HHS/DoT – Organ Procurement and Transplantation Network (OPTN) Domain 1 - Transformation

Contract Number: 75R60224D00028/75R60224F34001
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Deliverable Item Number: Item 8, Task 2 - Re-engineering Report
Due Date: 6/6/2025
Date of Submission: 6/6/2025

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Executive Summary

This Re-engineering Report builds on the previous Health and Human Services/Division of Transplantation (HHS/DoT) Organ Procurement and Transplantation Network (OPTN) Mapping Report to deliver evidence-based and best practice recommendations to transform the policy development and governance structures to efficiently modernize and address challenges identified and validated across stakeholders.

Scope and methodology

Using a structured, comprehensive service design approach to transform the HHS/DoT OPTN, this Re-engineering Report builds on the deep understanding of the critical challenges affecting the current policy development and oversight process described in the Mapping Report. These re-engineering recommendations are drawn from evidence-based methods and selected to support a restructuring of the OPTN policy development and oversight process around patient outcomes and experiences as well as feedback received from HHS/DoT. Human Centered Design (HCD) best practices were used to align pain points to HHS/DoT-identified themes and process metrics and tailor future state recommendations to drive improvements.

Project development methodologies and principles include evidence-informed design, thematic problem framing, collaborative, expert engagement, participatory prioritization, and transparency and traceability. A transformational policy development and governance model were developed using the Business Process Re-engineering (BPR) strategic management approach to fundamentally rethink and redesign the OPTN policy process. Using BPR will improve OPTN policy development, efficiency, quality, and stakeholder engagement. These systematic processes use scientific analysis and incorporate adaptive strategies to drive hypothesis development, prioritization, and analysis methods to test those hypotheses, using continuous feedback to enable the swift delivery of sustainable system improvements.

Six-Phase Policy Development Framework

The new Six-Phase Policy Development Framework (SPPDF) focuses on strategic alignment and stakeholder engagement from idea generation through implementation. The objective of the SPPDF is to bring transformational change through modernization and standardization of the OPTN policy development process, address the demand for advanced technologies that enhance mission performance and operations, and address key pain points identified in the current process. Pain points include inefficient prioritization of policies, limited feedback loops, lack of clarity in stages, inconsistent stakeholder engagement, and insufficient tracking of real-world policy impact.

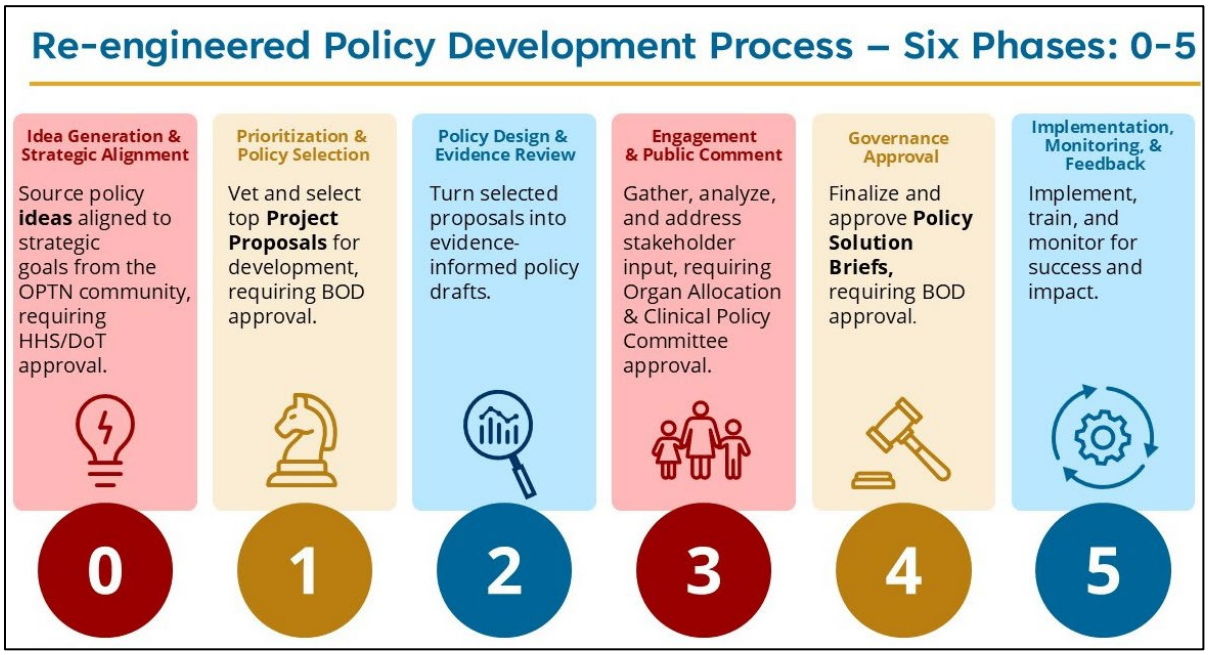

Figure 1: Six Phase Policy Development Process

Governance structure

Modernization of the OPTN policy development and oversight process will be achieved by implementing an expanded Public-Private Partnership (PPP) governance model. This model restructures and strengthens OPTN's current PPP governance structure by creating a functionally distributed, modular governance framework. In this PPP, HHS/DoT collaborates with a streamlined 15 - 20 member OPTN Board and ten function-based committees to guide strategic projects supported by private vendors, promoting innovation and efficiency.

