

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**  
**Meeting Minutes**  
**July 11-13, 2017**  
**Chicago, Illinois**

**Jeffrey Orlowski, MS, CPTC, Chair**  
**John Friedewald, M.D., Vice Chair**

## **Introduction**

The Membership and Professional Standards Committee met in Chicago, Illinois, on July 11-13, 2017, to discuss the following agenda items:

1. Overview of MPSC Projects
2. Living Donor Follow-up Reporting
3. Member Related Actions
4. Living Donor Adverse Events
5. Due Process Proceedings and Informal Discussions
6. Site Survey Update Summary
7. Collaborative Innovation Improvement Network (COIIN) Update
8. Member Education Opportunities Identified

The following is a summary of the Committee's discussions.

### **1. Overview of MPSC Projects**

UNOS staff provided status updates for a number of Board of Directors approved Bylaws changes that are pending implementation. Besides making the MPSC aware of the current status of these efforts, the update served to impress upon the committee that it will be reviewing a substantial number of applications in preparation for the implementation of these Bylaws changes.

- *Updating Primary Kidney Transplant Physician Requirements; Changes to Transplant Program Key Personnel Procurement Requirements; Addressing the Term "Foreign Equivalent" in OPTN/UNOS Bylaws*
  - Awaiting Office of Management and Budget (OMB) approval
  - Transplant programs will not need to reapply in response to these Bylaws changes. Applications received on or after the implementation date will be reviewed relative to these changes.
- *Membership Requirements for Intestine Transplant Programs*
  - Awaiting OMB approval
  - These Bylaws changes will require all intestine transplant programs to reapply and meet the new requirements.
- *Membership Requirements for VCA Transplant Programs*
  - Awaiting OMB approval
  - These Bylaws changes will require all VCA transplant programs to reapply and meet the new requirements.
- *Histocompatibility Bylaws Rewrite Phase II*
  - Awaiting OMB approval

- These Bylaws changes will require all histocompatibility transplant programs to designate a general supervisor
- Language from this proposal pertaining to the “general supervisor” as histocompatibility laboratory key personnel is pending implementation (OPTN Bylaws Appendices C.3; C.4; C.4.2; C.5.A; C.5.A.2; C.5.A.3; C.5.B; C.6.B); UNOS implemented the remaining changes from this proposal on September 1, 2015.

As OMB approval impacts the implementation of all these changes, UNOS staff provided additional detail about this process. The federal government’s OMB must approve any new or modified OPTN data collection form, including membership applications. Since these approved Bylaws changes impact the membership application forms, OMB must approve these forms before the Bylaws changes can be implemented. The OPTN has submitted the necessary forms to OMB, and is currently awaiting its feedback.

Staff reviewed a general timeline of what can be expected for collecting, processing, and reviewing applications in preparation for the implementation of the new membership requirements for intestine transplant programs, VCA transplant programs, and histocompatibility labs. First, the implementation of all these changes will be staggered due to the volume of applications expected in response to any one of these proposals. UNOS will provide members notice approximately 30 days in advance of when it will send applications out to current programs (or labs). Approximately 30 days following that notice, UNOS will distribute applications and opt out forms. Members that currently have one of these programs, but that do not intend to reapply, will be asked to document their decision by completing an opt out form. Other members that wish to continue their program, or start a new one, prior to the implementation of the new Bylaws will be given approximately four months to compile the necessary information and submit their application. Approximately three months will then be allotted for UNOS staff to process and the MPSC to review all the submitted applications. The implementation of the corresponding Bylaws changes will be set as the MPSC meeting date that the MPSC is slated to consider approval of these applications. UNOS will alert members of the exact implementation date in advance as that date becomes clearer. It is important to note that that the time frames presented for each step are approximate, and will vary for each Bylaws implementation effort.

UNOS staff proceeded to provide status updates on two other Board-approved, not yet implemented Bylaws projects- *Updating the OPTN Definition of Transplant Hospital*, and *Pediatric Training and Experience Bylaws Requirements*. The implementation of these Bylaws changes have longer timelines due to the need for programming changes to the UNOS membership database to process these applications.

- *Updating the OPTN Definition of Transplant Hospital*
  - Awaiting programming changes- UNOS membership database
  - These Bylaws changes will require OMB approval of application forms.
  - These Bylaws changes will require each transplant hospital to provide certain information, and includes the possibility of more extensive applications involving exception requests, the separation of a single transplant hospital into multiple transplant hospitals, and the combination of multiple transplant hospitals into a single transplant hospital.
- *Pediatric Training and Experience Bylaws Requirements*
  - Awaiting programming changes- UNOS membership database
  - These Bylaws changes will require OMB approval of application forms

- These Bylaws changes will require proposed primary pediatric transplant surgeons and physicians to meet the current key personnel Bylaws requirement and the to-be-implemented, pediatric key personnel Bylaws requirements.

