

# Changes after the 'Final Rule'

BY TIMOTHY L. PRUETT, M.D.

The function of the OPTN/UNOS board in the '90s, the early days, was constrained by recognition that there was minimal ability to enforce policy. Much time was spent making policy with which most of the community would agree and in cajoling members to comply with that policy. Much effort also was spent determining if member institutions had the required resources and personnel.



Since 2000 and the Final Rule, the OPTN's function has become more goal-directed, with delineation of its areas of responsibility. The issues of equitable organ allocation, patient safety, minimizing errors in organ labelling and transport, and assuring that recipients appear on

the match run have taken on a new role. Much also has changed with liver, lung and heart allocation, and the task of finding the right model to allocate kidneys has proven challenging.

The shortage of organs and the expansion of organ donation into populations that previously were not used has revealed areas in which there was no existing policy. The need to develop and oversee consistent and realistic policy about donation after cardiac death and expanded criteria donors has become important. Standardizing risk and preventing transmission of disease through organ transplantation has taken on a new role.

The addition in 2006 of living organ donation to UNOS' oversight responsibilities was significant. Although bylaws have been approved, the metrics have yet to be completed.

Kidney paired donation (KPD) also looms as a great possibility, but still must go through the consensus and policy-development process. The community also will have to decide whether KPD is allocation or a form of directed donation. The policy models will look very different depending upon that decision.

Electronic notification (DonorNet®) has been a significant outlay of effort and resources by the OPTN, UNOS and transplant community. It is incumbent upon the OPTN to maximize information and automation of the multiple policy enforcement elements.

And, finally, although the scope of responsibility for overseeing the transplant system continues to increase, resources to pay for it are stagnant. There must be some congruence of resource availability and responsibility.

Policy that is evidence-based is a great goal and an excellent metric to keep in front of the transplant community. A significant difficulty resides, however, in assessing the degree of reliability of the evidence, the applicability of the evidence to the problem and observations required to validate a change in policy to accomplish the hoped-for goal.

The transplant community is composed of very smart individuals who can find flaws in the "evidence." There clearly is a need for supporting information when discussing policy development and implementation, but the information is sometimes of questionable reliability. Policy based on bad data is bad policy.

In summary, the OPTN doesn't look anything like it looked before the Final Rule. How much is the Final Rule and how much is the expansion of transplantation is a bit like the age-old chicken-and-the-egg question.

One thing is certain, though. The world is much different. **U**

Timothy L. Pruett, M.D., is director of transplantation at the University of Virginia Health Sciences Center in Charlottesville. A member of the OPTN/UNOS board of directors and executive committee, he recently completed a term as OPTN/UNOS president. He has served in many OPTN/UNOS capacities and also has been a member of the review board (liver) for his region for more than 10 years.