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Directors' Report – Biannual Update on UNOS July 2014

OPTN/UNOS Board of Directors Meeting Highlights

The OPTN/UNOS Board of Directors met June 23-24 in Richmond, Va. The Board took action on a number of items, with key topics described below.

Board Actions:

Budget and fees; financial reserves

The Board approved a budget and fees for fiscal year 2015. The combined OPTN and UNOS fee will remain unchanged at \$957. The OPTN component of the fee will decrease from \$810 to \$793, while the UNOS fee will increase from \$147 to \$164.

The OPTN fee decrease is due to increased funding from candidate registrations and an expected increase of \$500,000 in federal appropriations. OPTN expenditures will increase slightly from the fiscal year 2014 budget.

The majority of the UNOS fee increase is to accelerate funding of UNOS' corporate reserves as recommended by the Finance Committee.

The Board also approved OPTN and UNOS bylaws governing reserves that established reserve cash goals and specified conditions in order to withdraw funds.

VCA policies and guidance

The Board accepted the first OPTN policies and standards for vascularized composite allograft (VCA) transplantation, effective July 3, 2014. They include:

- criteria for defining VCAs to be covered in OPTN policy
- OPTN membership requirements for VCA transplant programs
- initial policies for VCA allocation
- guidance for gaining specific consent for donation of VCAs

The requirements will be in effect for 15 months, allowing public comment in the fall of 2014 regarding potential improvements. The OPTN/UNOS Vascularized Composite Allograft Transplantation Committee will also continue development of other aspects of VCA policy. Priorities include refining allocation policy, data requirements and data collection procedures for VCAs.

Pediatric heart allocation

The Board approved amendments to heart allocation policy for pediatric candidates, with the goals of reducing wait list deaths and providing better access to available organ offers. The amendments include a redefinition of medical criteria for Status 1A and 1B to lessen the effect of waiting time among candidates in these status groups. Infants with high medical urgency will also have greater access to hearts from donors of incompatible blood types. Incompatible blood type hearts can be transplanted safely for some infant candidates because their immune system has not developed enough to reject such organs. In addition, to better reflect current clinical practice, the policy eliminates a rarely used provision that allowed candidates to be listed for a transplant *in utero* (shortly before birth).

Kidney paired donation

The Board adopted a recommendation to the Health Resources and Services Administration (HRSA) that the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) should become a permanent function of the OPTN. This action, assuming HRSA approval, would thus end the pilot phase of the program's development. The Board separately approved transferal of the priority points used in the current KPDPP into OPTN policy.

Liver allocation

The Board adopted an amendment to liver allocation policy adding serum sodium to the calculation of MELD scores for transplant candidates with an initial MELD score of 12 or higher. This action is expected to reduce waitlist mortality by more accurately prioritizing urgent candidates.

Living donation

The Board approved minimum requirements for living liver donor transplant programs to report post-operative outcome data on those donors at intervals up to two years from the donation. Similar to standards enacted previously for reporting of data on living kidney donors, living liver donor transplant programs must report accurate, complete and timely donor status information for at least 80 percent of donors who donate on or after September 1, 2014. They must also report accurate, complete and timely laboratory data on living donors for at least 70 percent of donors one year from donation.

In separate action, the Board accepted a policy amendment that requires all candidates for living donor transplantation to be added to the deceased donor waiting list. This is intended to assure that the same patient safety procedures would apply to them as would candidates who are only awaiting a deceased donor transplant.

Donor disease screening

The Board adopted a number of amendments to OPTN policies addressing screening of deceased and living potential donors for the risk of donor-transmissible disease. The policies are intended to comply with the 2013 Public Health Service Guideline while allowing member institutions latitude to select appropriate tests while maintaining patient safety.

Histocompatibility standards

The Board approved a comprehensive rewrite of histocompatibility standards in OPTN policy. The amendments align OPTN testing requirements with those in federal regulations and standards required by histocompatibility accrediting agencies (ASHI and CAP). Additional provisions resolve questions regarding the ability to monitor compliance with the standards.

Member review methodology and functional inactivity processes

The Board approved new methodology to be codified in the OPTN bylaws for review of patient and graft survival at transplant programs. The new approach is expected to identify more accurately the programs who would be most in need of outcome review and assistance by the Membership and Professional Standards Committee.

The Board separately adopted changes to the OPTN bylaws that clarify a transplant program's obligation to notify all candidates and potential candidates in case of the program's functional inactivity.