The MPSC also received updates on other efforts that it is involved with, including those projects being worked on with other committees:

- Pediatric Emergency Membership Exception
  - The Pediatric Transplantation Committee and MPSC are working to improve the emergency exception language, introduced with the newly approved, but not yet implemented, pediatric training and experience Bylaws. The emergency exception language from this proposal allows heart and liver programs without an approved pediatric component to list pediatric candidates in certain urgent circumstances. The proposed changes are slated for public comment during the upcoming cycle which will run from July 31 – October 2.
- Memo to the Ad Hoc Disease Transmission Advisory Committee regarding Policy 15.3 (Informed Consent of Transmissible Disease Risk)
  - At its March 2017 meeting, the MPSC raised concerns about Policy 15.3, which states that, “Transplant programs must obtain specific informed consent before transplant of any organ when...the donor has a known medical condition that may, in the transplant hospital’s medical judgment, be transmissible to the recipient.” The MPSC raised concerns that this policy seems to be written in a way that requires informed consent for medical conditions that are transmissible but very common in organ transplantation, e.g., donors that are cytomegalovirus (CMV) or Epstein-Barr Virus (EBV) positive. The MPSC suggested that most programs do not obtain explicit consent for these common positive donor serologies, and would be in violation of this policy. Prompted by these concerns, the MPSC sent the Ad Hoc Disease Transmission Advisory Committee (DTAC) a memo asking if it is really the policy’s intent to require prior informed consent for these more common transmissible diseases, and whether the policy might need to be modified.

MPSC and DTAC leadership met in May via teleconference to discuss this memo. DTAC leadership indicated that it understood the MPSC’s concerns and that it would bring this topic to the full committee’s attention. Subsequent to this discussion, DTAC met and agreed that it should pursue changes to this policy through public comment.
- Pancreas Program Functional Inactivity Work Group
  - The Pancreas Committee is sponsoring an effort and has formed a work group to investigate possible changes to the pancreas program functional inactivity Bylaws requirements. MPSC representatives are also a part of this work group. This work group has had two teleconferences, and a data request is pending.
- Expedited Organ Placement Work Group
  - The OPO Committee is sponsoring an effort and has formed a work group to explore possibilities for adding more structure to expedited organ placement. MPSC representatives are also a part of this work group. This work group has had two teleconferences so far that have primarily focused on reviewing data, and creating additional data requests.
- Addressing Approved Transplant Fellowship Training Programs Bylaws
  - The MPSC is sponsoring this proposal that is slated for the upcoming public comment cycle. Staff reviewed the history of this proposal that would most simply be described as a Bylaws cleanup effort. UNOS staff informed the committee that it anticipates this proposal to be included on the regional meeting non-discussion

agenda, but that this remains to be determined. To inform new committee members about this proposal, and in case anyone on the committee received questions about it, staff reviewed the slides created for presenting this proposal during the upcoming public comment cycle.

### Appendix L Update

UNOS staff updated the MPSC on the progress made to revise OPTN Bylaws Appendix L. Reviewing potential changes, staff specifically requested the MPSC's feedback as members of the committee and as members of the transplant community. Feedback is particularly critical at this point because all of these suggestions are a work in progress. Considering the significant amount of content, staff also requested that the MPSC consider ideas to present this material effectively and efficiently in future discussions with the transplant community. After staff introduced this topic and the goals for the discussion, the MPSC reviewed and discussed the following concepts for revising Appendix L:

- *Consolidate pathways*- Currently the Bylaws establish three different pathways to review potential noncompliance with OPTN Obligations- Imminent Threat Review, Expedited Review, and Routine Review. The MPSC previously had discussed consolidating this to two options- Accelerated Review and Routine Review. Accelerated Reviews would be pursued at the MPSC Chair's discretion when a member needs to take action to mitigate a potentially urgent and severe risk to patient health, public safety, or the integrity of the OPTN. All other matters would be reviewed through the Routine Review Pathway. If the MPSC began reviewing a potential noncompliance through the Accelerated Review Pathway, that review would be downgraded to the Routine Review Pathway as soon as the member sufficiently mitigates the risk.

The MPSC Chair stated, as someone who has had to make the determination regarding which review pathway is appropriate, that this consolidation will simplify this process and these decisions.

