of the  
2456 MPSC Chair's decision.

2457

2458 **B. MPSC Informal Discussion Requests**

2459 The MPSC may offer members currently under review one or more informal discussions at any  
2460 time. The MPSC must offer a transplant program an informal discussion before recommending  
2461 that the program inactivate or withdraw its designated transplant program status due to functional  
2462 inactivity or transplant program performance reviews according to *Appendix D: Membership*  
2463 *Requirements for Transplant Hospitals and Transplant Programs.*

2464

2465 **C. Waiving an Informal Discussion**

2466 Members that decline the MPSC's informal discussion request may submit additional written  
2467 information for the MPSC's review. The MPSC Chair will set a date by which the member must  
2468 provide any additional written information.

2469

2470 Members that decline an MPSC informal discussion request do not waive their right to future  
2471 interactions with the MPSC, including interviews and hearings.

2472

2473 **D. Informal Discussion Format**

2474 Informal discussions will be conducted by teleconference and will include:

2475

- 2476 1. At least 10 minutes for the member to present information
- 2477 2. At least 15 minutes for the member to respond to questions from the MPSC
- 2478 3. At least 4 MPSC members

2479

2480 **E. Informal Discussion Outcome**

2481 Within 21 days, the OPTN will provide the member with a written summary of the informal  
2482 discussion.



2483  
2484 The group that conducted the informal discussion may request that the member submit additional  
2485 information for the MPSC's review after the informal discussion, but will not take an action as  
2486 outlined in Section L.12 OPTN Actions. The group will present its findings to the MPSC, along  
2487 with any additional materials requested, no later than the MPSC's next in-person meeting.  
2488 Following this presentation, the MPSC will continue its review and will notify the member of any  
2489 decisions or actions, including the reasons for the MPSC's decision.  
2490

## 2491 **L.9. Interviews**

2492 An interview is an opportunity for the MPSC and member to discuss an ongoing review. During an  
2493 interview, the member has the opportunity to present information, including any steps the member has  
2494 taken to correct the issue and to address any concerns the MPSC shared with the member prior to the  
2495 interview. The MPSC will ask the member questions and will determine an appropriate action based on  
2496 the interview findings.  
2497

### 2498 **A. Right to an Interview**

2499 The MPSC may offer a member currently under MPSC review one or more interviews at any  
2500 time.  
2501

2502 The MPSC must offer an interview:  
2503

- 2504 1. Before recommending that the Board of Directors places a member on Probation or declares  
2505 a member Not in Good Standing.
- 2506 2. If the MPSC rejects a member's request for release from Probation or Member Not in Good  
2507 Standing.
- 2508 3. If the MPSC recommends that the Board of Directors rejects a membership application as  
2509 outlined in Appendix A: Membership Application and Review.
- 2510 4. If the MPSC rejects a key personnel change application as outlined in Appendix C:  
2511 Membership Requirements for Histocompatibility Laboratories or Appendix D: Membership  
2512 Requirements for Transplant Hospitals and Transplant Programs.  
2513

### 2514 **B. Waiving an Interview**

2515 Members that do not respond to the interview offer by the specified date waive their right to an  
2516 interview.  
2517

2518 Members that waive their right to an interview with the MPSC also:  
2519

- 2520 • Waive their right to a hearing
- 2521 • Waive their right to appear before the Board of Directors

2522 Members that waive their right to an interview must still respond to any MPSC requests for written  
2523 information and may provide additional written information for the MPSC to review. The MPSC  
2524 Chair will set a date by which the member must provide any additional written information.  
2525

### 2526 **C. Interview Format**

2527 Interviews may be conducted by teleconference or at an in-person MPSC meeting, as determined  
2528 by the MPSC Chair. Interviews will include:  
2529

- 2530 1. At least 15 minutes for the member to present information  
2531 2. At least 30 minutes for the member to respond to questions from the MPSC  
2532 3. At least 10 MPSC members

2533  
2534 At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue  
2535 that is the subject of the review. If there are not at least 2 subject matter experts available from  
2536 the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN  
2537 committees. These individuals may participate in all aspects of the interview process, but they  
2538 serve in an advisory role and do not have a vote.

2539  
2540 **D. Possible Interview Outcomes**

2541 Immediately following the interview, the MPSC will determine an appropriate action and notify the  
2542 member of the interview outcome. Within 21 days of the interview, the OPTN will provide the  
2543 member with documentation of the reasons for the MPSC's decision and a written summary of  
2544 the interview.