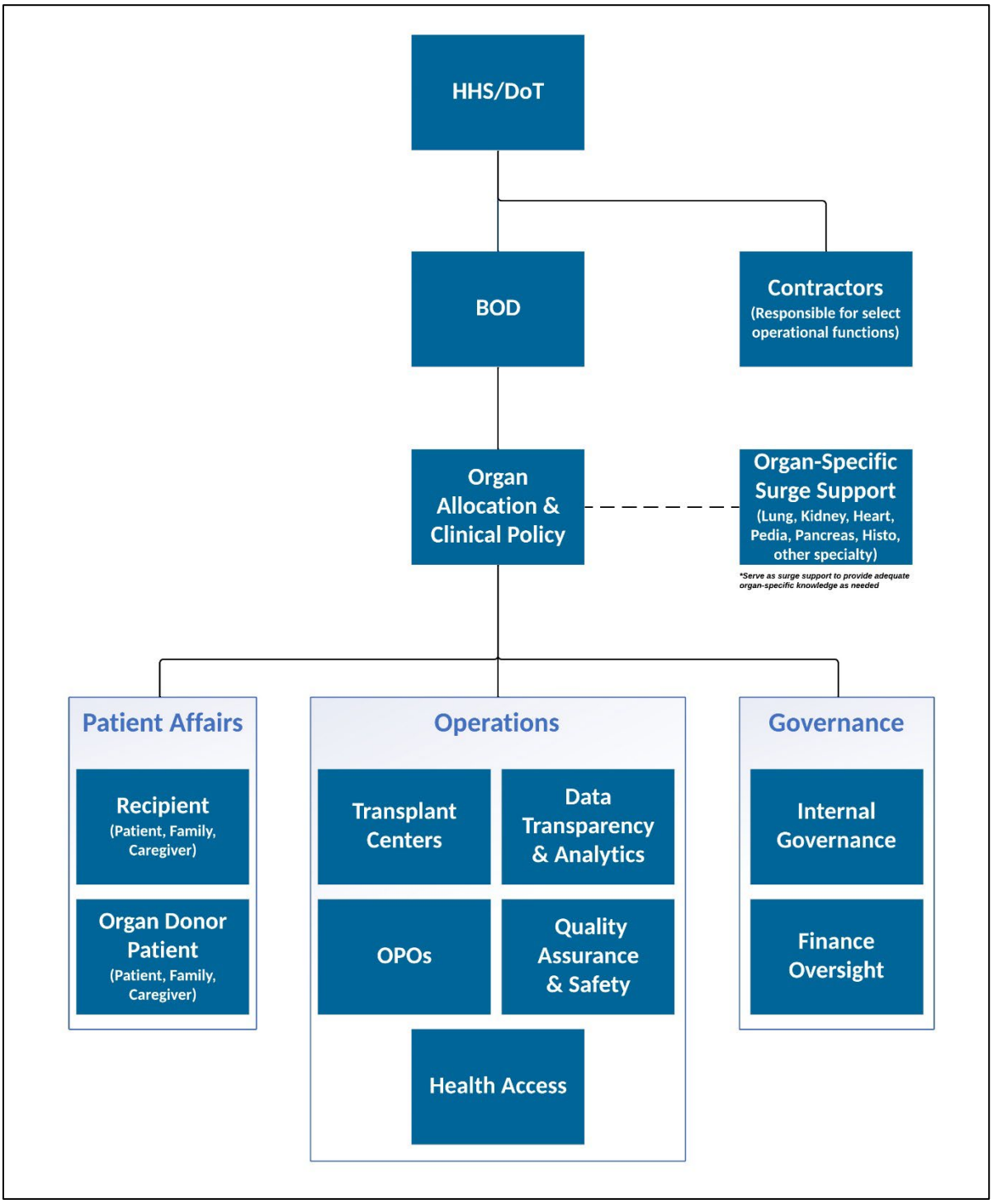

Figure 2: Restructured Governance and Committees Framework

Refer to Section 4.7 for more details on the key components of the PPP, which include the roles and functions illustrated in Figure 2 (above).

Evaluation and Monitoring

Evaluation and monitoring are critical to successful transformation, enabling understanding of how the transformation process is working, quantify and qualify progress, and signal when adjustments are needed. Policy development and governance structures require different evaluation and monitoring approaches using performance metrics to measure outcomes such as committee composition, meeting attendance and engagement, policy proposal status, and the timeframe for policy advancement and implementation.

Risk Assessment and Mitigation

Transformation of system governance and policy development can introduce risks. By identifying these risks early and monitoring them during implementation, actions can be taken to mitigate effects on operations and the implementation of process changes.

Documentation and Reporting

Process documentation is a critical element of OPTN modernization representing a major change from previous OPTN management. Clear, concise documentation provides program transparency, facilitates knowledge transfer, training, and quality management, and serves as a foundation for compliance and auditing. Transparent, clear documentation will lead to increased stakeholder satisfaction and engagement. Initial documentation undergoes continuous improvement through regular reviews, communication, and process enhancement, which will support change adaptation to the new policy and governance models.

Technology Solution Recommendations

Project management tools increase program transparency and accountability and enable tracking of project metrics. This type of tool should be implemented to track policy proposals, workflow automation, team collaboration, deadline management, and visibility across the policy development process. Key features include task dependencies, alerts for bottlenecks, dashboards for leadership oversight and communications and real-time monitoring of progress. Several tools that have customized policy case management support features are described.

Policy Gap Analysis and Opportunities

A policy gap analysis identified policies and documented processes in OPTN that do not currently exist as well as policies that exist but should be revised to strengthen OPTN policy development and governance. Making these policy changes will help define and refine OPTN functions.

Limitations

During the development of the Re-engineering Report, limitations were identified that impacted the scope and depth of the analysis including limited access to existing program data and documentation, project delays, and shifting priorities due to the establishment of the new Administration.