- *Changing Review Pathways*- A goal of the proposed Accelerated Review Pathway is for members to sufficiently lessen the urgency and severity of the risk of the matter that prompted the Accelerated Review as soon as possible. Upon a member sufficiently mitigating the risk, the MPSC's review would be downgraded to a Routine Review. Downgrading a review from the Accelerated Review Pathway to the Routine Review pathway is appropriate when a member sufficiently mitigates an urgent risk because those mitigating steps will address the urgency of the matter. With this in mind, downgrading from an Accelerated Review Pathway to a Routine Review pathway is also one means to encourage members to promptly mitigate the risks that prompted an Accelerated Review.

If members do not take sufficient mitigating steps, it is proposed that an explicit provision be added to Appendix L that would render this decision/non-action as a separate potential noncompliance of OPTN obligations.

- *Accelerated Review Member Discussion*- Currently, if the MPSC Chair determines that a potential noncompliance with OPTN Obligations necessitates an Imminent Threat Review, then the MPSC's first interaction with the member is during the member's hearing. The MPSC has found this to be problematic, wanting to speak with members about their particular situation prior to engaging the member during a hearing. In response to this, the MPSC proposed establishing a discussion between the MPSC and the member early in the Accelerated Review process. The Accelerated Review member discussion would occur after the MPSC provides the member with 24 hours to undertake the mitigating steps it has outlined. If the member does not take these mitigating steps, then the MPSC would request

an Accelerated Review member discussion. This discussion will occur via teleconference unless the member and MPSC Chair agree on this discussion occurring at an in-person MPSC meeting.

The MPSC Chair commented from his recent experiences having to make review pathway decisions, that this approach is a lot more reasonable. This will allow the MPSC to interact with a member before deciding an action. The Chair stated that conversations with members often uncover additional problems or provide a better understanding of the matter such that it is not as urgent as initially thought. Either way, it seems that the MPSC and the member should have the benefit of this conversation before the MPSC make a determination regarding what action to pursue.

- *Accelerated Review Public Notice*- Currently, if the Board of Directors takes an adverse action against the member, then the Bylaws require that UNOS distribute public notice of this action. UNOS staff and the MPSC have raised questions if there is a need to notify the public and transplant community earlier in the process in the event of an imminent and severe threat to patient health, public safety, or the integrity of the OPTN. In those instances when a member does not sufficiently mitigate the risks prompting an Accelerated Review, and the MPSC believes that public notice is appropriate at that time, it is proposed that the MPSC would make a recommendation for the Executive Committee to make a final determination about this public notice. This possibility would separate public notice from the final adverse action determination, and would eliminate adverse action recommendations to the Board of Directors that may be motivated in part by public notice considerations. Additionally, this approach would allow for more timely public communication of severe and urgent risks.

MPSC members asked about example scenarios that may result in the Executive Committee distributing public notice during the due process proceedings. Staff replied that the type of situation that would prompt this public notice has not been encountered and should be thought of as an extremely dire scenario. Understanding that this option would be intended for worst case scenarios, the MPSC pointed out that making a recommendation to the Secretary of HHS to take immediate action is already a possibility in the current Bylaws. Further, members expressed concern about distributing public notice before all due process has been completed. Due to these concerns, members indicated it is important to understand what circumstances would prompt the Executive Committee's public notice, particularly if other tools are available. The Chair acknowledged that providing a recommendation to the Secretary is a viable option, but the OPTN has no control over whether the Secretary will respond to these recommendations. Members are generally responsive to the MPSC's requests, but in an instance where the member is not, the ability for the Executive Committee – acting on behalf of the Board of Directors – to issue a public notice could be a beneficial option to have in place during a rare, but dire circumstance. In response, the MPSC asked if the purpose of this notice is to pressure members to take the mitigating actions or is it to alert the public of a threat. UNOS staff replied that both of those reasons contribute to the purpose of this public notice. Regarding alerting the public, the MPSC has debated pursuing an adverse action against a member for the purposes of alerting the public about the situation. The only way this is done currently is for the Board of Directors to approve an adverse action, in which public notice is required. Those discussions prompted an idea to separate public notice from final adverse actions. Additionally, if members repeatedly decline to take mitigating steps during an Accelerated Review, and there is no consequence for this decision, there would be no specific action that the OPTN could take in the instance of a worst case scenario. HRSA representatives also commented that HRSA is involved with all of these discussions as soon as they are

initiated. If a situation was dire and the member was not appropriately responding, HRSA representatives would be a part of the discussions determining whether UNOS should refer this matter to the Secretary of HHS.

The MPSC raised another question about public notice and informing patients. In a worst case situation, is it appropriate to expect members to contact their patients and thereby dilute their efforts and resources to rectify the concerning risk? UNOS staff clarified that the mitigating action required to be taken in 24 hours does not include patient notification. There is a difference between formal public notice by the OPTN contractor and the requirement that transplant hospitals notify their patients.