2545  
2546 If the MPSC considers recommending an adverse action, then the member will be entitled to a  
2547 hearing with the MPSC before the MPSC forwards its recommendation to the Board of Directors.  
2548

2549 **L.10. Hearings**

2550 The MPSC will offer hearings to members when the MPSC is considering recommending that the Board  
2551 of Directors takes certain actions. Hearings are formal procedures during which the OPTN presents  
2552 information explaining the rationale for its recommendation. Hearings are the final opportunity for the  
2553 member to present information for the MPSC to consider before the MPSC makes its recommendation to  
2554 the Board of Directors.

2555  
2556 **A. Right to a Hearing**

2557 The MPSC must offer a member a hearing if the member participated in an interview and  
2558 afterwards, one of the following conditions is met:

- 2559  
2560 • The MPSC considers recommending that the Board of Directors places a member on  
2561 Probation or declares a member Not in Good Standing.  
2562 • The MPSC rejects a member's request for release from Probation or Member Not in Good  
2563 Standing.  
2564 • The MPSC recommends that the Board of Directors rejects a membership application as  
2565 outlined in *Appendix A: Membership Application and Review*.  
2566 • The MPSC rejects a key personnel change application as outlined in *Appendix C:*  
2567 *Membership Requirements for Histocompatibility Laboratories or Appendix D: Membership*  
2568 *Requirements for Transplant Hospitals and Transplant Programs*.

2569  
2570 **B. Waiving a Hearing**

2571 Members that do not respond to the hearing offer by the specified date waive their right to a  
2572 hearing.

2573  
2574 Members that waive their right to a hearing with the MPSC also:  
2575

- 2576 • Accept the MPSC's adverse action recommendation
- 2577 • Waive their right to appear before the Board of Directors

2578 Members that waive their right to a hearing must still respond to any MPSC requests for written  
2579 information and may provide any additional written information for the MPSC to consider. The  
2580 MPSC Chair will set a date by which the member must provide any additional written information.

2581  
2582

### **C. Hearing Format**

2583 Hearings will be conducted during an in-person MPSC meeting. The member and the OPTN have  
2584 the right to be represented by an attorney during a hearing.

2585  
2586  
2587

Hearings include all of the following:

- 2588 1. Equal time for the member and the OPTN to present information
- 2589 2. At least 60 minutes for the member to present information
- 2590 3. At least 60 minutes for the OPTN to present information
- 2591 4. At least 60 minutes for the MPSC to question any member and OPTN representatives  
2592 present at the hearing
- 2593 5. At least 10 MPSC members

2594 At least 2 of the 10 MPSC members must have expertise in the organ system or specific issue  
2595 that is the subject of the review. If there are not at least 2 subject matter experts available from  
2596 the MPSC, the MPSC Chair will select individuals with the appropriate expertise from other OPTN  
2597 committees. These individuals may participate in all aspects of the hearing process, but they  
2598 serve in an advisory role and do not have a vote.

2599  
2600

### **D. Possible Hearing Outcomes**

2601 Following the hearing, the MPSC will determine an appropriate action and notify the member of  
2602 the hearing outcome. Within 21 days of the hearing, the OPTN will provide the member with  
2603 documentation of the reasons for the MPSC's decision and a transcript of the hearing.

2604  
2605  
2606

If the MPSC recommends an adverse action, then the member will be entitled to appear before  
the Board of Directors.

2607

2608 If the MPSC determines the matter represents a potentially urgent and severe risk to patient  
2609 health or public safety, the MPSC may recommend to the OPTN President that the OPTN  
2610 Executive Committee considers the MPSC's recommendation to allow for a more timely  
2611 resolution of the matter. The OPTN will notify the member following the hearing if the MPSC's  
2612 recommendation also includes a recommendation that the OPTN Executive Committee considers  
2613 the recommendation.

2614  
2615

## **L.11. Appearances before the Board of Directors**

2616 Members and the MPSC Chair may appear before the Board of Directors prior to the Board of Directors  
2617 taking a final action on an MPSC recommendation. Appearances before the Board of Directors are formal  
2618 procedures that provide an opportunity for the MPSC Chair to explain the MPSC's recommendation and  
2619 for a member to present specific reasons as to why the Board of Directors should not support the MPSC's  
2620 recommendation.

