

## **Background Information**

### **OPTN Member Not in Good Standing**

#### **What is the OPTN?**

The Organ Procurement and Transplantation Network (OPTN) is a national transplant network established by federal law and regulation. It has various key functions, including the following:

- Establishment of policies for the allocation of transplantable organs nationwide
- Collection of clinical data on all transplant candidates (patients accepted by a transplant center for a transplant operation), organ donors (living and deceased), and transplant recipients (people who have received an organ transplant) in the United States
- Establishment of key network membership requirements for transplant hospitals, organ procurement organizations and independent histocompatibility laboratories, as well as monitoring of these institutions for compliance with established standards, policies and key measures of transplant quality

United Network for Organ Sharing (UNOS), based in Richmond, Va., operates the OPTN under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

The authority, structure and overall processes of the OPTN are established by federal law (the National Organ Transplant Act of 1984) and federal regulation (the OPTN Final Rule). All transplant centers, organ procurement organizations and independent histocompatibility laboratories in the U.S. are OPTN members and are subject to the OPTN's authority.

#### **What is "Member Not in Good Standing?"**

Member Not in Good Standing is a public designation of an OPTN member institution that has failed to meet key expectations for compliance with OPTN requirements. It could also apply to a member 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.

The OPTN does not have the authority to close a member institution or remove it from the OPTN network. The U.S. Department of Health and Human Services has sole authority to consider or take an action involving involuntary closure or suspension of an OPTN member institution.

#### **What does Member Not in Good Standing mean?**

Member Not in Good Standing does not directly affect the ability of an OPTN member institution to continue to provide services. A transplant hospital or laboratory may continue to provide transplant services; an organ procurement organization may continue to recover organs from deceased donors.

Should a member institution continue to provide services, it must provide detailed corrective action plans to the OPTN to address the issue(s) of concern. It would also undergo enhanced monitoring of its activities and outcomes, including OPTN reviews of data and onsite visits (announced or unannounced) by UNOS staff and/or peer visitors representing the transplant profession.

While OPTN members in good standing are allowed to vote on OPTN matters including approval of bylaws and election of Board of Directors members, a Member Not in Good Standing would not be allowed to vote. Nor would any representative from the member institution be allowed to participate on the OPTN Board or any of the advisory committees that develop proposals for Board consideration as national transplant policy.

A transplant center designated as a Member Not in Good Standing has the option to inactivate some of its services on a voluntary basis (for example, suspend or close one of its organ-specific transplant programs) or end transplant operations entirely. These decisions would be made by the institution's leadership.

### **How does the OPTN reach a finding of Member Not in Good Standing?**

UNOS staff and the OPTN/UNOS Membership and Professional Standards Committee (MPSC) review member performance for issues within the OPTN's authority. They investigate these issues under confidential medical peer review. This is done first to determine fact and context (for example, were the institution's actions in keeping with established medical practice? Is the issue a unique event or something that might recur without detailed correction?). It is also intended to maintain the continuity of patient care if the review reveals no violation, or if the issue may be successfully identified and resolved with minimal to moderate effort.

Confidential medical peer review often involves review of relevant data and documents, results of site visits by UNOS staff and/or medical peers, and a discussion or formal interview with key staff from the member institution before the MPSC. After confidential medical peer review, the MPSC may apply findings to a member institution that would not involve public notice, such as a notice of uncontested violation or a letter of warning or reprimand. These generally would be issued for events or concerns that the member acknowledges and that, in the committee's assessment, the institution is able to resolve on its own through corrective action.

Member Not in Good Standing is the strongest possible designation the OPTN may impose. If the MPSC conducts an initial review and believes this action is warranted, the committee will offer the member institution the opportunity for a formal hearing (again under confidential medical peer review). If after the hearing the committee continues to believe Member Not in Good Standing is appropriate, it will present this recommendation to the OPTN/UNOS Board of Directors for final action. Should the member institution choose to appeal the committee's recommendation, it can request an appellate hearing before the board before a final vote is taken.

A finding of Member Not in Good Standing is public and will include a summary of the events or concerns that prompted the action. Additional details beyond the public summary remain part of the OPTN's confidential record of the institution and are not subject to public disclosure.

**Can a Member Not in Good Standing regain full standing in the OPTN?**

Yes, if the member demonstrates needed improvements to the satisfaction of the MPSC and the Board of Directors. Again under confidential medical peer review, the committee and the board would consider the result of additional monitoring and corrective action. A member might be placed on Probation (also requiring public notice and enhanced monitoring, but with fewer member restrictions) for a period of time before becoming a member in good standing. The OPTN would give public notice for a member's full status reinstatement, just as it does when it initially applies the designation of Member Not in Good Standing.