The Committee also expressed concerns about public notice prior to the conclusion of due process. Regardless if members are required by the Bylaws to notify their patients, they will still have to engage these patients as well as the media, and other interested parties. Might members responding to inquiries prompted by this public notice alter the pending investigation?

Conversation returned to discussing what the goal of the public notice really is. If primarily to encourage the member to take the mitigating factors, members expressed concern about using public notice of an ongoing matter to effect this. This led to a question about other mechanisms that would be more appropriate. Would the committee be comfortable with a scenario where a member's failure to take mitigating steps only prompts another potential policy violation?

MPSC members commented that it seems unreasonable that the Board of Directors would distribute this public notice for any other reason than extreme concern for patient health and public safety. Other members acknowledged that there need to be certain safety nets in place because the Policy and Bylaws cannot possibly detail every possible scenario. Ultimately, it seems very unlikely that a member's potential noncompliance with OPTN Obligations would yield this notice before the member responded, and CMS and HRSA became involved.

Discussion about a safety net in case of emergent situations prompted questions about if members ever refused to take the mitigating actions requested by the MPSC? Yes, there is an example of this. Other members suggested that the intent for having a safety net in place to address a worst case scenario could be lost over time, such that having this option available may result in it being used in situations other than what the committee originally intended.

The MPSC commented in the absence of due process, referring these dire matters to the Secretary of HHS seems most reasonable. Without all information and complete due process, the Secretary can determine what the appropriate action should be. Staff suggested a possible change to this process would be that the MPSC would make a recommendation to the Executive Committee regarding a referral to the Secretary. Currently, members are given due process if a recommendation to the Secretary is being considered. In these instances, it might be necessary to specify that the possibility of these referrals, during an Accelerated Review, and after a member has not taken the necessary mitigating steps, do not entitle a member to due process.

Moving forward on this subject, additional consideration will be necessary. The Committee requested that the proposed Bylaws focusing on this topic separate the goal of immediate mitigation from public announcement.

- *Routine Review Pathway* – No proposed changes to current Routine Review due process steps. The proposed revisions are intended to increase flexibility on timing and format of due

process steps and to give member increased opportunity to demonstrate sustainable changes.

The MPSC did not express any concerns with this approach.

- *Requesting an Interview-* During a Routine Review, if the MPSC believes a Letter of Reprimand or adverse action may be appropriate, staff are proposing that the MPSC will request an interview with the member, and then determine what action to take after engaging the member.

The Chair referenced discussions during the previous day's MPSC new member orientation, stating that this provision is intended to directly address the current MPSC practice of specifying the highest possible action it may take. The MPSC operates in this way as it may always select a lower action than what it initially recommended; however, it is discouraged from recommending a higher action as this restarts the entire due process proceedings. As the MPSC makes the action recommendation fairly early in the due process proceedings, the recommended action is often more severe than necessary so that the MPSC may more efficiently conduct those due process proceedings should it later determine that a more severe action is appropriate.

The Committee stated this would be a helpful change, and indicated its support.

- *Routine Review Interview Format-* To allow for additional flexibility when scheduling interviews with members, staff propose specifying in the Bylaws that interviews may be conducted via conference calls. The MPSC Chair and the member may agree to this alternative arrangement, with the default remaining that the interview will occur at the MPSC's next regularly scheduled meeting.

A related topic that remains to be discussed is how to expedite the timing of an interview during a Routine Review. Defaulting to the next in-person MPSC meeting could be an extended period, and longer than what would be ideal. For example, if a member is offered an interview after the MPSC's October meeting, usually, the next in-person meeting is in March. Committee members suggested another option might be to establish that the interview must occur within some period of time so that members are guaranteed appropriate notice to prepare for the interview. The MPSC Chair will determine if the interview should be conducted at the next MPSC meeting or during a conference call. If a conference call, the member will be given a certain amount of time before the teleconference interview is scheduled so that the member has sufficient time to prepare.

- *Deferred Disposition-* Staff proposed eliminating the current Bylaws requirements that restrict when the MPSC can offer deferred disposition. The MPSC may still consider these as factors for not offering deferred disposition, but this will be left to the MPSC's discretion. Currently, members are very rarely offered deferred dispositions because of the restrictive nature of these requirements. These are critical changes to support a shift towards the MPSC review process having a greater focus on quality improvement. If the MPSC recognizes substantial member improvement in response to a potential noncompliance that prompted an adverse action recommendation, a deferred disposition period allows the member to demonstrate the sustainability of these improvements, which could ultimately influence the MPSC to recommend a lesser final action.

Additionally, staff recommends limiting members to one deferred disposition opportunity, either after an interview or after a hearing. The MPSC has sole discretion as to whether and when a member is offered a deferred disposition.