2621  
2622

If the OPTN President determines that an urgent and severe risk to patient health or public safety exists

2623 and that allowing the OPTN Executive Committee to consider the recommendation will allow for a more  
2624 timely resolution of the matter, the OPTN President may permit the appearance to take place before the  
2625 OPTN Executive Committee instead of the Board of Directors. In these instances, all requirements,  
2626 considerations, and actions described in the sections that follow that pertain to appearances before the  
2627 Board of Directors will apply to appearances before the OPTN Executive Committee.  
2628

2629 **A. Right to a Appear before the Board of Directors**

2630 A member has the right to appear before the Board of Directors if the member has participated in  
2631 a hearing and afterwards one of the following conditions is met:

- 2632
- 2633 1. The MPSC recommended that the Board of Directors places the member on Probation or  
2634 declares a member Not in Good Standing.
  - 2635 2. The MPSC rejected a member's request to be released from Probation or Member Not in  
2636 Good Standing.
  - 2637 3. The MPSC recommended that the Board of Directors rejects a membership application as  
2638 outlined in Appendix A: Membership Application and Review.
  - 2639 4. The MPSC rejected a key personnel change application as outlined in Appendix C:  
2640 Membership Requirements for Histocompatibility Laboratories or Appendix D: Membership  
2641 Requirements for Transplant Hospitals and Transplant Programs.

2642 **B. Accepting or Waiving a Board of Directors Appearance**

2643 Members must accept or waive their right to appear before the Board of Directors within the  
2644 period specified. Members that fail to respond to the offer of a Board of Directors appearance  
2645 within the specified period waive their right to appear.

2646

2647 At the same time the member accepts its right to appear before the Board of Directors, the  
2648 member must also provide its specific disagreements with the OPTN's findings of fact,  
2649 conclusions, or procedural issues that the member plans to contest before the Board of Directors.

2650

2651 Members that waive their right to appear accept the MPSC's adverse action recommendation.  
2652 Members that waive their right to appear may provide additional written information for the Board  
2653 of Directors to consider. The OPTN President will set a date by which the member must provide  
2654 any additional written information.

2655

2656 **C. Scheduling a Board of Directors Appearance**

2657 The OPTN President will determine when a member's appearance before the Board of Directors  
2658 will occur. Factors that will influence the scheduling of a member's Board of Directors appearance  
2659 include, but are not limited to, any of the following:

- 2660
- 2661 • The urgency and severity of the issue
  - 2662 • Whether the member has taken appropriate actions that mitigate the urgency and severity of  
2663 the risk
  - 2664 • The Board of Directors' meeting schedule

2665 The OPTN will notify the member when the member is entitled to an appearance before the  
2666 Board of Directors. The OPTN's offer notice will include all of the following:

- 2667
- 2668 1. The reason the member is entitled to an appearance before the Board of Directors
  - 2669 2. The reasons for the MPSC's recommendation to the Board of Directors
  - 2670 3. The date by which the member must accept or decline the offer
  - 2671 4. A summary of what the member should address during the interaction

2672  
2673

**D. Board of Directors Appearance Format**

2674 A member's appearance before the Board of Directors may be by teleconference or at an in-  
2675 person Board of Directors meeting, as determined by the OPTN President.

2676  
2677 The member and the OPTN have the right to be represented by an attorney during a Board of  
2678 Directors appearance.

2679  
2680 Board of Directors appearances include all of the following:

- 2681  
2682 1. Equal time for the member and the MPSC Chair to present  
2683 2. At least 10 minutes for the member to present information to the Board of Directors  
2684 3. At least 10 minutes for the MPSC Chair to present information to the Board of Directors  
2685 4. At least 15 minutes for the Board of Directors to ask questions of the member and MPSC  
2686 Chair

2687  
2688 A majority vote of the Directors present at any meeting at which a quorum is present is required  
2689 to approve an adverse action.

2690  
2691

**E. Burden of Proof**

2692 Appearances before the Board of Directors are to address specific disagreements with the  
2693 findings of fact, conclusions, or procedural issues raised at any step in the review process. The  
2694 member will have the burden of proving that the MPSC's recommendation lacks substantial basis  
2695 or that such basis or the conclusions drawn are arbitrary, unreasonable, or capricious.

2696  
2697

**F. Possible Board of Directors Appearance Outcomes**

2698 At the conclusion of the Board of Directors appearance, the Board of Directors will approve the  
2699 MPSC's recommendation or issue a lesser action and will notify the member of the outcome.  
2700 Within 21 days of the Board of Directors appearance, the OPTN will provide the member with a  
2701 written summary of the Board of Directors appearance.

