



# 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

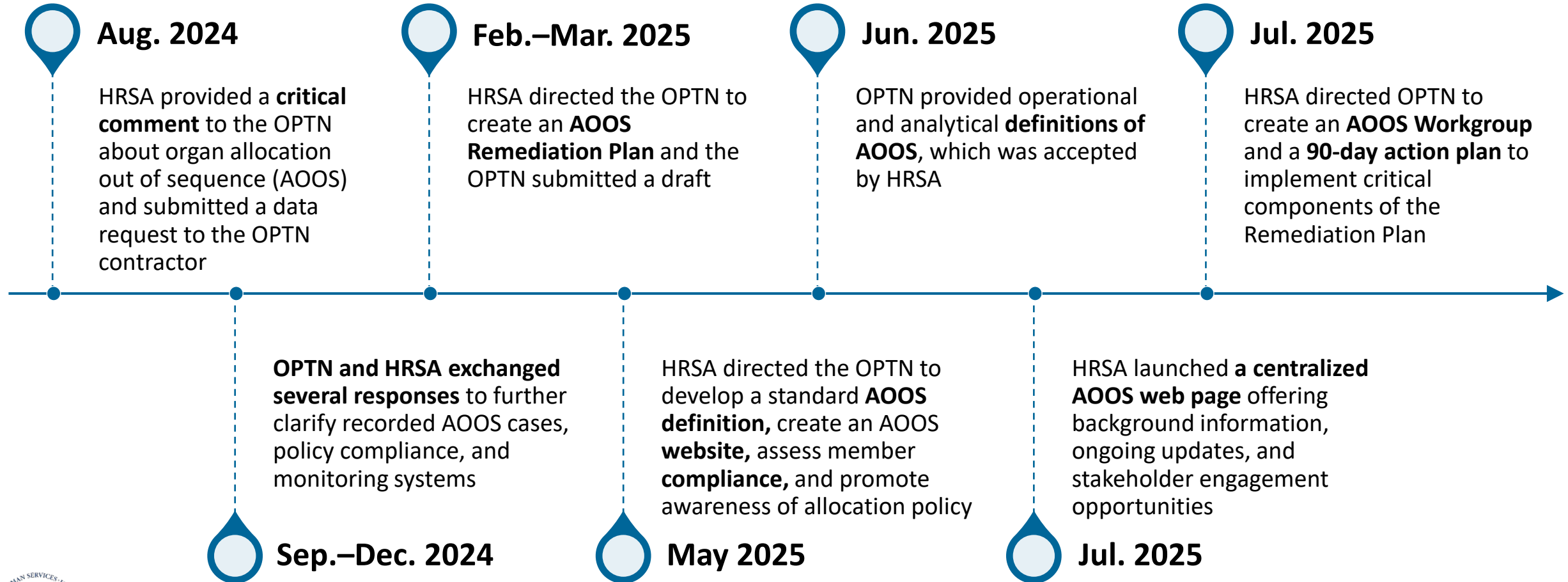


# Patient Safety Policy Reform

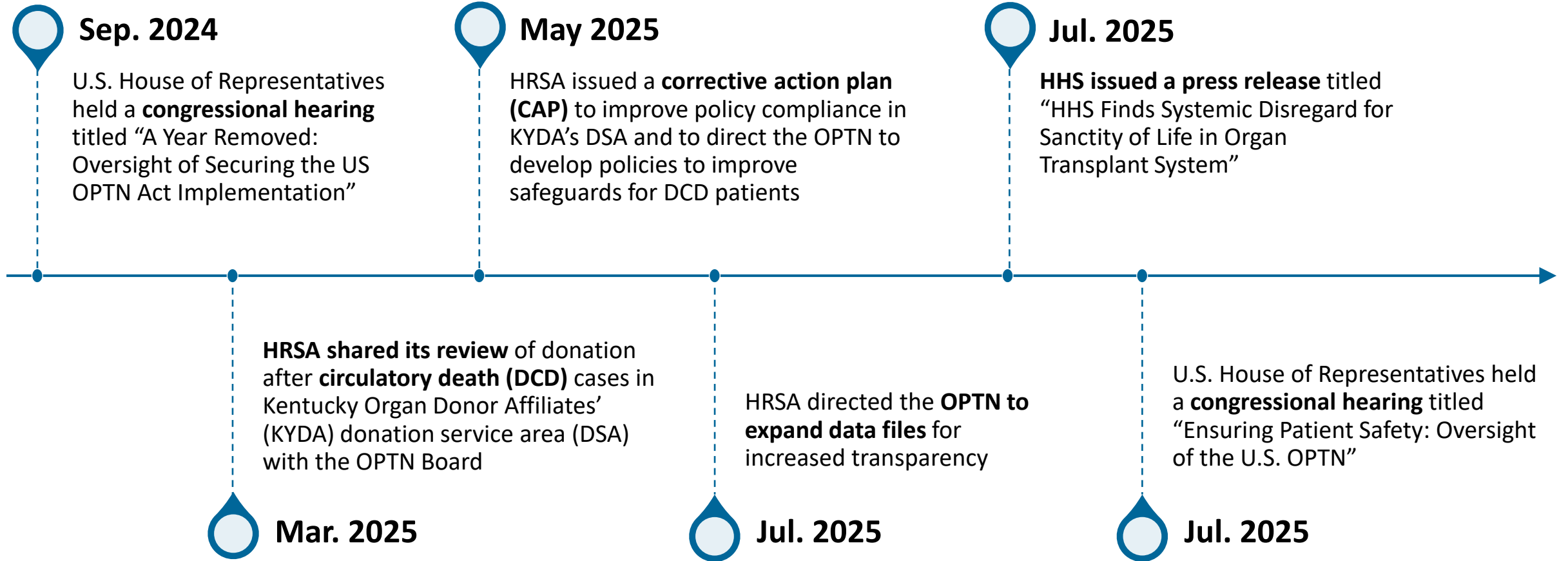
- Patient safety is at the heart of the OPTN Modernization
- A responsive, transparent system is essential to meet emerging clinical, ethical, and operational challenges across donation, procurement, and transplant