Focusing on the suggestion that the MPSC may only offer a member deferred disposition once, either after an interview or after a hearing, the Chair added that this consideration is mainly to prevent cases from being drawn out over multiple years. The MPSC can still recommend a lesser action as appropriate as the member goes through due process, but this recommended Bylaws change would only allow the MPSC to offer a member deferred disposition one time. Following this discussion, the MPSC reviewed a Routine Review flowchart showing all the steps of this pathway, including the deferred disposition possibilities.

- *Exhausting Due Process Rights* - Currently members may waive due process steps to proceed to steps later in the process (e.g., waiving a hearing and then present before the Board of Directors). In these instances, members often present information to the Board they did not provide to the MPSC. The MPSC Chair added that when members skip due process steps, it rarely results in an optimal resolution. When a member presents information to the Board that it did not provide to the MPSC, often times it seems that this information could have affected the MPSC's final recommendation. Board members have recommended that Appendix L be modified so that members must exhaust all due process steps before appearing before the Board.

An MPSC member asked if the cost of each of these steps had been considered when arriving at this recommendation. The MPSC Chair responded that he believes the MPSC can only be concerned about cost to the extent that it doesn't impact patient safety. The cost of these due process steps is minor relative to transplant hospitals' revenue streams. As such, it seems imprudent to let cost considerations drive the development of Bylaws intended to protect public health and patient safety. Staff added that members will still have the right to waive these steps, and may submit documentation for review in consideration of any action, but members that elect to waive due process steps will also be waiving their right to appear before the Board of Directors.

The Committee indicated its support for this approach.

- *Subject Matter Expertise Requirement* - The Bylaws currently require that there must be at least two subject matter experts involved in a review; however, the Bylaws do not specify the process or expectations if there are not two available subject matter experts on the MPSC. Staff is proposing to add additional detail in the Bylaws to address this. If the MPSC does not have two subject matter experts available, then the MPSC Chair will select other OPTN Committee members to serve in an advisory, non-voting role to meet this requirement. One reason staff is recommending other OPTN Committee members (at the MPSC Chair's discretion) is that all OPTN committee members must sign confidentiality agreements at the beginning of their terms, and so they should have an understanding of the strict confidential nature of the MPSC's proceedings.

A committee member asked if there are concerns that there could possibly be no subject matter experts voting on an issue. Staff replied that this recommended change is intended to make sure that an expert is a part of the discussion to give the MPSC the information it needs to make informed decisions. This is not much different than how the MPSC currently operates- members are frequently expected to vote on matters outside of their area of expertise. Additionally, this is how the MPSC has operated when there aren't a sufficient number of subject matter experts on the MPSC, and in the absence of these details in the Bylaws.

The Committee indicated its support for this approach.



- *MPSC Chair Designee* – The Bylaws specify a number of critical roles for the MPSC Chair, but they do not specify who fulfills these roles if the MPSC Chair is unavailable or conflicted on any given matter. In these instances, the responsibilities have fallen to the MPSC Vice Chair; however, the Bylaws do not detail who would serve in these critical roles if the MPSC Vice Chair were also unavailable or conflicted. To clarify this, staff recommends that the Bylaws specify that the MPSC Vice Chair would be the first individual called upon to serve as the MPSC Chair’s designee. If the Vice Chair is also unavailable or conflicted, then staff is proposing that the OPTN President would select one of the MPSC’s regional representatives to fulfill this role. As there are 11 regional representatives, at least one of these individuals are very likely to be available. Additionally, staff thought it would also be advantageous to use regional representatives since they are elected by their respective regions to serve in these roles.

The Committee indicated its support for this approach.

- *Changing Review Pathways* – The MPSC Chair may change review pathways as new information is obtained; however, the Bylaws are silent on the details when transitioning between pathways. To clarify this for members and the MPSC, staff proposes detailing in the Bylaws the transitions between pathways depending on when the decision is made to change review pathways. Using a flow chart that demonstrated both the Routine Review Pathway and the Accelerated Review Pathway, staff reviewed each possible transition.

The Committee indicated its support for this approach.

- *Public Notice of Adverse Actions* – Staff is proposing that the Bylaws further specify that when members must send letters to notify certain parties that the Board of Directors has taken an adverse action against them, that these letters must refer to the public notice sent by the OPTN Executive Director. The purpose for referencing the OPTN’s public notice is to assure that the letters include appropriate context.

