

Staying within the Lines

A selected review of the MPSC's role in compliance monitoring

Editor's note: The following is a distilled look at compliance monitoring; no mention is made, for example, of the work of review boards or the MPSC's role in reviewing member applications.

Who would think that a complex system governed by constantly changing policies, regulations and medical procedures—one in which lives are at stake every day—could be managed by the *voluntary* compliance of the very participants who fund that system?

It may seem implausible...but it's true. And it's been the preferred and successful approach for more than two decades.

The complex system, as you've certainly already figured out, is the OPTN transplant system, which UNOS administers, under a contract with the Department of Health and Human Services (HHS). The system involves hundreds of transplant centers, OPOs and histocompatibility labs across the country.

The OPTN Final Rule requires the network to “design appropriate plans and procedures...for compliance.” Education, not punishment, is the goal. And it is HHS, not UNOS, that has the authority to enforce sanctions that may be imposed.

Although a cast of hundreds of volunteers and UNOS staff work to monitor, encourage and support OPTN members' compliance efforts, the key to the system's success can be summed up in one concept: *confidential peer review*.

EVALUATION AND QUALITY

UNOS' department of evaluation and quality (DEQ) conducts data analysis and site surveys of OPTN members. These activities form the foundation of the compliance system, and both are handled with the strictest confidentiality throughout.

In their data analysis, DEQ staff evaluate the clinical and administrative data members must submit to UNOS, making sure that the data indicate compliance with OPTN policies and bylaws.

In their site surveys, DEQ staff travel across the country to visit centers and review pertinent medical records, verifying the information submitted to UNOS is documented in the patient's medical record and that OPTN policies and bylaws are followed.

If DEQ staff's monitoring reveals a potential policy violation, staff first seek an explanation or clarification from the member. If the member's explanation or clarification is insufficient to rule out a potential policy violation, then DEQ reports the case to the OPTN/UNOS membership and professional standards committee (MPSC) and its policy and compliance subcommittee (PCSC) for review.

The PCSC reviews the case to determine if a policy violation has occurred. If the PCSC believes a policy violation has occurred, it then makes a recommendation to the full MPSC about what sanctions, if any, are warranted by OPTN bylaws under the circumstances.

Central to this process is the *confidential* nature of the peer review. The identity of the member in question is not known to members of the PCSC or MPSC unless, of course, the MPSC's review requires a subsequent formal disciplinary proceeding.

The PCSC's recommendations are reviewed by the full MPSC, whose members may accept PCSC's recommendations, make a different determination or refer the issue back to the PCSC.

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If required by the OPTN bylaws, the MPSC may, in turn, refer a disciplinary matter to the OPTN/UNOS board of directors for formal action and, in the case of the most egregious and significant violations of OPTN bylaws or policies, the board may, itself, refer the matter to the Secretary of HHS for additional adverse action under HHS' authority and discretion.

Throughout the process, OPTN members' rights are protected through the “due process” provisions of the OPTN bylaws, which provide members a right to participate and explain themselves during the review process. The consequences for violating OPTN bylaws or policies can range from a simple notice of violation or letter of warning to a recommendation that the Secretary of HHS terminate a member's membership in the OPTN or designated transplant program status.

The overarching goal of the entire process of monitoring members' compliance is, of course, protecting patient safety and successful organ transplantation. **U**

ONLINE UNOS' department of evaluation and quality (DEQ) maintains a document on the OPTN website, the “evaluation plan,” which DEQ staff update at the end of each calendar quarter. The plan gives guidance on what is expected regarding policy compliance and provides the member with information about how compliance with the bylaws and policies is measured.

For a copy of the evaluation plan, visit [optn.transplant.hrsa.gov/policy management > evaluation plan](http://optn.transplant.hrsa.gov/policy-management/evaluation-plan). For more information about the plan, see “The Help Is Out There,” p. 18, March–April Update.