

OPTN Board of Directors Meeting

January 16, 2025

Zoom

Agenda

- ✔ Welcome and Announcements
- ✔ OPTN Budget Update
- ✔ Board Overview of MPSC Recommendation of Adverse Actions
- ✔ Transitional Nominating Committee Update
- ✔ Adjourn

Welcome and Announcements

Richard Formica

OPTN Budget Update

Richard Formica

HRSA Representative

Board Overview of MPSC Recommendation of Adverse Actions

Betsy Warnick, UNOS

Krissy Laurie, UNOS

MPSC Charge

The OPTN Membership and Professional Standards Committee (MPSC) is an operating committee of the OPTN.

- The MPSC maintains membership criteria and monitors OPTN member compliance with PTN membership criteria, bylaws and policies, and the OPTN Final Rule.
- The MPSC takes action or **makes recommendations for further action to the OPTN Board of Directors as needed.**

Through peer review, the MPSC:

- Reviews events identified as presenting a risk to patient safety, public health or the integrity of the OPTN
- Evaluates and supports OPTN members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems
- Reviews applications for membership in the OPTN, approval of designated transplant programs, and changes in OPTN member key personnel

OPTN Management and Membership Policies, Appendix L

- Provides OPTN's ability to address urgent and severe risks to patient health and public safety
 - MPSC Chair can ask members to take action to mitigate urgent and severe risks
- Provides the framework for MPSC review of potential policy and bylaw violations
- Describes Member rights when under review
- Defines actions MPSC can take or recommend

OPTN Actions (Appendix L.13)

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

Adverse Actions (Appendix L.13.D)

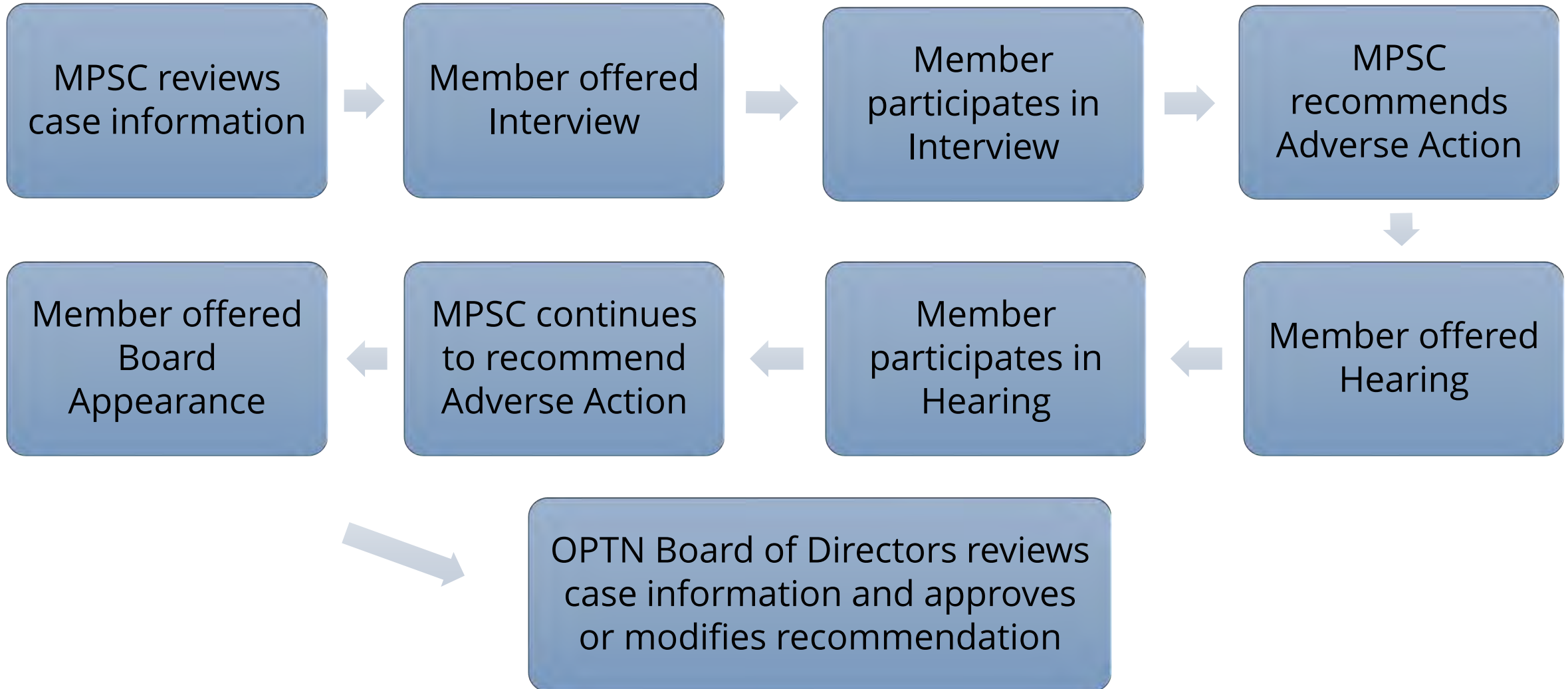
- Include Probation and Member Not in Good Standing (MNGS)
- A member's ongoing failure to comply with OPTN Obligations or a member's failure to promptly address a potentially urgent and severe risk to patient health or public safety may result in the MPSC recommending that the OPTN Board of Directors takes an adverse action against the member
- Must be approved by the Board of Directors and requires public notice