Conclusions, Implementation Roadmap & Next Steps

Ensuring that OPTN's modernization addresses key challenges experienced by stakeholders requires major changes to the policy development process, governance, and stakeholder engagement followed by ongoing monitoring and continuous improvement to ensure that the system processes and technologies are always supported by best practices.

A structured 12-month implementation roadmap describes high level milestones and deliverables broken down into four quarters to support implementation of this policy modernization initiative.

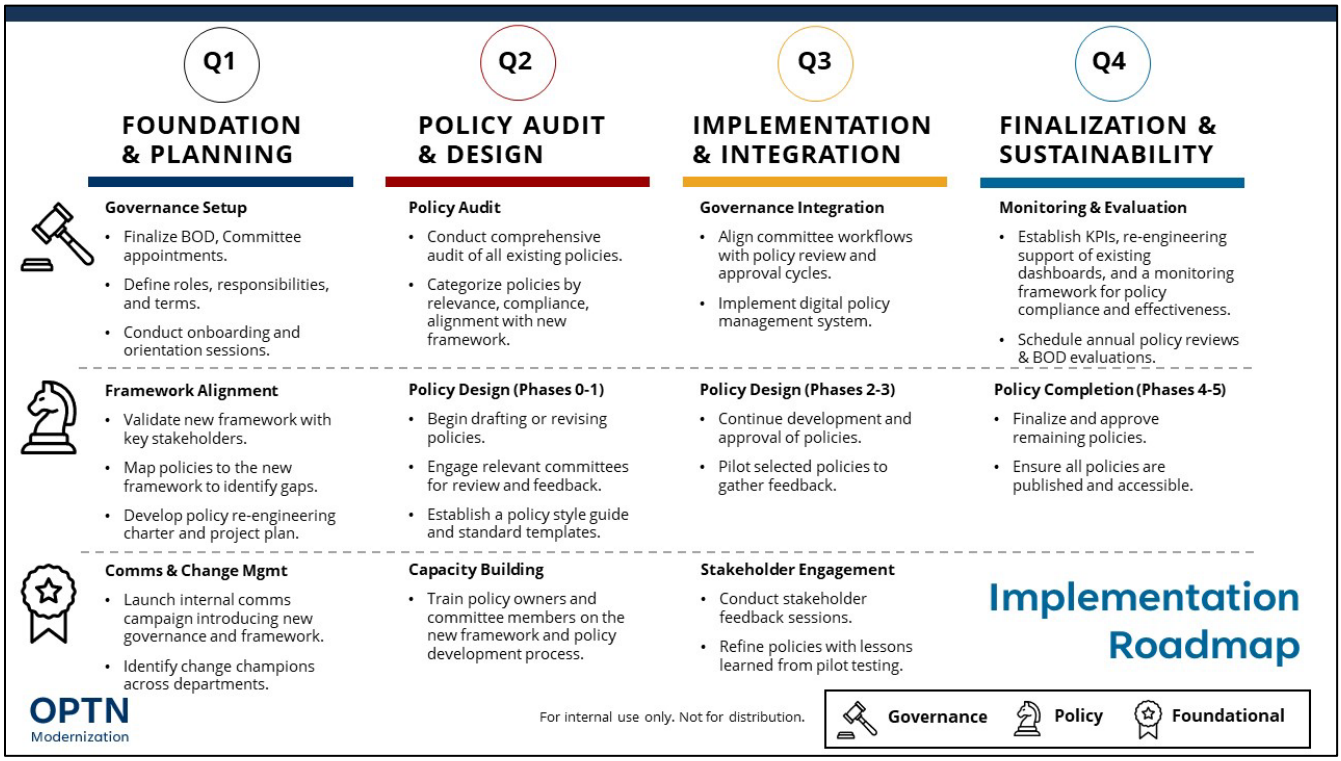

Figure 3: Implementation Roadmap

1 Current State Analysis

The current state analysis of the OPTN policy development process was developed by reviewing OPTN's processes, operations, and required resources using Service Design and Human-Centered Design methodologies. These methods identified the following top OPTN-specific challenges:

- Ineffective policy prioritization
- Long timelines for policy implementation
- Failure to define systems and roles, leading to system inefficiencies
- Lack of transparency and role definition in the Board of Directors (BOD) and committees
- Data quality and availability challenges
- Failure to engage stakeholders.

For additional details on analysis methods and the current OPTN policy development process and analysis findings, please see Appendix A: Current-State Analysis Methodology and Appendix B: Current-State Mapping.

1.1 Synopsis of Key Findings

The most frequently cited overarching gaps and challenges were:

- Lack of clear documentation of criteria and processes
- Lack of transparency and engagement
- Lack of data standardization, collection, and analysis
- Lack of timeliness and efficiency

These issues present different challenges within each theme and were therefore grouped or aligned with solutions addressing multiple themes and gaps to increase efficiency of modernization efforts and transform stakeholder experiences.

For more details on these findings, including excerpts from interviews, desktop review, and meetings of OPTN committee and regional meetings, see Appendix C: Current-State Assessment.

1.1.1.1 Key Stakeholder Insights

Stakeholder segment engagement in the policy development process was analyzed based on Process Metric themes. The table below identifies how stakeholders engage with the policy development process, summarizes the primary issues and identifies where policy enhancements and resource investments will be most effective.

Stakeholder Quote

> *"You know, so you wouldn't know what policies are out there being considered or what policies that you can lend your voice to say if it's bad, good, negative, neutral, whatever, because as the patient, no one tells you that you can actually participate."* – Patient

Table 1: Stakeholder Segments and Primary Insights

Stakeholder Segment	Primary Insights
Patients, Families & Caregivers	Need additional support and training to engage with the OPTN effectively.
Community	Need consistent, timely updates about OPTN policy to effectively advocate for patients, families, and caregivers.
Providers	Need more diverse representation and access to data to inform clinical and policy decision-making.
Industry	Need representation and the ability to provide input on logistical requirements of policy proposals.
Governance (Regulatory, OPTN, Investigation)	Need understanding and ongoing engagement with the updated OPTN oversight system to build trust and coordinate efforts.