2702  
2703 If the Board of Directors approves an adverse action, the OPTN will issue a public notice and the  
2704 member must provide additional notice within 30 days of receiving the Board of Directors  
2705 appearance summary as required according to Section L.12.D: OPTN Adverse Actions.

2706  
2707

**L.12. OPTN Actions**

2708 The OPTN may impose actions based on a member's failure to comply with OPTN Obligations. The  
2709 OPTN may impose a separate action for each noncompliance or may choose to impose a single action  
2710 for all related instances of noncompliance. The OPTN may also require a member to perform specific  
2711 activities to address a noncompliance. The OPTN will document all actions in the member's compliance  
2712 history.

2713  
2714

**A. Deferred Disposition**

2715 Deferred Disposition is a period to allow the member additional time to demonstrate improvement  
2716 and its ability and willingness to meet OPTN Obligations. Only the MPSC may offer a member a  
2717 Deferred Disposition period. The MPSC may offer a Deferred Disposition period at any time  
2718 before a hearing and may offer a member more than one Deferred Disposition period during a

2719 review.

2720

2721 During this period, the member must demonstrate compliance with OPTN Obligations, including  
2722 implementation of and adherence to the member's corrective action plan or plan for quality  
2723 improvement. The MPSC will specify the length of the Deferred Disposition period, and may end  
2724 the Deferred Disposition period at any time if the MPSC determines, at its discretion, the member  
2725 is not demonstrating sufficient improvement or is not adhering to the member's corrective action  
2726 plan or plan for quality improvement. After the Deferred Disposition period, the MPSC will  
2727 evaluate whether the member has demonstrated improvement and implemented sustainable  
2728 corrective actions and will determine an appropriate action

2729

2730 The member is not entitled to an informal discussion, interview, hearing or Board of Directors  
2731 appearance to challenge the MPSC's decision to not offer or to end a Deferred Disposition  
2732 period.

2733

2734

## **B. Types of Actions**

2735 The OPTN may offer Deferred Disposition or take any of the following actions:

2736

2737

- Close with No Action
- Issue a Notice of Noncompliance
- Issue a Letter of Warning
- Place a member on Probation
- Declare a member Not in Good Standing

2738

2739

2740

2741

2742

2743

2744

2745

2746

2747

2748

2749

These actions represent a range, from Close with No Action to Member Not in Good Standing. Close with No Action, Issuing a Notice of Noncompliance, and Issuing a Letter of Warning are non-adverse actions. Non-adverse actions do not require approval by the Board of Directors and are not made public. Probation and Member Not in Good Standing are adverse actions. Adverse actions are further described in *Section L.12.D: OPTN Adverse Actions*.

## **C. Determining Appropriate Action**

2750 Factors considered when determining the appropriate action include, but are not limited to, the  
2751 extent to which:

2752

2753

2754

2755

2756

2757

2758

2759

2760

2761

2762

2763

2764

2765

- The member has demonstrated an awareness of and accountability for the noncompliance, including:
  - whether the member self-reported the noncompliance
  - whether the member took corrective action when learning of the noncompliance
- The noncompliance poses an urgent and severe risk to patient health or public safety
- The noncompliance poses or fails to avoid a substantial risk to the integrity of or trust in the OPTN
- Patient medical records or other documentation provide sufficient detail to determine the presence of mitigating factors at the time the noncompliance occurred
- The noncompliance demonstrates lack of stewardship of donated organs
- The noncompliance is likely to recur
- The member has demonstrated previous and ongoing compliance with OPTN Obligations

2766  
2767  
2768  
2769  
2770  
2771  
2772  
2773  
2774  
2775  
2776  
2777  
2778  
2779  
2780  
2781

**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**

**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 as follows:

<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>

2801  
2802  
2803  
2804

These notices must communicate that the Board of Directors has placed the member on Probation and must also refer to the public notice about this action distributed by the OPTN.

2805  
2806  
2807  
2808  
2809  
2810  
2811  
2812  
2813  
2814  
2815  
2816  
2817  
2818  
2819  
2820  
2821  
2822  
2823  
2824  
2825  
2826  
2827  
2828  
2829  
2830

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

**c. Probation Monitoring Requirements**

The MPSC will monitor members throughout the Probation period.

**2. Member Not in Good Standing**

**a. Loss of OPTN Privileges**

Members Not in Good Standing are prohibited from voting in OPTN matters and any personnel associated with the member are prohibited from serving on OPTN Committees and the Board of Directors. However, members designated Members Not in Good Standing must continue to comply with their OPTN member responsibilities.

