

OPTN Executive Update

Summer/Fall 2025

OPTN Restricted

Agenda

- Securing the U.S. OPTN Act
- OPTN Strategic Plan
- Seating of New Board
- Board Support Contractor: AIR
- Introduction of Doug Fesler, New Executive Director
- INVEST Insurance Updates
- HOPE Act Update
- Registration Fee Increase
- Updates on HRSA Directives
- OPTN Policy Development Process
- FY26 Policy Projects
- Committee Vacancy Process
- Upcoming Board Activities
- Questions & Discussion



Securing the U.S. OPTN Act—2023

The OPTN Modernization Initiative, including a new multi-vendor environment, were driven by Congressional action. The **Securing the U.S. OPTN Act**, signed in 2023, allowed HRSA to bring multiple vendors to the OPTN for the first time in 40 years.



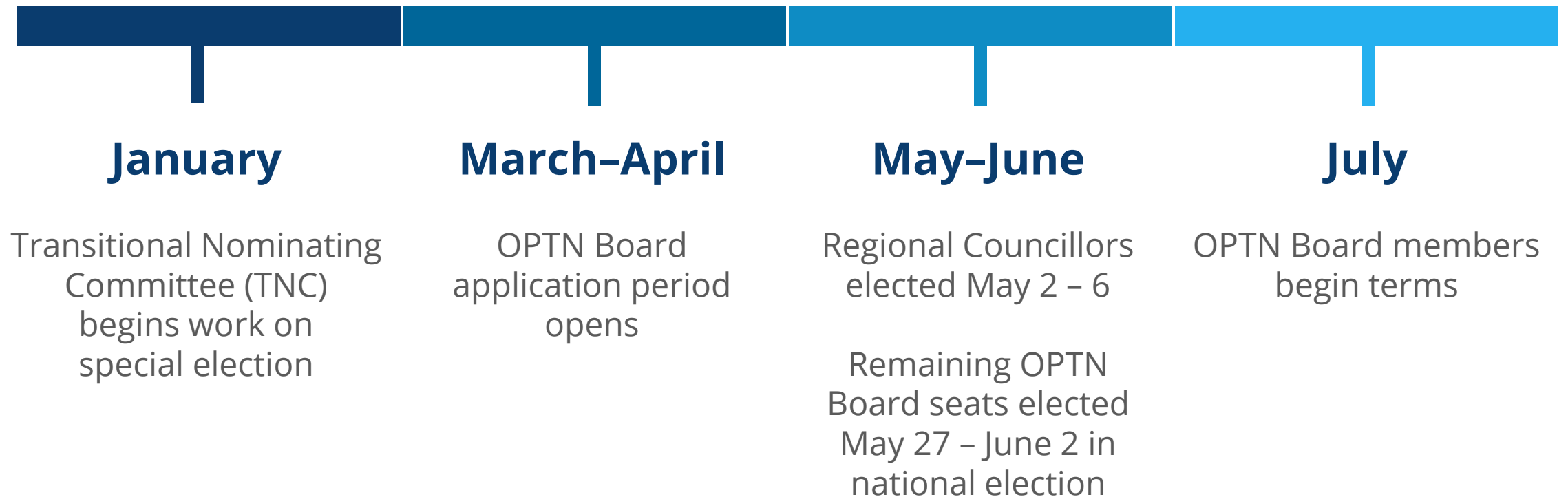
- These changes aim to improve management of the OPTN, increase accountability, and help patients.
- Allowed for creation of Independent Network of Volunteers for Equitable and Safe Transplants (INVEST)
- HRSA can now quickly and efficiently purchase products and services as opportunities arise or as changes are needed.

OPTN Strategic Plan

GOAL	METRICS	TACTICS
1. Increase Opportunities for Tx	<ul style="list-style-type: none"> • ↑ offer acceptance ratio annually • ↓ variability/time from first offer to acceptance • ↓ median # of declines • ↑ live donor transplants 	<ul style="list-style-type: none"> • Develop/disseminate educational programs • Improve offer acceptance process
2. Optimize Organ Use/Equity	<ul style="list-style-type: none"> • ↓ non-use rates • ↑ Access To Transplant Scores (ATS) 	<ul style="list-style-type: none"> • Share best practices & strategies • Evaluate new/improved allocation schemes • ↑ Equity
3. Enhance OPTN Efficiency	<ul style="list-style-type: none"> • Quarterly review of Strategic Plan/Metrics • Improve policy development and implementation • ↑ project benefit 	<ul style="list-style-type: none"> • Refine the policy development process • Enhance data collection
4. Support Modernization Efforts	<ul style="list-style-type: none"> • Develop/implement collaboration metrics for OPTN, HHS, & contractors 	<ul style="list-style-type: none"> • Support OPTN & BOD • Create effective partnerships for HHS & contractors • Improve technology systems