Pediatric lung transplant exception

The Board approved on a permanent basis a policy change allowing transplant programs to request additional, exceptional priority for adolescent or adult donor lung offers for transplant candidates younger than 12 years old. The action followed additional review of a temporary exception adopted in 2013.

Other Highlights:

UNOS staff updates

UNOS officers and staff have been interviewing finalists for the executive staff position of Chief Medical Officer. UNOS will separately announce the final decision for this position.

In recent months, three executive staff positions have been filled: Alex Tulchinsky as Chief Technology Officer, Stephen Harms as Chief Operating Officer and Maureen McBride, Ph.D., as Chief Contract Operations Officer.

Ryan Ehrensberger, Ph.D., recently joined the staff as Director of Research. He has experience in healthcare leadership and planning, both at Hammes Company and Bon Secours Richmond Health System.

Liver concept document and forum

The Liver and Intestinal Organ Transplantation Committee released a concept document and questionnaire in June to seek public input on ways to optimize equity in liver distribution. Responses to the questionnaire will be accepted through July 11. The committee will host a public forum on September 16, 2014, to review responses gathered through the questionnaire and seek further public input to guide future policy development.

Data Advisory Committee

Appointments are being made to the OPTN/UNOS Data Advisory Committee, as called for in the OPTN contract renewed in 2013. The committee will make policy recommendations on issues involving the collection, release and use of data collected by the OPTN. Additional information will be provided about the committee once the appointments are complete.

Policy development schedule/Expedited action proposal

UNOS is developing a revised schedule of meetings and public comment cycles to allow more timely action on policies and bylaws. Key features of the schedule, to be implemented in 2015, will be slight adjustments to the timing of Regional and Board meetings and a somewhat shorter public comment period for proposals.

In the Fall 2014 public comment cycle, the Executive Committee will also distribute a proposed new pathway to allow expedited consideration and action on rare issues that must be addressed more quickly than the usual process allows. Under the proposed pathway, public comment would be sought after an initial Board approval. If significant concerns or questions are raised during the public comment, the policy would be referred back for additional consideration and action under the standard policy development process.

IT update

Between June 2013 and June 2014, 58 UNOS staff positions in information technology areas have been filled, with 22 remaining vacancies (some currently posted and some on hold). UNOS is continuing to identify and fill skill gaps among the staff to be better positioned for efficiency and innovation.

A major emphasis in planning is to move from the current technology infrastructure of tightly coupled systems, requiring major effort to complete fairly small system changes, to a more modular system where changes can be accomplished more quickly and with lesser impact. Assessment and planning is also underway to ensure appropriate business continuity for continuing technology operations in the event of natural disasters or failure of supporting technology such as phone or Internet access.

Electronic tracking and transportation (ETT)

UNOS continues work on the Electronic Tracking and Transportation (of organs) project, which began as a HRSA Innovation project, fully funded by DHHS. It involves the development and eventual implementation of technology that will reduce/prevent organ labeling and transport errors, which continue to represent the most frequent patient safety incidents in organ transplantation.

Five OPOs participated in the original pilot and field testing on a staggered schedule starting in August 2013. In a survey of initial participants, the vast majority indicated that they strongly agree or somewhat agree that ETT makes donation processes safer in the OR and ICU.

Development of the ETT version for beta testing is now underway and expected to be complete by August 2014. Beta testing will start in September 2014 following training. Beta testing will involve the original five OPOs as well as three additional OPOs and associated transplant hospitals. It will include new testing components: transplant hospital printing of recipient ID bands, a bar code scan at organ check-in and a bar code scan in the operating room for both the recipient and organ received. Following beta testing, an application is planned to be available for voluntary OPO national deployment.

OPTN/UNOS KPDPP educational initiatives

A virtual Town Hall meeting will be held August 21 to provide members updates about the status of the Kidney Paired Donation Pilot Program, upcoming plans for its further development, and professional and patient educational resources available.

Among the recently developed resources is a series of brief videos to educate potential donors and candidates about the option of kidney paired donation. The videos are available through the Kidney Paired donation page on the UNOS website:

<http://www.unos.org/donation/index.php?topic=kpd>

How to Stay Current

UNOS's website and monthly communication via [Transplant Pro](#) maintains up to date information on policy activities, including policy notices and public comment; compliance and safety information; OPTN guidelines, OPTN committee newsletters and more. Anyone who doesn't currently receive the monthly e-newsletter may [subscribe here](#).