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

When the Board of Directors declares a member Not in Good Standing, 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 Member Not in Good Standing designation as determined by the Board of Directors.

After the OPTN notifies the member that it has been declared Not in Good Standing, the member must provide notice within 30 days as follows:

<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>

2831  
2832  
2833  
2834  
2835  
2836  
2837  
2838  
2839  
2840  
2841  
2842  
2843

These notices must communicate that the Board of Directors has declared the member Not in Good Standing and must also refer to the public notice about this action distributed by the OPTN.

The member must provide the OPTN Contractor a list of each patient and organization to whom it sent notice, along with an example of the notice it sent, by the date specified by the OPTN Contractor.

**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:



- 2844 • One or more unannounced on-site reviews.
- 2845 • One or more presentations by the member before the MPSC to provide an
- 2846 update on the member's corrective action plan and ongoing compliance with
- 2847 OPTN Obligations.

2848 **3. Release from Probation or Member Not in Good Standing**

2849 **a. Request for Release**

2850 A member on Probation or a Member Not in Good Standing must submit a  
2851 written request to the OPTN requesting release from the adverse action. The  
2852 MPSC will consider the member's request and will forward any recommendations  
2853 to release a member from an adverse action to the Executive Committee for  
2854 approval.

2855  
2856 A member on Probation or a Member Not in Good Standing may request release  
2857 from the adverse action when at least nine months have passed since *both* of the  
2858 following occurred:

- 2859
- 2860 1. The MPSC approved the member's corrective action plan
- 2861 2. The Board of Directors approved the adverse action
- 2862

2863 The MPSC may consider member requests to be released from an adverse  
2864 action at any MPSC meeting where a quorum is present.

2865

2866 **b. Burden of Proof for Release**

2867 When determining whether to release a member from Probation or a Member  
2868 Not in Good Standing, the MPSC will consider whether the member can  
2869 demonstrate *all* of the following:

- 2870
- 2871 1. It has implemented and adhered to its corrective action plan
- 2872 2. Its corrective action plan is effective and sustainable
- 2873 3. Its ongoing compliance with OPTN Obligations

2874 The burden is on the member at all times to demonstrate that release from  
2875 Probation or Member Not in Good Standing is appropriate.

2876

2877 **c. Possible MPSC Review Outcomes**

2878 If the MPSC approves the member's request for release from Probation or  
2879 Member Not in Good Standing, the MPSC will forward its recommendation to the  
2880 OPTN Executive Committee. The OPTN President will determine the time and  
2881 format for the OPTN Executive Committee to consider the MPSC's request.

2882  
2883 If the MPSC rejects the member's request for release from Probation or Member  
2884 Not in Good Standing, the MPSC must offer the member an interview.

2885

2886 **d. Possible OPTN Executive Committee Review Outcomes**

2887 The OPTN President will determine the time and format, either in person or by  
2888 teleconference, of the review. The OPTN Executive Committee will act on the  
2889 MPSC's recommendation within 45 days of receiving it.

2890  
2891 If the OPTN Executive Committee approves the MPSC's recommendation and  
2892 releases the member from Probation or Member Not in Good Standing, the

2893 OPTN will provide notice to the public. This may include, but is not limited to,  
2894 communication using the OPTN website. The MPSC may still require ongoing  
2895 monitoring of the member even after the OPTN Executive Committee has  
2896 released the member from Probation or Member Not in Good Standing.

2897  
2898 If the OPTN Executive Committee rejects the MPSC's recommendation to  
2899 release the member from Probation or Member Not in Good Standing, the OPTN  
2900 will provide the member with a written summary of the reasons for declining the  
2901 MPSC's recommendation. The member may submit another request to be  
2902 released from Probation or Member Not in Good Standing to the MPSC only after  
2903 it has addressed all of the reasons that the OPTN Executive Committee declined  
2904 the MPSC's recommendation.  
2905  
2906

#### **4. Downgrading Member Not in Good Standing**

2907 At its discretion, the MPSC may recommend that the Board of Directors downgrades  
2908 a Member Not in Good Standing designation to Probation. The OPTN President will  
2909 determine the time and format for the OPTN Board of Directors to consider the  
2910 MPSC's request.

2911 The burden is on the member at all times to demonstrate that the lesser adverse  
2912 action is appropriate. The member is not entitled to an informal discussion, an  
2913 interview, a hearing or a Board of Directors appearance if the MPSC or the Board of  
2914 Directors does not support downgrading the Member Not in Good Standing to  
2915 Probation.