The MPSC asked if members had sent misleading letters in the past following an adverse action. Staff replied that misleading was not the right term, but that sometimes letters are sent that don’t address why the member is under an adverse action. The current Bylaws only require the member to send letters, with no other requirements regarding the content of those letters. Since the OPTN does release a public notice following all adverse actions, it seemed reasonable to require that members reference this notice in their letters so that the recipients have some official context. The MPSC proceeded to ask if UNOS also receives the letters that members are required to send after the Board takes an adverse action against them. Staff replied that it also recommended that the Bylaws specify that the member must send the OPTN Contractor a template or copy of the notice it sent, and transplant hospital members must retain a copy of the notification letter on file for each individual patient to whom it provided this letter.

- *Clarify “Medical Peer Review”*- Staff recommends clarifying Appendix L.5 (Medical Peer Review) to better explain members’ and the OPTN Contractor’s medical peer review expectations. Specifically, staff recommends adding language that members must keep all materials and information created by or for the peer review body confidential.

The MPSC noted that peer review privilege is the OPTN’s, and asked why it would want to prevent members from disclosing information it has provided to the OPTN? Staff replied that this is the focus of these clarifications. Currently, the Bylaws state that members must, “keep these records, review activity, and documents confidential to promote quality improvement and full disclosure by OPTN members.” The goal of the clarifications is to inform members that it does not have to keep everything it provides to the MPSC confidential, just those

materials that it receives or has created solely for the MPSC. For example, if a member is working on a corrective action plan before the MPSC is ever involved, and this is later shared with the MPSC, it would be permissible to share that corrective action plan as the member sees fit. With the current Bylaws, members seem to be confused about what they can share about their experience, particularly lessons learned that may be beneficial to others. These clarifications are intended to help members with this, and promote more sharing of these learning opportunities. It is critical that the MPSC's deliberations are kept confidential, and members may not disclose information regarding its direct interactions with the MPSC, e.g., what the MPSC asked for, said during deliberations, etc.

The Chair provided a recent example of an OPO on probation. This OPO has been very public with OPO community about the lessons it has learned and how it is applying those lessons to its operations. These types of communications are permissible; however, if the member used, for example, copies of its correspondences with the MPSC when sharing these lessons, this would not be permissible.

The Committee agreed that the current Bylaws regarding medical peer review is confusing and stands to be improved. The Committee will continue to work on this language and what changes should be proposed. The Committee also noted that educational efforts to highlight and explain the eventual changes to this Bylaws language would be beneficial to support members in understanding the implications of these Bylaws.

- *Determining Appropriate Action* - Appendix L.15.A (Determining Appropriate Action) provides a non-exclusive list of factors that the MPSC considers when reviewing potential noncompliance with OPTN Obligations. To highlight the varying magnitude of these considerations is what the MPSC focuses on when determining the appropriate action to take, staff is recommending the following changes:
  1. The degree to which ~~Whether~~ the potential noncompliance poses an urgent and severe risk to patient health or public safety.
  2. The degree to which ~~Whether~~ the potential noncompliance poses a substantial risk to the integrity of or trust in the OPTN.
  3. [...]

Additionally, staff is recommending adding two additional considerations to this non-exclusive list to bring more explicit attention to these considerations. Those two additions are the degree to which the noncompliance demonstrates inadequate stewardship of donated organs and whether the member self-reported the potential noncompliance.

The Committee commenting that greater acknowledgment of member self-reporting is a much needed update. Members should be encouraged to self-evaluate and self-report potential issues as this lends itself to a more effective review and quality improvement system.

The Committee indicated its support for these changes.

- *Actions in Response to Noncompliance with OPTN Obligations* – Staff recommend rewriting how Notice of Uncontested Violation, Letter of Warning, and Letter of Reprimand are defined. Instead of focusing on what types of noncompliance would prompt these actions, shift towards describing the impact on members and what the expectations are following the issuance of one of these actions. Additionally, staff has had preliminary discussions about possibly renaming these actions.

These proposed changes are prompted by members calling staff to say they received notice of an action taken against me, but what does this mean? Does the member need to do anything in response to this action?

Working with the current action names, the following summarizes the recommended modifications:

- Notice of Uncontested Violation- No further action needed
- Letter of Warning- Member should implement, follow, and document corrective action plan according to their quality processes
- Letter of Reprimand- More significant concerns; MPSC conducts formal monitoring

Members noted that previously during this meeting they had recommended Notices of Uncontested Violation and that the member also provide a corrective action plan. How would these modifications align with what the MPSC is currently doing? The Chair reminded the Committee that these are all proposed modifications. If these changes are ultimately adopted, then that would alter the actions the MPSC takes. These changes are intended to increase the consistency of each decision made by the MPSC. Historically, some members may receive a Notice of Uncontested Violation with a request for additional information, other members may receive a Letter of Warning or Letter of Reprimand with no additional requests included. Instead of focusing on what action to take based on the situation, these changes are intended to get the MPSC to first focus on what they want the member to do in response to a noncompliance with OPTN Obligations. The required follow-up will then guide which action the MPSC should take.