Link: <https://optn.transplant.hrsa.gov/about/strategic-plan/>

Special Election 2025



OPTN Board Leadership



John Magee
President



Shelley Hall
Vice President



William "Bill" Ryan
*Vice President of Patient
and Donor Affairs*



Alan Reed
Treasurer



Justin Wilkerson
Secretary

OPTN Board Ex-Officio Members (Non-Voting)



Stephanie Grosser
Senior Advisor, HRSA, HHS



Raymond Lynch
*Organ Transplantation Branch
Chief
Division of Transplantation, HHS*



Doug Fesler
Executive Director of the OPTN

OPTN Board Patient, Donor, and Family Representatives



William "Bill" Ryan
(VP of Patient & Donor Affairs)



Cody Reynolds



Gitthaline "Candie" Gagne



James "Jim" Cason



Jen Benson



John Hodges



John Sperzel

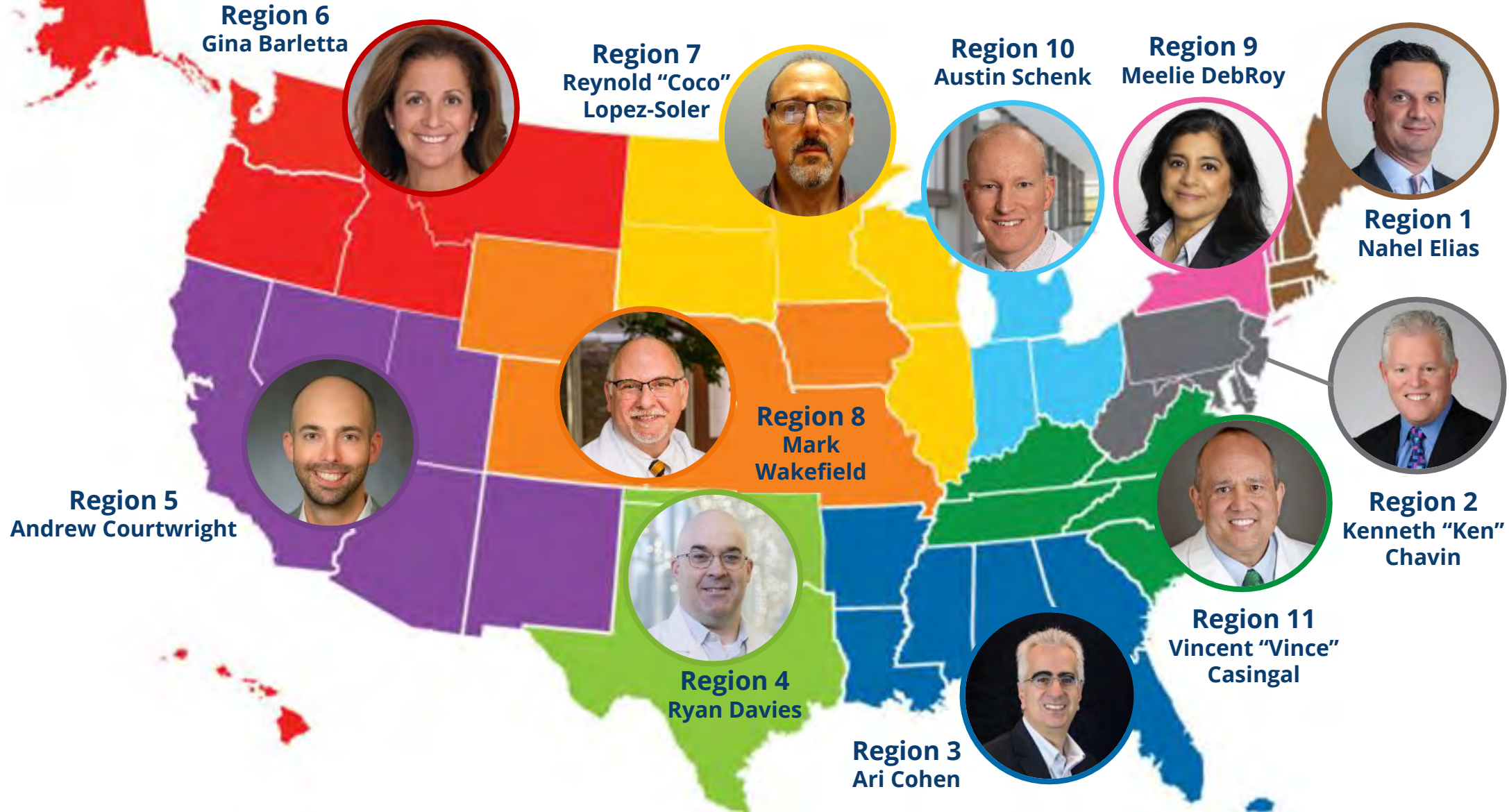


Peter Nicastro



Justin Wilkerson
(Secretary)

OPTN Board Regional Councillors



OPTN Board Transplant Physician and Surgeon Representatives



Alan Reed
(Treasurer)



Dan Meyer



Shelley Hall
(Vice President)



Kymberly "Kym" Watt



George Bayliss



Joseph "Joe" Magliocca

OPTN Board Representatives



Samantha "Sam" Endicott
Organ Procurement Organization Representative



Kevin Lee
Organ Procurement Organization Representative



Darren Larhman
Organ Procurement Organization Representative



Annette Needham
NEA-BC, CCTC, Voluntary Health Association Representative



Cathi Murphey
Histocompatibility Representative



Jerold "Jerry" Mande
Non-Transplant Professional Representative



Mary Homan
Non-Transplant Professional Representative



Joshua "Josh" Gossett
Transplant Hospital Representative

OPTN Executive Committee



**John
Magee**
*President
(Chair)*



**Shelley
Hall**
*Vice President
(Vice Chair)*



**George
Bayliss**
At Large



**Jen
Benson**
*General Public