Determining Actions

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

Member Rights and Review Process



Board Appearance (Appendix L.12)

- Appearances before the Board of Directors 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 should not support the MPSC's recommendation
 - Appearances before the Board are to address specific disagreements with the findings of fact, conclusions, or procedural issues raised at any step in the review process
- Members that waive their right to appear accept the MPSC's adverse action recommendation
- Board appearances include equal time for the member and the MPSC Chair to present
 - At least 10 minutes for the member
 - At least 10 minutes for the MPSC Chair
 - At least 15 minutes for the Board to ask questions
- At the conclusion, the Board will approve the MPSC's recommendation or issue a lesser action and will notify the member of the outcome

What MNGS Means for a Transplant Hospital

Member Not in Good Standing	<ul style="list-style-type: none"> • Must be approved by a majority of quorum of the Board of Directors
Notifications	<ul style="list-style-type: none"> • All transplant hospital patients in all programs, including any new transplant hospital patients, during the entire effective period of the adverse action. • Formal Notice to the Secretary of HHS • Formal Notice to State representative with oversight over healthcare institutions • Notice posted on the OPTN website
Duration	<ul style="list-style-type: none"> • Effective upon vote of the Board • MPSC will consider request to restore membership at least 9 months after approval and implementation of the member's corrective action plan or after final action of the Board (whichever is longer) • MPSC can recommend Probation as intermediate step to restoration • All restoration decisions are made by the Board
Additional	<ul style="list-style-type: none"> • Continue to receive organ offers and function as a transplant program • Loss of voting in OPTN affairs • Personnel cannot serve on Board or Committees • Member's burden to demonstrate compliance prior to restoration of membership

What Probation Means for a Transplant Hospital

Probation	<ul style="list-style-type: none"> • Must be approved by a majority of quorum of the Board of Directors
Notifications	<ul style="list-style-type: none"> • All patients of the designated transplant program/living donor component receiving the adverse action including any new patients during the entire effective period of the adverse action • Notice posted on the OPTN website
Duration	<ul style="list-style-type: none"> • Effective upon vote of the Board • MPSC will consider request to restore membership at least 9 months after approval and implementation of the member’s corrective action plan or after final action of the Board (whichever is longer) • All restoration decisions are made by the Board
Additional	<ul style="list-style-type: none"> • Continue to receive organ offers and function as a transplant program • Member’s burden to demonstrate compliance prior to restoration of membership

After a Member Not in Good Standing Vote

- The OPTN will provide notice to the public using the OPTN website
- The member must provide notice to all transplant patients within 30 days
- The MPSC will monitor the member throughout the Member Not in Good Standing period, which will include the following:
 - One or more unannounced on-site reviews
 - One or more presentations by the member before the MPSC to provide an update on their corrective action plan and ongoing compliance with OPTN Obligations

Release From Member Not in Good Standing

- At least nine (9) months after the Board's vote and the MPSC's approval of the member's corrective action plan, the member must submit a written request to the OPTN requesting release from the adverse action
- The MPSC will consider the request and will forward any recommendations to the OPTN Executive Committee for approval
- At its discretion, the MPSC may recommend that the Board downgrade the Member Not in Good Standing designation to Probation

Questions

OPTN Modernization Update

HRSA Representative

Contact Us

AIR OPTN Board Support Team

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