The Committee suggested that the Bylaws should also include greater incentive for those programs to audit internally and promptly correct any issues that are uncovered prior to the MPSC's involvement. An approach to do this would be to add another action for these types of situations, which acknowledges that an issue did occur but that the member has taken steps to prevent this event from occurring again. Something to the effect of a "Notice of Internal Correction." Ideally, programs would be self-aware and focused on improving without the MPSC's assistance, and this may be a means to help achieve that. These situations would still be documented in the member's compliance history, but it would also acknowledge the member's proactive approach.

The MPSC proceeded to discuss potential modifications to the Bylaws' descriptions of adverse actions – Probation and Member Not in Good Standing. A lot of the changes include reorganization of content currently in the Bylaws. Additionally, staff is recommending that the Bylaws explicitly state that unannounced on-site reviews and ongoing presentations before the MPSC will occur as requested by the MPSC when the member is under Probation, and will be required when the Board has designated a member as not in good standing.

The MPSC asked if there had been any discussions about modifying the adverse action notice provisions for OPOs. Staff replied that this had not been discussed thus far, but is something that should be reviewed during the course of this project.

Acknowledging that more work was necessary on the action descriptions, the Committee indicated its general support for modifying what actions may be taken.

- *Appearances Before the Board* – Staff recommends specifying in the Bylaws how member appearances before the Board of Directors will be conducted. Including this detail in the Bylaws will allow all to know what to expect procedurally during a Board appearance, and also provides an opportunity to improve how this process currently occurs. Currently, the

member will enter the Board meeting, give its presentation, address any questions from the Board, and then exit the Board meeting. Following the member's exit, the MPSC Chair enters the Board meeting, gives their presentation, addresses questions from the Board, and then exits the Board meeting. At this time the Board will deliberate and make its final determination.

Staff is proposing that the member and the MPSC Chair will enter the Board simultaneously. The member will present, address the Board's questions, and then the MPSC Chair will present and address any questions from the Board. Following these discussions, both the member and the MPSC Chair will exit the Board meeting and the Board will deliberate and make its final recommendation. The proposed changes are intended to provide greater transparency for the member and the MPSC Chair regarding what the other has discussed with the Board. The MPSC Chair commented that this is a much needed change based on his previous experiences before the Board of Directors.

The Committee indicated its support for this approach.

## **2. Living Donor Follow-up Reporting**

Policy 18.5.A (Reporting Requirements after Living Kidney Donation) requires that hospitals report accurate, complete, and timely follow-up donor status and clinical information for at least 60% of living kidney donors and report laboratory data for at least 50% of living kidney donors who donated between February 1 and December 31, 2013, and these thresholds increase by 10% for 2014 and 2015 donors. The Committee continued its review of its process for reviewing members that do not meet the thresholds.

Since at this time over half of the existing living donor recovery programs were below the policy threshold for at least one of the form groups reviewed, the Committee discussed the best way to stratify member compliance, in order to focus on the members that may need the most help to come into compliance. The Committee leadership met with the Living Donor Committee leadership, to discuss the impact of this policy, determine whether they are getting the information they need, and whether the policy requirements are still appropriate.

In October 2016, the Committee discussed three options for monitoring the form submission. The work group and the full MPSC agreed an option that continued the process of Committee review from the first time that a member missed a threshold, was not sustainable.

At its March 2017 meeting, the Committee reviewed two options for focusing the MPSC's review of members that seem to be having the hardest time complying with the policy. The Committee approved an operational rule that the MPSC will review all programs whose follow up rates are at least 50 percent below the policy threshold. The Committee determined that a member should be at 50 percent on all thresholds on all three forms newly available for review. For the members identified, the Committee will request a CAP and evidence of improvement. The member's review will continue until the MPSC determines the program has made satisfactory progress. All programs not identified for special review will have their follow up rates reviewed as a part of their next site survey. The MPSC will evaluate the effectiveness of the operational rule each year and may change the process as needed.

At the July meeting, the Committee reviewed data on members that qualified for a special MPSC review of living donor follow-up data submission. The Committee requested additional information from those members, and sent a reminder to other programs that did not meet the Policy requirements. The Committee will continue to evaluate its operational rule before the next round of data is available.

### **3. Member Related Actions**

During the meeting, the Committee considered the following member specific issues.