Representative*



**Nahel
Elias**
*Minority
Transplant
Representative*



**Samantha
"Sam"
Endicott**
*Organ Procurement
Organization
Representative*



**Stephanie
Grosser**
*Ex Officio
(non voting)*



**Raymond
Lynch**
*Ex Officio
(non voting)*



**Cathi
Murphey**
*Histocompatibility
Representative*



**Annette
Needham**
*Transplant
Coordinator
Representative*



**Alan
Reed**
Treasurer



**William
"Bill"
Ryan**
*VP of Patient &
Donor Affairs*



**Justin
Wilkerson**
Secretary

OPTN Nominating Committee



Shelley Hall
*Vice President
(Chair)*



**Vincent
"Vince"
Casingal**
At Large



**Meelie
DebRoy**
At Large



**Nahel
Elias**
*Minority
Transplant
Representative*



**Gitthaline
"Candie"
Gagne**
*Patient and Donor
Affairs Representative*



**Joshua
"Josh"
Gossett**
At Large



**Stephanie
Grosser**
*Ex Officio
(non voting)*



**Darren
Larhman**
*Organ
Procurement
Organization
Representative*



**Raymond
Lynch**
*Ex Officio
(non voting)*



**John
Magee**
President



**Cathi
Murphey**
*Histocompatibility
Representative*



**Annette
Needham**
*Transplant
Coordinator
Representative*



**Cody
Reynolds**
*Patient and
Donor Affairs
Representative*



**William "Bill"
Ryan**
*VP of Patient and
Donor Affairs*



**John
Sperzel**
*Patient and
Donor Affairs
Representative*



**Kymberly
"Kym"
Watt**
At Large

OPTN Finance Committee



**Alan
Reed**
*Treasurer
(Chair)*



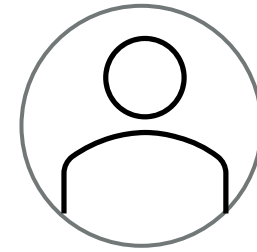
**Vincent
"Vince"
Casingal**
At Large



**Ari
Cohen**
At Large



**Ryan
Davies**
At Large



**Mesmin
Germain**
*Ex Officio
(non voting)*



**Joshua
"Josh"
Gossett**
At Large



**Stephanie
Grosser**
*Ex Officio
(non voting)*



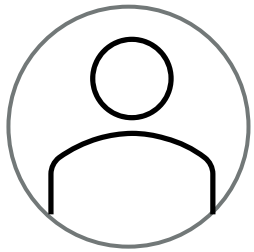
**Amy
Harbaugh**
*Ex Officio
(non voting)*