- HRSA is collaborating with the OPTN Board to spearhead reform for patient safety issues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



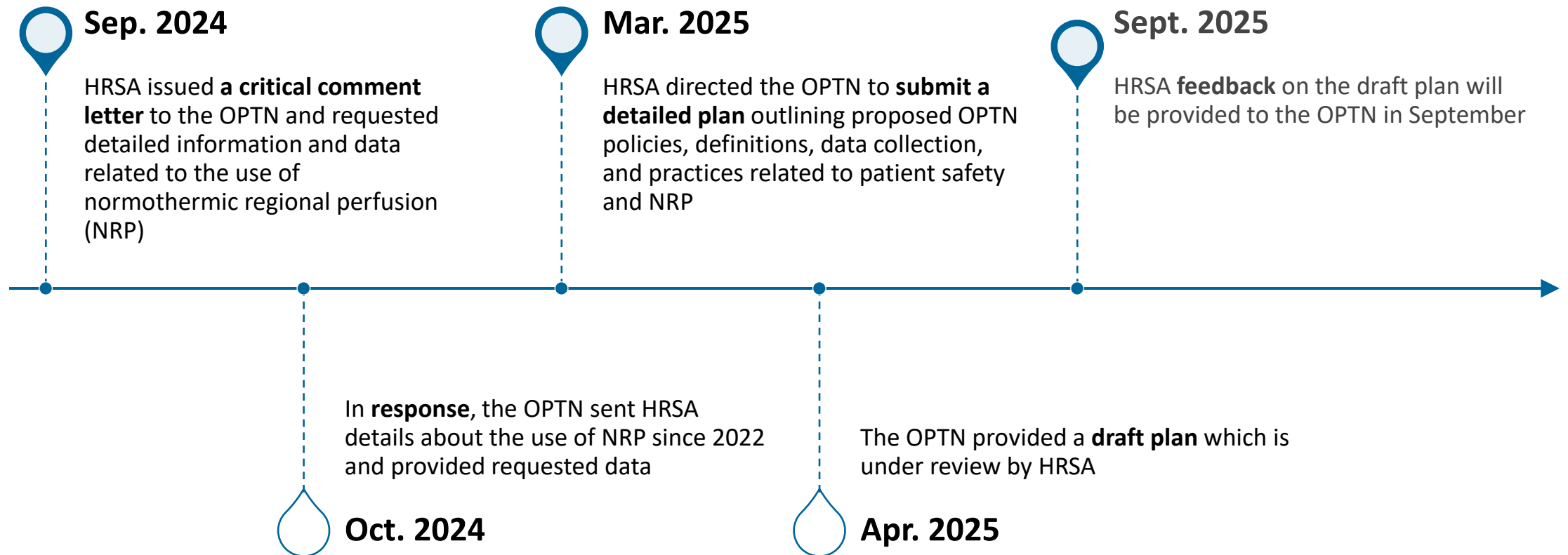
# Allocation Out of Sequence Timeline



# Donation After Circulatory Death Timeline



# Normothermic Regional Perfusion Timeline





# 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**.

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