For more details on these findings, please see Appendix D: Stakeholder Segment Findings.

1.2 Goals, Pain Points, Recommendations

Developing a transformational strategy to re-engineer the OPTN's policy development process and governance structure required identifying specific goals. Using a design process, SMART goals (Specific, Measurable, Achievable, Relevant, Time-Bound) were created that address the OPTN's current policy development pain points while incorporating strategies to improve stakeholder experiences.

The following SMART goals align with the Mapping Report's pain points and recommendations, enabling effective monitoring, and will ultimately support the development of the strongest, safest, and most effective national organ procurement and transplantation system. Our recommendation for implementing these SMART goals is to prioritize the most critical pain points and the associated SMART goals for optimal achievement.

Refer to Appendix F: Pain Points and Appendix H: Goals, which show pain points and goals in greater detail.

1.2.1 Theme 1: BOD/Committee Composition & Size

1. **SMART Goal:** 100% of committees meet minimum representation criteria.

Table 2: BOD/Committee, Goal 1, Pain Points, Recommendations

Pain Points	Recommendation
• Patient Involvement • Size and Variety	Foster greater representation on committees and the OPTN committee structure

2. **SMART Goal:** 100% of BOD members meet minimum representation criteria.

Table 3: BOD/Committee, Goal 2, Pain Points, Recommendations

Pain Points	Recommendation
• Patient Involvement • Size and Variety	Reduce the number of members and diversify the composition of the BOD and various committees

Pain Points	Recommendation
• Performance Variability	

3. **SMART Goal:** 100% of stakeholders report understanding how BOD and committee members are nominated and selected.

Table 4: BOD/Committee, Goal 3, Pain Points, Recommendations

Pain Points	Recommendation
• Patient Involvement • Accountability & Process Clarity • Diverse Idea Sources	Publish nomination and selection criteria online and disseminate widely. Maintain nominee and selection documentation. Periodically review to identify engagement gaps and consider targeted engagement

4. **SMART Goal:** 100% of members complete member training within 60 days of onboarding.

Table 5: BOD/Committee, Goal 4, Pain Points, Recommendations

Pain Points	Recommendation
• Role Misalignment & Training	Implement an orientation program for new OPTN members
• Patient Involvement • Accountability & Process Clarity	Ongoing training development for committee members
• Accountability & Process Clarity. • Size and Variety • Performance Variability	Include training or learning program for non-medical professionals who are participating on the BOD or a committee

5. **SMART Goal:** Reduce number of committees by 57% from 26 to 10 committees under the new PPP Governance Structure.

Table 6: BOD/Committee, Goal 5, Pain Points, Recommendations

Pain Points	Recommendation
• Size and Variety • Performance Variability	Reduce the number of current committees by identifying areas of overlapping expertise to gain efficiencies
• Performance Variability	Employ a facilitator to expedite the policy process, mitigate conflicts of interest (COI), and improve engagement and transparency

1.2.2 Theme 2: Engagement & Transparency

1. **SMART Goal:** 100% of valid policy data requests acknowledged and completed according to Service Level Agreement (SLA) pertaining to specific data request categories.

Table 7: Engagement & Transparency, Goal 1, Pain Points, Recommendations

Pain Points	Recommendation
• Transparency & Engagement	Review and repurpose existing OPTN dashboards to make them more patient centric.

Pain Points	Recommendation
• Patient Involvement • Long-Term Data Visibility	
• Transparency in Idea Movement	Data lineage, quality, and workflow management (e.g., Collibra, Informatica, Alation)

2. **SMART Goal:** Increase the number of stakeholders who are engaged with organ procurement and transplant policy, procedures, and policy idea submission process.

Table 8: Engagement & Transparency, Goal 2, Pain Points, Recommendations

Pain Points	Recommendation
• Accountability & Process Clarity • Transparency in Idea Movement	Implement a policy platform (e.g., Salesforce)
• Accountability & Process Clarity	Implement a clear process and role definition framework
• Role Misalignment & Training • Accountability & Process Clarity	Expand public awareness and education programs
• Transparency & Engagement • Misaligned Metrics	Scoring criteria for policies or other areas in the process
• Accountability & Process Clarity • Transparency in Idea Movement	Improving the transparency of organ allocation and distribution - Build public trust through openness
• Transparency & Engagement • Patient Involvement • Long-Term Data Visibility	Review and repurpose existing OPTN dashboards to make them more patient centric
• COI • Functional Misalignment	Strengthen OPTN governance structures and communications about them (Overall)

3. SMART Goal: Increase the number of patients added to or engaged with OPTN communication channels.

Table 9: Engagement & Transparency, Goal 3, Pain Points, Recommendations

Pain Points	Recommendation
• Accountability & Process Clarity • Transparency in Idea Movement	Describe and promote updated HHS/DoT oversight and authority content to increase transparency of OPTN processes and build public trust through openness
• Patient Involvement • Public Engagement • Transparency & Engagement	Website and other communications to promote engagement activities for patients and the public
• Transparency & Engagement • Misaligned Metrics	Scoring criteria for policies or other areas in the process
• Transparency & Engagement • Patient Involvement • Long-Term Data Visibility	Review and repurpose existing OPTN dashboards to make them more patient centric.

4. **SMART Goal**: 100% BOD and Committee members complete COI disclosures annually.

