

## **Background Information**

### **OPTN Probation**

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

The Organ Procurement and Transplantation Network (OPTN) is the national transplant network 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. Key functions of the OPTN include 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
- Operation of a highly secure, computerized system to match donated organs with candidates waiting for transplants nationwide
- 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., serves as the OPTN under contract with the Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services.

#### **What is Probation?**

Probation is a public designation indicating that an OPTN member institution is undergoing extensive corrective action for compliance with OPTN requirements, 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 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 or potential removal of the member's ability to receive Medicare or Medicaid funding. Under the OPTN Final Rule, the OPTN/UNOS Board of Directors could make a recommendation to the Secretary of Health and Human Services regarding these potential additional actions.

### **What does Probation mean?**

Probation 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 will also undergo enhanced monitoring of its activities and outcomes, including OPTN reviews of data and onsite visits by UNOS staff and/or peer visitors representing the transplant profession.

An institution under probation is obligated to provide notification of its status to the individuals it serves (for example, a transplant program would need to notify transplant candidates as well as recipients undergoing follow-up care and monitoring).

A transplant center under probation 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 determine probationary status?**

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.

If the MPSC conducts an initial review and believes probation 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 probation 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 probation is public and will include a public 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 under probation 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. The OPTN would give public notice for a member's full status reinstatement, just as it does when it initially applies the designation of probation.