2916  
2917 If the Board of Directors downgrades a Member Not in Good Standing to Probation,  
2918 the OPTN will provide notice to the public. This may include, but is not limited to,  
2919 communication using the OPTN website. After the OPTN notifies the member that it  
2920 has been downgraded to Probation, the member:

- 2921  
2922  
2923 1. Will regain the ability to vote in OPTN matters  
2924 2. Will regain the ability for any personnel associated with the member to serve on  
2925 OPTN committees and the OPTN Board of Directors  
2926 3. Must comply with all Probation notification requirements  
2927 4. May request release from Probation when at least 3 months have passed since  
2928 the Board of Directors downgraded the member to Probation

### **L.13. Secretary of HHS Notice and Actions**

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

2931 The medical peer review privilege will not be extended to withhold any document from the  
2932 Secretary of HHS, or the Secretary's designee. The OPTN Contractor is required to provide the  
2933 Secretary with any information acquired or produced under the OPTN Contract, including  
2934 information that would otherwise be protected by the medical peer review privilege. As specified  
2935 in the OPTN Final Rule, the OPTN Contractor will provide any data or documentation to the  
2936 Secretary that the Secretary requests, in the format requested by the Secretary.

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

2937  
2938 The Project Officer for the OPTN Contract and the Director of the Division of Transplantation  
2941 within the Health Resources and Services Administration (HRSA) of HHS, serve as *ex-officio*,  
2942 non-voting members of the OPTN Executive Committee and Board of Directors. As non-voting  
2943 members of the Executive Committee and Board of Directors, they, or their designees, are

2944 granted full access to all deliberations, determinations and actions. Representatives of HRSA are  
2945 also *ex-officio*, non-voting members of the Membership and Professional Standards Committee  
2946 (MPSC) and granted full access to all MPSC deliberations, determinations, and actions as well.  
2947 Other designees of the Secretary may also attend OPTN meetings.

2948  
2949 **C. Special Secretarial Reviews**

2950 At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when  
2951 the Secretary has reason to believe that the member may not be in compliance with the OPTN  
2952 Final Rule or may be acting in a way that poses a risk to patient health or public safety. A Special  
2953 Review is a review of the member in the manner and within the period specified by the Secretary.  
2954 This may include, but is not limited to, requests for root cause analysis, corrective action, and due  
2955 process proceedings completed in the period and as specified by the Secretary. Members must  
2956 fully comply with all OPTN Contractor requests as part of a Special Review.

2957  
2958 **D. OPTN Recommendations and Requests to the Secretary**

2959 The OPTN Board of Directors will advise the Secretary of the results of any ongoing or periodic  
2960 reviews and evaluations, or Secretarial-directed reviews, of member OPOs and transplant  
2961 hospitals which, in the opinion of the Board of Directors, indicate noncompliance with OPTN  
2962 Obligations or indicate a risk to the health of patients or to the public safety, and will provide any  
2963 recommendations for appropriate action by the Secretary. Appropriate actions include, but are not  
2964 limited to, those described in the OPTN Final Rule, as described in Section L.13.E Secretarial  
2965 Actions that follows.

2966  
2967 At any time, the Board of Directors may make recommendations to the Secretary for specific  
2968 actions, on its own or after receiving a recommendation from the MPSC.

2969  
2970 A member's failure to come into compliance with OPTN Obligations while designated as a  
2971 Member Not in Good Standing may result in the Board of Directors recommending that the  
2972 Secretary take action against the member.

2973  
2974 If the Board of Directors finds, based on available evidence, that the member's potential violation  
2975 poses a severe and urgent risk to patient health or public safety, the Board of Directors may  
2976 recommend that a Secretarial action be made effective immediately, before completing any  
2977 required interview or hearing.

2978  
2979 **E. Secretarial Actions**

2980 The Secretary may impose sanctions or take other appropriate action at any time when a  
2981 member poses a risk to the health of patients or to the public safety.

2982  
2983 Consistent with the OPTN Final Rule, the Secretary can take action if an OPTN member:

- 2984  
2985 1. Violates the National Organ Transplant Act (NOTA).  
2986 2. Violates the OPTN Final Rule, 42 CFR Part 121.  
2987 3. Violates OPTN policies that have been approved by the Secretary as mandatory. For more  
2988 information on mandatory policies, see Section L.13.F: OPTN Policies Approved by the  
2989 Secretary as Mandatory.  
2990 4. Engages in behavior that poses a risk to patient health or public safety.