#### Membership Application Actions- Consent Agenda

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in December:

#### Existing Members

- Fully approve reactivation of 1 living donor component
- Fully approve 1 transplant program from conditional to full status

The Committee also reviewed and approved the following actions:

- 68 changes in transplant program and living donor component personnel
- 18 changes in histocompatibility lab personnel

The Committee also received notice of the following membership changes:

- 6 transplant programs and 2 living donor components inactivated
- 3 transplant programs and 1 living donor component withdrew from membership
- 3 OPO key personnel changes

The Committee issued six notices of uncontested violation to member transplant hospitals and histocompatibility laboratories that did not notify the OPTN of changes in key personnel within 7 days of departure as required in the bylaws.

### **4. Living Donor Adverse Events**

The Committee reviewed two living liver donor deaths within two years of donation and eight recovery procedures canceled after the patient received anesthesia. The Committee closed seven issues with no action and issued three Notices of Uncontested Violation for late reporting. The Committee is not recommending any further action to the Board at this time for any of the issues.

### **5. Due Process Proceedings and Informal Discussions**

During the meeting, the Committee conducted one informal discussion with a member organization.

### **6. Site Survey Update Summary**

UNOS staff provided the Committee with an update on the efforts of the site survey team to improve the site survey process with a goal of a more efficient and valuable audit that is intended to lead to less time spent reviewing data elements and more time spent on education and process improvement. This was an informational presentation and no vote or action was requested. The MPSC expressed support of the goals and approach, and suggested this would be good information to share with others in the transplant community.

### **7. Collaborative Innovation Improvement Network (COIIN) Update**

Staff presented on the Collaborative Innovation and Improvement Network (COIIN) project. The purpose of the presentation was to provide an overview of the COIIN project for new committee members, review the previously-voted-upon MPSC waiver for participation (in lieu of the newly

added Cohort B hospitals), to present the new Cohort B hospitals, and provide an update on Cohort A activities.

## **8. Member Education Opportunities Identified**

During the meeting, the following educational opportunities were identified:

- Educate transplant hospitals on effective practices for post-transplant recipient monitoring for potential disease transmission, if the recipient received a PHS Increased Risk organ
- Educate transplant hospitals and labs on requirement to notify UNOS of key personnel departure
- Educate transplant hospitals on living donor follow-up requirements and compliance tools that already exist for them, including a direct communication to all transplant programs. Continue to work with the Living Donor Committee to consider policy revisions.
- Work with the Histocompatibility Committee to remove the bylaw requirement for technician key personnel position since the position is not defined and does not correspond to any ASHI/CAP key personnel requirements.
- Educate transplant hospitals on different match run views in DonorNet, importance of reviewing the correct version of the match (all centers vs. their own center). Suggest DonorNet improvements to differentiate between views to System Optimization Work Group.
- Educate community on Member Quality and Site Survey process improvement efforts, possibly during regional meetings.
- Educate all members about Evaluation Plan and other resources that they may not know are available.

## **Upcoming Meetings**

- October 17-19, 2017, Chicago
- February 27-March 1, 2018, Chicago
- July 17-19, 2018, Chicago
- October 16-18, 2018, Chicago

## Attendance

- **Committee Members**
  - Jeffrey Orłowski
  - John Friedewald
  - Christina Bishop
  - Linda Bogar
  - Phillip Camp Jr.
  - Suzanne Lane Conrad
  - Patrick Dean
  - Daniel Dilling
  - Katie Evers
  - Luis Fernandez
  - John Friedewald
  - Alexandra Glazier
  - Alice Gray
  - Gaurav Gupta
  - Liz Heid
  - Julie Houp
  - Seth Karp
  - Rob Kochik
  - Baburao Koneru
  - Deborah Maurer
  - Clifford Miles
  - Walt Nickels
  - Susan Orloff
  - Sean Pinney
  - Steven Potter
  - Kunam Reddy
  - Rene Romero
  - David Rosenthal
  - Donna Smith
  - April Stempien-Otero
  - Timothy Stevens
  - Vinay Sundaram
  - Michael Voigt
  - Bryan Whitson
  - Atsushi Yoshida
- **HRSA Representatives**
  - Joyce Hager
  - Raelene Skerda
- **SRTR Staff**
  - Nicholas Salkowski PhD
  - Jon Snyder PhD, MS
- **OPTN/UNOS Staff**
  - Sally Aungier
  - Chad Waller
  - Ashley Ashton
  - Matt Belton
  - Ronnie Brown

- Bob Carrico
- Robert Fowler
- Shavon Goodwyn
- Henrisa Haskell
- Ann-Marie Leary
- Jason Livingston
- Christi Manner
- Maureen McBride
- Alan Nicholas
- Jacqueline O'Keefe
- Tina Rhoades
- Lisa Schaffner
- Sharon Shepherd
- Brian Shepard
- Betsy Warnick
- Robyn Zernhelt
- **Other Attendees**
  - None