Table 10: Engagement & Transparency, Goal 4, Pain Points, Recommendations

Pain Points	Recommendation
• COI	Strengthen COI policies in organ procurement and transplantation governance

1.2.3 Theme 3: Timeliness

1. **SMART Goal:** Reduce average policy development cycle time by 25%.

Table 11: Timeliness, Goal 1, Pain Points, Recommendations

Pain Points	Recommendation
• Process & Role Definition	Use modeling software to assess the success of policies (e.g., Simul8)
• Prolonged Timeliness	Establish defined timelines and specific guidelines for each stage of the policy development process
• Data Acquisition Delays	Develop a "data lake" or central platform for stakeholders to use
• Prolonged Timelines	Reduce and diversify the composition of the BOD and various committees
• Prolonged Timeliness • Process & Role Definition	Latency/timeliness tracking

2. **SMART Goal:** 100% of policy proposals tracked through standardized stage gate framework; (requires establishing standards, timelines per stage and defining milestones).

Table 12: Timeliness, Goal 2, Pain Points, Recommendations

Pain Points	Recommendation
• Transparency in Idea Movement • Transparency Issues	Website to track all policy proposals, updated to reflect where it is in the process
• Accountability & Process Clarity	Implement a clear process and role definition framework
• Prolonged Timeliness	Establish defined timelines and specific guidelines for each stage of the policy development process

1.2.4 Theme 4: Data Availability

1. **SMART Goal:** 100% of policies are reviewed for effectiveness within 12 months of implementation.

Table 13: Data Availability, Goal 1, Pain Points, Recommendations

Pain Points	Recommendation
• Oversight Challenges • Divergent Data Requirements	ugg

• Standardization Issues • Misaligned Metrics	
• Inadequate Dashboards	Leverage technology for real-time feedback and review and repurpose existing OPTN dashboards to make them more patient centric.
• Misaligned Metrics	Scoring criteria for policies or other areas in the process

2. **SMART Goal:** 100% of data request tools and dashboards are available and demonstrating ongoing member engagement.

Table 14: Data Availability, Goal 2, Pain Points, Recommendations

Pain Points	Recommendation
• Standardization Issues • Misaligned Metrics • System Integration	Implement a policy platform (e.g., Salesforce)
• Standardization Issues • Misaligned Metrics	Create a dynamic dashboard for real time data decision-making
• Inadequate Dashboards • Transparency & Engagement	Automate public comment feedback with a digital dashboard platform.
• Inadequate Dashboards • Oversight Challenges • Misaligned Metrics	Data lineage, quality, workflow management (Collibra, Informatica, Alation)

1.2.5 Theme 5: Prioritization & Post Implementation Review

1. **SMART Goal:** 100% of proposals scored using a rubric that reflect strategic HHS/DoT goals (e.g., as identified in the HHS/DoT Update on May 25, 2025, fairness, safety, effectiveness, as well as urgency, feasibility, impact).

Table 15: Prioritization, Goal 1, Pain Points, Recommendations

Pain Points	Recommendation
• Inefficient Prioritization • Poorly Set Metrics	Implement a policy prioritization framework for policy development using the Centers for Disease Control and Prevention (CDC) Polaris Policy Process
• Inefficient Prioritization	Use modeling software to assess the success of policies (e.g., Simul8)
• External Distractions	Establish a "fast-track" process for high-priority policies
• Poorly Set Metrics • Inefficient Prioritization	Scoring criteria for policies or other areas in the process

Pain Points	Recommendation
• Inefficient Prioritization • Transparency Issues	Addressing health fairness in organ procurement and transplantation: Eliminate disparities in listing, allocation, and post-transplant care
• Inefficient Prioritization	Cost effectiveness analysis
• Inefficient Prioritization • COI	Use key components of the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework which provides more structure in the policy development process

2. **SMART Goal:** All policy decisions shared publicly with rationale within 30 business days.

Table 16: Prioritization, Goal 2, Pain Points, Recommendations

Pain Points	Recommendation
• Transparency Issues	Review and repurpose existing OPTN dashboards to make them more patient centric.

3. **SMART Goal:** All policy decisions that require a formal vote include documented participation from a quorum of relevant committee members.

Table 17: Prioritization, Goal 3, Pain Points, Recommendations

Pain Points	Recommendation
• Transparency Issues • Role Definition	Implement a policy platform (e.g., Salesforce)
• Transparency Issues	Review and repurpose existing OPTN dashboards to make them more patient centric.

2 Scope & Methodology

Re-engineering the policy development and oversight process and documenting the plan to implement this transformational vision required a structured and comprehensive approach aligned with our service design methodology. This process builds on the understanding of the critical challenges affecting the current system identified during the mapping phase of the project. We used HHS/DoT feedback and evidence-based methods to reorient the process around patient outcomes and experiences.

HCD best practices identified the key interactions involved in the development, implementation, and public understanding of policy. Driving change required the ability to look holistically at problems, while rapidly narrowing down and executing specific solutions.

Based on pain points aligned to HHS/DoT-identified themes and process metrics, future state recommendations were tailored to improve those metrics.

2.1 Guiding Principles & Methodology for OPTN Policy Process Modernization

The following principles guided the methodology:

1. Evidence-informed design

A comprehensive synthesis of current state review and current state service blueprint was developed to uncover pain points and areas of dysfunction in the policy development process, based on process metric themes of BOD and Committee composition, Engagement and Transparency, Timeliness, Data Availability, and Prioritization Methodology.

2. Thematic problem framing

Recurring pain points were identified and clustered to reveal persistent structural and procedural barriers or problems in the process. These became the foundation for developing goals and solutions corresponding to identified problem areas.