2991  
2992 Termination of membership requires Secretarial approval. Membership can only be terminated if  
2993 the OPTN member no longer meets the requirements for membership as described in the OPTN  
2994 Final Rule.

2995

2996 In addition to Termination of membership in the OPTN described above, the Secretary may take  
2997 appropriate actions, which include, but are not limited to:

- 2998  
2999  
3000 1. Removal of one or more of the member's designated transplant programs. After designated  
3001 transplant program status is removed, the program will no longer be eligible to receive organs  
3002 for transplantation within the OPTN.  
3003 2. Termination of the member's reimbursement under Medicare or Medicaid.  
3004 3. Termination of a transplant hospital's participation in Medicare or Medicaid.  
3005 4. Request for information from the OPTN.  
3006 5. Any other action that the Secretary considers necessary.

3007 If Secretarial action has been taken against a member, only the Secretary of HHS can restore its  
3008 unrestricted membership privileges. If Secretarial action has been taken against a member and  
3009 the member has presented evidence to the MPSC that it has fully complied with OPTN  
3010 Obligations, including completion of any actions prescribed as a result of the adverse action, the  
3011 MPSC may recommend that the Secretary of HHS restore unrestricted membership privileges. If  
3012 a membership was suspended or terminated by the Secretary, the member must complete and  
3013 submit an application for OPTN membership.

3014  
3015 Actions recommended by the OPTN Board of Directors and taken by the Secretary for  
3016 noncompliance with mandatory policies will not become effective until the member has waived its  
3017 right to a hearing or the applicable hearing proceedings have been concluded.

## 3018 3019 **F. OPTN Policies Approved by the Secretary as Mandatory**

3020 When and if the Secretary approves any OPTN policies as mandatory, the U.S. Department of  
3021 HHS will publish lists of OPTN Policies in the Federal Register, indicating which policies are  
3022 enforceable under Sec. 121.10 of the OPTN Final Rule or are subject to potential sanctions of  
3023 Section 1138 of the Social Security Act. Violations of such policies can result in sanctions or other  
3024 actions by the Secretary.

3025  
3026 Section 121.11(b)(2) of the OPTN final rule requires OPTN members that are OPOs and  
3027 transplant hospitals to submit to the OPTN, to the Scientific Registry, as appropriate, and to the  
3028 Secretary certain information in the form required and in accordance with the schedule  
3029 prescribed.

3030  
3031 Data specified by the Secretary under this authority includes all data requested on forms  
3032 approved by the Office of Management and Budget (OMB), including all applications reviewed by  
3033 the OPTN. The Secretary may take an action described above for failure of a member to submit  
3034 accurate and complete data as required by the Secretary (including on OMB-approved forms).  
3035 Failure to submit accurate and complete data may also result in civil or criminal penalties.

## 3036 3037 3038 **L.14. Costs and Expenses**

### 3039 **A. Reimbursement of OPTN Contractor Costs and Expenses**

3040 Reasonable costs and expenses of conducting interviews and hearings as described in these  
3041 Bylaws will be paid by the member. Costs and expenses may include, but are not be limited to *all*  
3042 of the following:

- 3043 1. Travel and lodging expenses of member, volunteers, and OPTN Contractor representatives.  
3044 2. Compensation of OPTN Contractor representatives.  
3045 3. Court reporter fees.  
3046 4. The costs of preparing copies of the hearing record.

- 3047 5. The member's costs of preparing for and attending the interview or hearing.  
3048 6. The OPTN's costs of obtaining and compiling evidence and exhibits.

3049 OPTN Contractor representatives may include:

- 3050 • OPTN Contractor staff  
3051 • Outside counsel  
3052 • Consultants  
3053 • Volunteers  
3054 • Expert witnesses

3055 The OPTN will decide the nature and amount of expenses to be reimbursed. Reasonable costs  
3056 and expenses may be estimated and billed, wholly or partially, to the member in advance or may  
3057 be billed, wholly or partially, to the member as the matter is reviewed. If actual costs and  
3058 expenses otherwise reimbursable by the member for the entire matter before the MPSC are less  
3059 than \$500.00, or if member is not determined to be in violation of OPTN Obligations, no  
3060 reimbursement will be due from the member. In addition, any amounts previously reimbursed or  
3061 deposited will be returned. If the member has multiple matters before the MPSC within any 12-  
3062 month period, the \$500.00 amount will apply to all such matters cumulatively.  
3063