**John
Hodges**
At Large



**Raymond
Lynch**
*Ex Officio
(non voting)*



**Patrick
Mauro**
*Ex Officio
(non voting)*

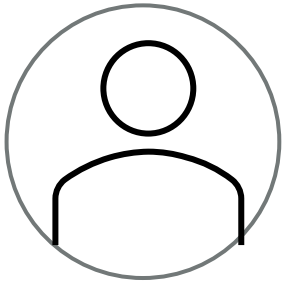


**Peter
Nicastro**
At Large



**Justin
Wilkerson**
At Large

Network Operations Oversight Committee



**James
Duff**
*Ex Officio
(non voting)*



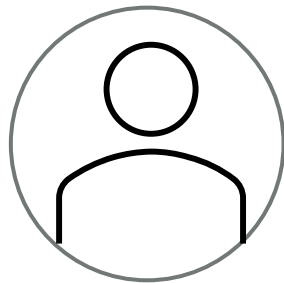
**Joshua "Josh"
Gossett**
At Large



**Shelley
Hall**
*Vice President
At Large*



**Darren
Lahrman**
At Large



**Reginald
Ralph**
*Ex Officio
(non voting)*



**William "Bill"
Ryan**
*VP of Patient and
Donor Affairs
At Large*



**Mark
Wakefield**
At Large

Board Support Contractor: American Institutes for Research (AIR)

American Institutes for Research (AIR) provides strategic and administrative services to HRSA and the OPTN Board, including:

- Facilitating nomination and election processes of an independent OPTN Board;
- Supporting OPTN Board governance, oversight, management, and strategic planning;
- Updating OPTN structure, composition, policies, processes, and procedures; and
- Fostering collaboration within a multi-vendor environment.

AIR's partners in the project are Foley Hoag, LLP, and LPE Associates.

OPTN Executive Director, Doug Fesler



Doug Fesler
Executive Director of the OPTN

INVEST Insurance

INVEST insurance expanded to provide coverage for committee and workgroup volunteers

- While there is no way to guarantee that a Director/Committee or Workgroup volunteer will not be sued, certain risk mitigation strategies and the structuring of certain insurance coverage will likely result in the prompt dismissal of any lawsuits or minimal damages.
 - Generally speaking, Directors acting with care and in the interest of INVEST/OPTN are shielded from liability because of the Business Judgment Rule. On the other hand, Directors who engage in misconduct, gross negligence, or who breach their duties may be held personally liable for their actions.
 - To guard against potential liability, Directors should regularly attend meetings, stay informed, make well-informed decisions, follow the law, act in support of the mission and governing documents, and avoid or disclose any real or potential conflicts of interest.
 - Delaware state law also offers other protections for Directors/Committee or Workgroup volunteers, including the Volunteer Immunity Statute, certain types of insurance coverage, and indemnification provisions.
 - As always, Directors/Committee or Workgroup volunteers should be mindful of their actions and decisions and ensure that they are performing their roles suitably.

HIV Organ Policy Equity (HOPE) Act Update

OPTN Board approves policy to expand transplant access for individuals living with HIV

- **HOPE Act Expansion Proposed:** To allow transplants of kidneys, livers, and combined liver-kidneys from HIV-positive donors to HIV-positive candidates without requiring NIH research participation or HOPE Act variance; ensure patient safety is maintained while expanding access for individuals living with HIV
- **Regulatory Alignment:** Aligns with the amended OPTN Final Rule and NIH Final Notice removing research requirements for kidney and liver transplants from HIV-positive donors
- **Variance Case Response:** Prior to Board approval of policy, OPTN Board responded to a special request from a transplant center regarding a pediatric variance case
- **Policy Approval:** Approved at the OPTN Board's biannual meeting in June 2025

Registration Fee Update

- OPTN Board of Directors voted on August 21, 2025, to approve recommending a **19%** increase to the registration fee, increasing it from **\$868.00 to \$1,035.38**
- HHS approved the Board's recommendation and set the new fee to **\$1,036**
- The increase allows the Board to cover expenses associated with Secretarial and HRSA directives, other OPTN initiatives, and priority activities
- First fee increase in 4 years
- As of October 1, 2025, HRSA collecting fees instead of UNOS



Updates on HRSA Directives

Allocating Organs Out of Sequence (AOOS)

AOOS remediation work includes:

- Created public AOOS website; dashboards displaying AOOS statistics
- Formed an AOOS Workgroup to execute the AOOS remediation plan; kick-off meeting held in August 2025. Workgroup will:
 - Ask MPSC to assess AOOS compliance and address patterns of non-compliance
 - Prioritize AOOS education for OPOs and transplant centers
 - Identify members with high or unusual AOOS volumes and conducting outreach to reduce risks

Normothermic Regional Perfusion (NRP)

- OPTN submitted a proposed framework for future NRP policy development in April 2025
- The framework outlines next steps, including:
 - policy development
 - data collection
 - stakeholder engagement
 - ethical and legal analysis
- The plan remains under HRSA review, as of August 2025

Updates on HRSA Directives (cont.)

Donor Derived Transmission Event

- OPTN obtained 12 months of data from 6 OPOs related to screening protocols for donors with risk factors for rabies
- Drafted interim communication sent to the OPTN membership jointly by HRSA, the OPTN, and OPTN DTAC chair to remind members of current guidance regarding screening for donor-derived infection

Current Policy Development Process, Steps 1 - 5



1. **Idea**—The sponsoring Policy Governance Committee (PGC) identifies a potential policy need.
2. **Problem Analysis**—The PGC defines and analyzes the problem the policy would address; projects are not yet approved.
3. **Project Approval**—The PGC presents the project to the Policy Oversight Committee (POC) and OPTN Board Executive Committee for approval.
4. **Evidence Gathering**—The PGC gathers information to develop the project proposal.
5. **Public Comment Approval**—The PGC seeks POC and Board Executive Committee approval for the project pending public comment period.

Current Policy Development Process, Steps 6 - 10



- 6. Public Comment**—The proposed policy is released for public comment.
- 7. Pending Board Approval**—A finalized project proposal is prepared for presentation at an upcoming Board of Directors meeting.
- 8. Board Approval**—The Board of Directors approves the project proposal.
- 9. Implementation**—Approved policies are put into practice within the OPTN community and communicated through a policy notice.
- 10. Post-Implementation Review**—The PGC evaluates the policy's impact and effectiveness and shares the findings with leadership.

FY26 Policy Projects Approved for Public Comment

- Update and Improve Efficiency in Living Donor Data Collection
- 2025 Histocompatibility HLA Table Update
- Require Patient Notifications for Waitlist Status Changes
- Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage
- Establish Comprehensive Multi-Organ Allocation Policy
- Require West Nile Virus Seasonal Testing for Donors



Link: <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/>

Committee Vacancy Process

- **The updated, streamlined process aligns with the description outlined in the OPTN Management and Membership Policies**

“The vice president, as incoming president, will appoint representatives to the Committees from a list of nominations received from the Regional Councillors.”

—*OPTN Management and Membership Policies, Policy A.1*

- **Responsibilities of Regional Councillors**
 - Compile recommendations for the vice president’s approval, considering region-specific vacancies and the expertise required for at-large committee positions
 - Regional Councillors may collaborate with Associate Councillors and committee leaders as needed
- **The selection process for Summer/Fall 2025 vacancies is currently in progress**
 - Appointed committee members will begin their terms on October 1
- **The selection process for Fiscal Year 2026 vacancies will begin in early 2026**

Upcoming Board Activities

Continue to:

- Maintain public/ private partnership
- Support the AOOS Workgroup
- Prioritize data directives and critical issues such as Donation after Circulatory Death
- Ensure Bylaws are in alignment with any HRSA updates to the Final Rule
- Prioritize projects for FY26



Potential Projects for FY 2026

Target Date to Board	Title
TBD	Establish National Kidney Expedited Placement Policy
TBD	Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement
TBD	Data Collection on Normothermic Regional Perfusion (NRP) and Machine Perfusion
TBD	Reduce the Risk of Rabies Transmission
TBD	Increase Priority for Multivisceral Transplant Candidates
June 2026	Ethical Analysis of Possible Impacts Xenotransplantation on Human Allograft Organ Allocation
June 2026	Standardize Lost to Follow-up Reporting and Enhance Data Collection on Lost to Follow-up & Transfers of Care (Pediatric Committee)
June 2026	Re-evaluation of Deceased Donor Testing Requirements
June 2026	Incorporate Multi-organ Post-Transplant Graft Survival into Performance Evaluations
June 2026	Clarify ABO Determination Post-Transfusion

Questions and Discussion