3. Collaborative, expert engagement

A multidisciplinary team of policy, public health, analysis, and service design experts co-created draft goals. The workshop-based model created triangulation of perspectives and built consensus, leveraging the team's expertise while strengthening validity by reducing individual bias through group synthesis and discussion.

4. Participatory prioritization

Broad goals for each process were developed, followed by specific and measurable objectives to accomplish them. The prioritization process followed a structured framework in which team members weighed potential goals by evaluation criteria such as alignment with public health best practices; impact, defined as applicability across multiple process metrics; operational and political feasibility; and adherence to OPTN Modernization goals including patient centric approaches. The prioritization process followed a structured framework in which team members weighed potential goal by evaluation criteria such as alignment with public health best practices; impact, defined as applicability across multiple process metrics; operational and political feasibility; and adherence to OPTN Modernization goals including patient centric approaches. This approach mirrors widely accepted practice in public sector strategy work, such as the development of the United Nations Sustainable Development Goals and community development initiatives in which community organizations and local governments identify and prioritize community-specific needs.

5. Transparency and traceability

Ensured that each goal and each objective was traceable to an identified critical pain point in the Mapping Report. This traceability strengthens our understanding of the holistic HHS/DoT OPTN system and ensures that goals remain tied to the operational realities and human impact of the program.

2.2 Policy Development Process Re-Design

The primary focus remained on the needs of key audiences, identifying and prioritizing their issues, and ensuring that solutions were validated by incorporating stakeholder feedback throughout the design process.

Stakeholder Quote

> *"I always think that we don't have enough patients, you know, or people who are involved. Sometimes physicians and nurses can get very medical, and if you're not a medical person and you're sitting in there, it can be a little bit overwhelming. Sometimes they forget about how this affects the patient."* – Committee Member

The collected information generated ideas and established priorities as hypotheses were refined. Special attention was given to reaching harder-to-engage or underrepresented groups. These strategies fostered an equitable and responsive environment where every voice was acknowledged and valued, and ultimately resulted in more holistic, effective, and sustainable policy recommendations.

Re-engineering Process Steps:

Step 1: Re-engineering the Process Around Patient Outcomes, Functionality, Engagement, and Accountability

The first step required re-engineering the policymaking process with a focus on patient outcomes and experiences, addressing the most critical challenges surfaced during the mapping phase of the project. After completing an extensive evidence-based review into policymaking methodologies and processes, the most impactful solutions were prioritized and documented in a future-state service blueprint, like the current-state document delivered in conjunction with the previous report. This blueprint emphasized patient outcomes and the overall patient experience, ensuring that the redesigned process is effective, patient-centered, and addresses the critical challenges discovered around functionality and accountability.

Step 2: Identify the Gaps Between Current and Future-State Processes

Next, an in-depth gap analysis was conducted to identify changes required in terms of people, processes, technology, and policy to guide OPTN stakeholders from the current process to the transformed future state.

Step 3: Document the Implementation Plan

Based on the findings from the gap analysis, a comprehensive implementation plan was developed to guide HHS/DoT and OPTN in successfully establishing the reimagined OPTN governance structure and policy development process. This plan outlines the necessary steps, resources, and timelines required to transition from the current state to the future state and proactively addresses key risks and mitigation strategies for them.

Step 4: Visualize the Implementation Roadmap

The visual roadmap outlines the necessary activities for transitioning to the transformed future state to ensure clear communication and effective execution. This roadmap offers a clear and concise overview of the implementation journey, highlighting key milestones, timelines, and responsibilities. Visualizing this roadmap ensures that all stakeholders share a common understanding of the process, enabling effective collaboration towards achieving the transformational vision.

2.3 Governance Model and Policy Framework Selection & Implementation Approach

Using the BPR strategic management approach, a transformational policy framework and governance model were developed that will ensure enhanced OPTN policy performance, efficiency, quality, and stakeholder satisfaction. An agile, user-centered BPR process incorporated best practices to identify, evaluate, and plan for process changes. These systematic processes use scientific analysis and continuous feedback to enable the swift delivery of sustainable improvements. Additionally, this tailored integrated framework incorporates adaptive strategies for hypothesis development, prioritization, and analysis methods to test those hypotheses. Successful transformation will require engagement and transparency during both the implementation phase and the post-implementation review phase.

The figure below (figure 4) explains the framework of activities during the comprehensive Policy Mapping, Analysis, and Design Mapping and Re-engineering Process that uses an agile, user-centered BPR process and best practices to identify, evaluate, and plan for implementing a process change. The blue side of the graphic illustrates the Policy Developer Design Mapping and Analysis Business Process. The green portion of the graphic illustrates the Integrated Approach to Hypothesis-Driven Business Process Re-engineering.