3064 **B. Reasonable Costs and Expenses**

3065 Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be  
3066 reimbursed by the member, including any of the following:  
3067

- 3068 1. Conducting other than routine on-site reviews.  
3069 2. Reviewing and monitoring corrective action plans or plans for quality improvement.  
3070 3. Conducting due process proceedings.  
3071 4. Monitoring and conducting evaluations of transplant programs with lower than expected  
3072 survival rates as described in Section D.12: Transplant Program Performance of these  
3073 Bylaws, including on-site visits and monitoring plans for quality improvement.  
3074

3075 **C. Advanced Deposit for Reimbursable Costs and Expenses**

3076 The Executive Director may require that the member make and maintain a deposit with the OPTN  
3077 Contractor in an amount equal to the currently projected costs and expenses of any of the  
3078 following:  
3079

- 3080 1. OPTN Contractor on-site reviews  
3081 2. OPTN member Peer on-site reviews  
3082 3. The interview  
3083 4. The hearing  
3084

3085 The failure to make the required deposit within 10 days after the Executive Director requests an  
3086 advance deposit will be considered a waiver of the member's interview or hearing rights.  
3087 Following such a waiver, the MPSC and the Board of Directors may impose any actions, including  
3088 adverse actions.  
3089

3090 **D. Default in Payment of Reimbursable Cost and Expenses**

3091 Any member who fails to reimburse costs and expenses within 30 days after receiving notice may  
3092 be referred to the Secretary for termination of OPTN membership.

3093 **Appendix M: Definitions**

3094 **Informal Discussion**

3095 ~~An informal discussion is not an adverse action or an element of due process. An informal discussion is~~  
3096 ~~conducted according to the principles of confidential medical peer review, as described in Appendix L of~~  
3097 ~~these Bylaws. An informal discussion may be with the MPSC, a subcommittee, or a work group, as~~  
3098 ~~determined by the MPSC. An informal discussion may be held with a member regarding performance~~  
3099 ~~reviews, or when a transplant program is seeking approval for a transplant surgeon through the~~  
3100 ~~predominantly pediatric pathway.~~

3101  
3102 *[Subsequent headings affected by the re-numbering of these bylaws will also be changed as necessary.]*  
3103

#

## 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.

SAMPLE



## 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. The 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 you 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

<b><i>Current Bylaws Section</i></b>			<b><i>Modifications for Public Comment</i></b>
	<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

<b><i>Current Bylaws Section</i></b>			<b><i>Modifications for Public Comment</i></b>
	<b>A.</b>	<b>Members' Right to an Interview</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.
	<b>B.</b>	<b>Requesting or Waiving the Right to an Interview</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.
	<b>C.</b>	<b>Notice of Interview</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.
	<b>D.</b>	<b>Notice to Member after an Interview</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.
	<b>E.</b>	<b>Informal Discussion</b>	<b>Now L.8 Informal Discussions.</b> Description now provides additional information on scheduling and potential outcomes
<b>L.18.</b>		<b>Hearings</b>	<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>A.</b>	<b>Members' Right to a Hearing</b>	<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>B.</b>	<b>Requesting or Waiving the Right to a Hearing</b>	<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>C.</b>	<b>Notice of Hearing</b>	<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>D.</b>	<b>Appointment of Hearing Panels</b>	<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>E.</b>	<b>Hearing Participants</b>	<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>F.</b>	<b>Service on Hearing Panels</b>	<b>Now covered by L.4 Conflicts of Interest</b>
	<b>G.</b>	<b>Appearance and Representation at Hearings</b>	<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
	<b>H.</b>	<b>Presiding Officer</b>	Deleted section
	<b>I.</b>	<b>Rights of Hearing Participants</b>	Deleted section
	<b>J.</b>	<b>Procedure and Evidence</b>	Deleted section
	<b>K.</b>	<b>Official Notice</b>	Deleted section
	<b>L.</b>	<b>Burden of Proof</b>	Deleted section
	<b>M.</b>	<b>Hearing Record</b>	<b>Now in L.10 Hearings</b>
	<b>N.</b>	<b>Postponement</b>	Deleted section
	<b>O.</b>	<b>Presence of Hearing Panel</b>	Deleted section
	<b>P.</b>	<b>Recesses and Adjournment</b>	Deleted section
	<b>Q.</b>	<b>Action after Hearing</b>	<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”

<b>Appendix L Section</b>	<b>Language</b>
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.*