



# **HRSA OPTN Modernization Update**

**Summer 2025 Regional Meeting** 

Division of Transplantation (DoT)
Health Systems Bureau (HSB)

Vision: Healthy Communities, Healthy People



## **OPTN Modernization Discovery Tasks**

In September 2024, HRSA awarded multiple OPTN Modernization discovery contracts to apply their expertise and proven experience to improve the national organ transplant system.

They were contracted to **conduct a current state evaluation of the OPTN** and **recommend opportunities for improvement on:** 

- Patient safety
- Patient-centered communication
- OPTN financial management
- Transparency and public engagement in OPTN policy development







# **Applying Insights from Discovery Tasks**



**Patient Safety:** HRSA is collaborating with the OPTN Board to advance critical patient safety initiatives focused on addressing allocation out of sequence (AOOS) and strengthening organ donation and procurement practices



**Communication:** HRSA enhanced OPTN communications by launching detailed webpages on emerging issues and sharing regular Modernization updates to promote transparency



**OPTN Financial Management:** HRSA strengthened oversight of the OPTN operating budget and began developing a new OPTN fee structure and webpage to improve transparency and inform the community of changes



**OPTN Policy Development:** HRSA is working with the OPTN Board, volunteers, and contractors to address AOOS and policy noncompliance, while helping the Board prioritize and implement policy proposals





### **Tools for Increased Accountability and Transparency**

As part of the OPTN Modernization, HRSA took steps to increase transparency, patient safety, and OPTN oversight by improving the processes the public can use to report concerns on how the OPTN operates

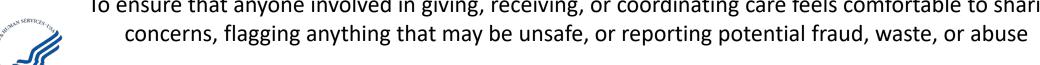
### **Reporting Allegations of Misconduct**

- In April 2025, HRSA instituted a new process to report allegations of misconduct related to organ donation, organ procurement, or organ transplantation
- Under the new process, HRSA will directly receive reports, which were previously routed through the OPTN operations contractor
- HRSA will promptly investigate and take appropriate corrective action if warranted

#### **Critical Comment Process**

- In 2024, HRSA provided the OPTN directives in response to two critical comments
- The critical comment process, as outlined in the Final Rule, allows individuals or organizations to submit written concerns about OPTN policies or practices directly to HRSA
- HRSA may choose to reject the comment, direct the OPTN to revise the policy or practice, or take other appropriate action

To ensure that anyone involved in giving, receiving, or coordinating care feels comfortable to sharing concerns, flagging anything that may be unsafe, or reporting potential fraud, waste, or abuse





## **Patient Safety Policy Reform**

- Patient safety is at the heart of the OPTN Modernization
- A responsive, transparent system is essential to meet emerging clinical, ethical, and operational challenges across donation, procurement, and transplant
- HRSA is collaborating with the OPTN Board to spearhead reform for patient safety issues including:
  - Allocation out of sequence (AOOS)
  - Donation after circulatory death (DCD)
  - Normothermic regional perfusion (NRP)







# **Allocation Out of Sequence Timeline**



Aug. 2024

HRSA provided a critical comment to the OPTN about organ allocation out of sequence (AOOS) and submitted a data request to the OPTN contractor



Feb.-Mar. 2025

HRSA directed the OPTN to create an **AOOS Remediation Plan** and the OPTN submitted a draft



Jun. 2025

OPTN provided operational and analytical **definitions of AOOS**, which was accepted by HRSA



Jul. 2025

HRSA directed OPTN to create an AOOS Workgroup and a 90-day action plan to implement critical components of the Remediation Plan

**OPTN and HRSA exchanged several responses** to further clarify recorded AOOS cases, policy compliance, and monitoring systems



Sep.-Dec. 2024

HRSA directed the OPTN to develop a standard AOOS definition, create an AOOS website, assess member compliance, and promote awareness of allocation policy



HRSA launched a centralized AOOS web page offering background information, ongoing updates, and stakeholder engagement opportunities







# **Donation After Circulatory Death Timeline**



### Sep. 2024

U.S. House of Representatives held a **congressional hearing** titled "A Year Removed: Oversight of Securing the US OPTN Act Implementation"



### May 2025

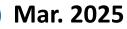
HRSA issued a corrective action plan (CAP) to improve policy compliance in KYDA's DSA and to direct the OPTN to develop policies to improve safeguards for DCD patients

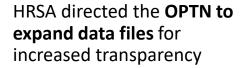


### Jul. 2025

HHS issued a press release titled "HHS Finds Systemic Disregard for Sanctity of Life in Organ Transplant System"

HRSA shared its review of donation after circulatory death (DCD) cases in Kentucky Organ Donor Affiliates' (KYDA) donation service area (DSA) with the OPTN Board







U.S. House of Representatives held a **congressional hearing** titled "Ensuring Patient Safety: Oversight of the U.S. OPTN"







# **Normothermic Regional Perfusion Timeline**



### Sep. 2024

HRSA issued a critical comment letter to the OPTN and requested detailed information and data related to the use of normothermic regional perfusion (NRP)



#### Mar. 2025

HRSA directed the OPTN to **submit a detailed plan** outlining proposed OPTN policies, definitions, data collection, and practices related to patient safety and NRP



#### Sept. 2025

HRSA **feedback** on the draft plan will be provided to the OPTN in September

In **response**, the OPTN sent HRSA details about the use of NRP since 2022 and provided requested data

Oct. 2024

The OPTN provided a **draft plan** which is under review by HRSA

Apr. 2025





### **Recent Modernization Milestones**







HRSA announced new investments to secure financial support for living donors and expand public education efforts to raise awareness about available resources and support.

The 2025 Continuing
Appropriations Act shifted
collection of registration fees
from UNOS to HHS, enabling
improved oversight, transparency,
and funding opportunities for
Modernization.

The Office of Management and Budget (OMB) approved HRSA's request to collect better data to improve the organ matching process.





### **Connect with HRSA**

### Stay up-to-date with OPTN Modernization:



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