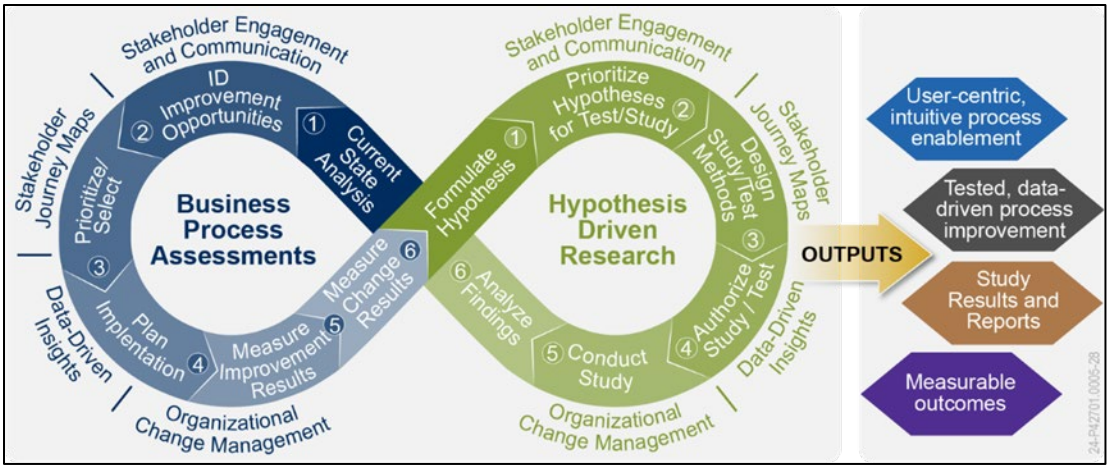

Figure 4: Activity Flow for the Policy Mapping, Analysis, & Design Mapping & Re-engineering Process

The proposed hybrid policy framework and governance structure brought together in a comprehensive future-state blueprint aims to incorporate evidence-based practices to address critical pain points raised during the current state assessment.

1. Prioritizing Pain Points

The first step was to prioritize the most critical pain points affecting core process metrics discovered during the current state assessment. This step ensured that the focus remained on solving problems that significantly impacted accountability, functionality, and patient outcomes, structuring the analysis and ideation around the areas of the current process most in need of improvement.

Stakeholder Quote

> *"If you wipe away all the patients, you don't have an OPTN or United Network for Organ Sharing (UNOS) because you just got doctors talking to each other with no result."* – Patient

2. Analyzing Evidence-Based Frameworks

Following the prioritization of pain points, extensive review, study, and analysis was conducted to explore proven, evidence-based policy design frameworks and governance structures, including best practices for committee structures. This analysis included a review of best practices and frameworks that had successfully addressed similar challenges in other contexts, like at the CDC and the Organisation for Economic Co-operation and Development (OECD). The goal was to identify solutions most likely to resolve the issues identified during the current state assessment.

3. Collaborative Prioritization and Hybrid Model Development

In this phase, the team set evaluation criteria to rank and assess various features that could be included in a hybrid model. The criteria ranged from alignment to OPTN Modernization Initiatives (e.g., Governance, Operations, Quality Improvement, and Innovation, etc.) to resolving COIs to assessing the feasibility of implementation.

Voting was conducted on a 3-point scale, with 1 indicating the least alignment and 3 the strongest, followed by discussion to align on the best features and integrating them into a cohesive, hybrid framework that aimed to fill gaps in the current process and address the core pain points prioritized.

4. Developing the Future-State Service Blueprint

The final phase involved visualizing a detailed, comprehensive future-state service blueprint. This blueprint illustrated how the hybrid policy framework and governance structure would function in practice, addressing the critical pain points identified earlier. The blueprint will serve as a roadmap for implementing the new framework, ensuring a clear and actionable plan for transformation.

3 Six-Phase Policy Development Framework Overview

3.1 Background (Current Limitations)

An analysis of OPTN's current policy development process revealed challenges that impede effective and efficient policymaking, contributing to a lack of trust in the overall OPTN system. As described earlier in this report, issues with OPTN's policy development process include:

- Inconsistent policy prioritization standards
- Prolonged policy development and implementation timelines
- Undefined systems and roles
- Lack of transparency and role clarity
- Data quality and availability issues
- Lack of stakeholder engagements

Stakeholder Quote

> *"Transplant, relative to many other healthcare contexts, is highly dynamic and changing. The technologies are changing very rapidly, the science is changing very rapidly, so there's a clear failure in us to keep up on a policy…. and so, we can't be five years behind the curve to really be informative."* – Committee Member

3.2 Description of New Six-Phase Policy Development Framework (SPPDF)

The SPPDF focuses on strategic alignment and stakeholder engagement from idea generation through implementation. The stages of this framework include:

- Phase 0: Idea Generation and Strategic Alignment
- Phase 1: Prioritization and Selection of Policies
- Phase 2: Policy Design and Evidence Review
- Phase 3: Stakeholder Engagement and Public Comment
- Phase 4: Governance Approval
- Phase 5: Implementation, Monitoring, and Feedback

