OPTN

Organ Procurement & Transplantation Network

# HRSA Directive to Reduce the Risk of Donor-Derived Rabies Transmission Policy Approval



OPTN Ad Hoc Disease Transmission Advisory Committee

# Timeline of Policy Development

- **April 2, 2025**: HRSA issued a directive to the OPTN to further reduce the risk of donor-derived rabies transmission.
- **May 6, 2025**: The Committee held its first meeting to discuss the directive; data collection from OPOs initiated
- **Since August 2025:** The Committee, Centers for Disease Control, HRSA, and other OPTN committees have held multiple meetings in support of this effort

**OPTN Meetings and Events Contributing to Policy Development**

| Date | OPTN Meeting or Event |
|---|---|
| May 6, 2025 | DTAC Committee Meeting |
| August 12, 2025 | DTAC Committee Meeting |
| August 18, 2025 | Data Advisory Committee Leadership Meeting[1] |
| August 21, 2025 | Organ Procurement Organization Committee Meeting<br>Transplant Coordinators Committee Meeting |
| August 29, 2025 | Patient Affairs Committee Leadership Meeting<br>Living Donor Committee Leadership Meeting<br>DTAC Committee Leadership Meeting[2] |
| September 2, 2025 | DTAC Committee Meeting |
| September 8, 2025 | Data Advisory Committee Meeting |
| September 22, 2025 | DTAC Committee Meeting |
| November 7, 2025 | Board of Directors Meeting<br>*Board vote to advance to public comment*<br>*Vote tally: 27 approve, 1 reject, 0 abstain* |
| December 19, 2025 – January 18, 2026 | Public comment period |
| March 23, 2026 | DTAC Committee Meeting[3]<br>*Committee vote to advance policy to Board*<br>*Vote tally: 13 approve, 0 reject, 0 abstain* |
| December 2025 – September 2026 | Federal administrative work to ensure access to rabies testing was available to members |
| September 11, 2026 | DTAC Committee Leadership Meeting |
| September 29, 2026 | OPTN Board of Directors Meeting[4] |

# Proposal for Board Consideration

- **Require screening** of all deceased and living donors for high-risk rabies exposures within the last 12 months:
  - Direct contact with bats
  - Bite or scratch from a wild mammal in the United States
  - Bite or scratch from a stray or feral cat
  - Bite or scratch from any mammal outside the United States
- **Require CDC consultation** when any criterion is met (24/7 availability confirmed)
  - Donors are not automatically excluded; Risk assessment is case-by-case
- **Require intended recipient notification** and post-transplant monitoring, including PEP-specific monitoring when applicable

# Public Comment

- 27 total comments received from individuals, organizations, and anonymous commenters
- The community expressed broad support for the proposal

# Committee Response to Public Comment

- **No changes were made to the proposed policy language or data collection requirements**
- The community confirmed the proposal is directionally correct and aligned with existing OPTN processes for similar risk screening
- Primary feedback centered on implementation clarity, not opposition to the policy itself
- Voluntary participation has been ongoing
  - The Committee highlights pre-implementation, voluntary participation as being successful and supportive to increased screening as well as organ utilization
- The Committee determined that a supplemental **implementation guidance document** would further address detailed operational questions

# Implementation

- **OPOs:** Screen all deceased donors, consult CDC if criteria are met, report screening responses (Yes/No) to the OPTN Computer System, and communicate findings to transplant programs
- **Living Donor Transplant Programs:** Include rabies risk criteria in the Living Donor Medical Evaluation and report to OPTN on the Living Donor Registration Form
- **Transplant Programs:** Notify transplant candidates when risk criteria are present; document notification and provide monitoring to transplant recipients per clinical guidelines

# Implementation

- **OPTN:** Will develop and deploy implementation package including notice of policy implementation, guidance document and supportive materials
  - Package may include national webinar, FAQs, UNOS Connect modules, and scenario-based education addressing:
    - CDC consultation process, 24/7 contact information, and workflow
    - Clarified definitions of high-risk exposures, including bat contact scenarios
    - Candidate notification timing and minimum disclosure elements
    - Documentation expectations and compliance standards
    - PEP considerations for immunosuppressed recipients
    - Rationale reinforcing that negative testing does not eliminate risk

# Implementation Resources and Proposed Timeline

*Committee Leadership Review
**DTAC Committee Feedback Requested

| Resource | Audience | Location | Responsible Party | Date |
|---|---|---|---|---|
| Notice of Policy Implementation* | OPTN Members, Public | OPTN Website | Policy Support, Web Team | T- 90 Days |
| Webinar, Recorded* | OPO, Living Donor, and Transplant Hospital Professionals; Public | OPTN Website | Policy Support, Committee | T- 75 days |
| Policy Webpage/ Guidance & FAQ** | OPO, Living Donor, and Transplant Hospital Professionals; Public | OPTN Website | Policy Support, Committee | T- 45 days |

**PENDING BOARD APPROVAL- POLICY STILL UNDER CONSIDERATION**

# Implementation Resources and Proposed Timeline Continued

*Committee Leadership Review
**DTAC Committee Feedback Requested

| Resource | Audience | Location | Responsible Party | Date |
|---|---|---|---|---|
| UNOS Connect Module* | OPOs, Living Donor programs, Transplant Centers, and Vendors with UNET login | UNET | UNOS | T- 45 Days |
| Final Policy Implementation Notice* | OPTN Members, Public | OPTN Website | Policy Support, Web Team | T- 30 Days |

**PENDING BOARD APPROVAL- POLICY STILL UNDER CONSIDERATION**

# Discussion

# Voting Resolution Language

- RESOLVED, that the Board hereby approves the Reduce the Risk of Donor Derived Rabies Transmission Policy as reviewed and approved by the OPTN Ad Hoc Disease Transmission Advisory Committee; and
- RESOLVED FURTHER, that the President and/or their designees are authorized to take all actions necessary to implement this resolution.