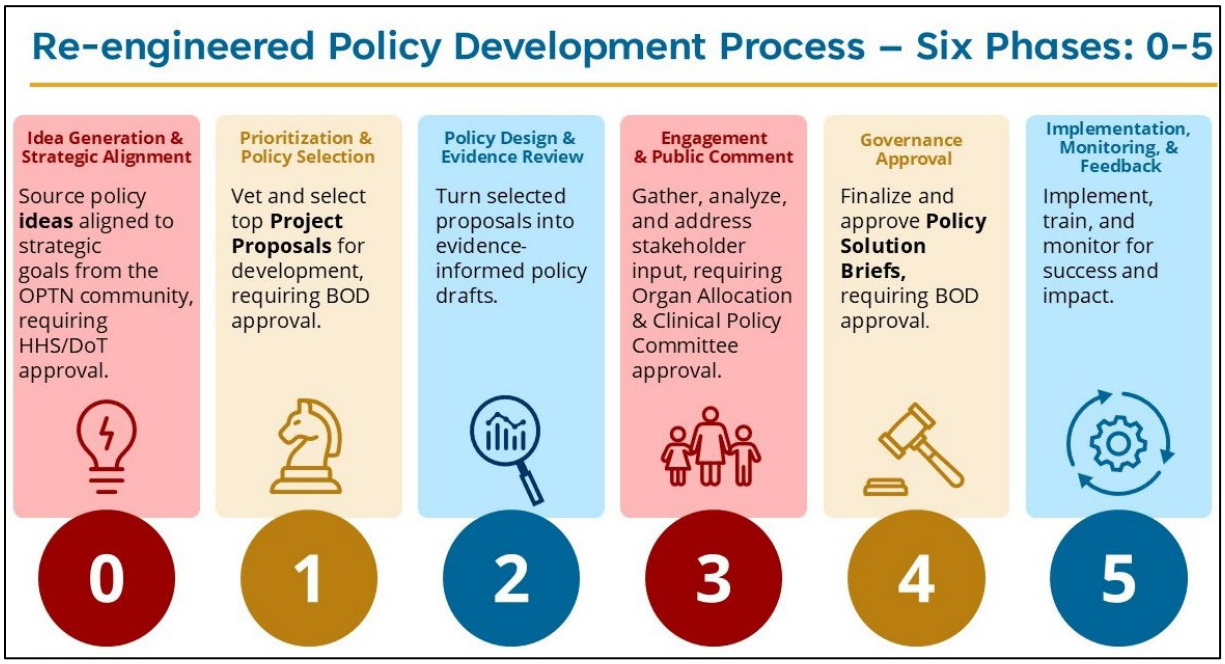

Figure 5: Six-Phase Policy Development Process

3.3 Objective

The SPPDF brings transformational changes that address enhanced mission performance and operations through stakeholder engagement enabled by advanced technologies. In tandem with the expanded PPP governance model, they address key pain points like: inefficient prioritization of policies, limited feedback loops, lack of clarity in stages, inconsistent stakeholder engagement, and insufficient tracking of real-world policy impact.

3.4 Rationale for Choosing SPPDF

The SPPDF draws from the following public health and implementation science models: the CDC Polaris Policy Process, the RE-AIM Framework, the Exploration, Preparation, Implementation, and Sustainment (EPIS) Framework, the Pew Charitable Trusts evidence-based, policymaking Framework, and the Agile Policy Development Framework (APDF), adapted to meet the OPTN's unique needs.

This recommendation emerged from internal review of the key gaps in the existing OPTN policy development and oversight processes and mapping them to evidence-based solutions drawn from implementation science. Pain points in the current model included limited stakeholder engagement, inefficient prioritization of policies, lack of timeliness, feasibility concerns with approved policies, and absence of a structured feedback loop to assess whether policies achieved intended outcomes after implementation.

Grounded in the evidence-based CDC Polaris Policy Process, the SPPDF addresses these gaps by providing a structured and dynamic approach to policy development (problem identification, policy analysis, strategy and policy development, and policy enactment) that provides flexibility and addresses

process ambiguity. Key strengths of this process are strategic alignment, stakeholder involvement, and evidence-based decision-making.

The SPPDF is tailored for the OPTN with enhanced elements from the RE-AIM framework to establish a formal mechanism for performance measurement and post-implementation review. This addition allows for assessing whether individual policies are effective in practice and whether the framework itself is functioning as an equitable and evidence-driven system.

The EPIS framework improves the implementation of an approved policy by evaluating system-level and governance functions, and the interaction between these elements and the policy being implemented. EPIS guides stakeholder engagement, identifying contextual factors that influence policy adoption by stakeholders such as Organ Procurement Organizations (OPOs) and transplant centers, and supports the monitoring of an implemented policy.

The Pew policy framework provides approaches to funding decisions using performance data and return on investment (ROI) estimates to prioritize programs. A well-functioning performance measurement system can assist stakeholders in determining where to allocate funding using summaries, rankings, and dashboards that aid in decision-making. Moreover, it will ensure that relevant review and evaluation findings are discussed during budget processes and that findings are based on data, performance metrics, and other evidence.

The APDF ensures stakeholder input and accountability and incorporating continuous feedback loops and metrics in policy development. This framework treats policies like software components, allowing for continuous improvement cycles where policies are defined, tested, deployed, then refined as needed to achieve desired health outcomes. Sprints occur in two–to-six week cycles after which policy development team(s) document lessons learned and best practices with each cycle, creating a continuous improvement feedback loop. The APDF is most effective when supported by resources like GRADE Evidence to Decisions tool to understand policy trade-offs, digital platforms (e.g., Jira, Trello) for backlog and sprint tracking, stakeholder management tools for transparent feedback and testing, and HHS/DoT's modernization infrastructure to support agile workflows.

3.5 Advantages and Expected Benefits of the SPPDF

Advantages and expected benefits of the proposed framework include:

- Streamlined policy process, cutting time from idea submission to implementation.
- Strong policy sequencing construct tailored for the OPTN with pre-policy engagement and post-policy monitoring.
- Outcome monitoring and targeted evaluation, effectiveness, scoring methodology allowing tracking of impact, outcomes, long term viability, and learning.
- Built-in feedback loops, refinement stages, and adaptation capabilities to encourage an iterative and adaptive process, including incorporating HHS/DoT feedback from end to end.

- Spans policy strategy, governance, implementation, and stakeholder roles while keeping patients at the center.
- Stakeholder engagement opportunities built into each phase of the framework.
- Modeled after public health and implementation science frameworks to ensure fairness, transparency, stakeholder engagement and alignment to team policy outcomes and goals.

Stakeholder Quote

> *"Probably the most important thing in creating change on policy is looping back and closing the loop with those who've been involved in it. So, I'd say it's been a less than stellar experience having people understand, both professionals and patients, at the point of origination, where did it end up? And then what was the implementation of it?"* – Family Member

Reducing the duration of the policy development process is a pillar of the SPPDF, addressing complaints that the current process takes too long. For example, the average time from idea to project approval to OPTN BOD approval in the past 5 years (2020 to 2024) was approximately 368 days (low 257, high 525 days), and the average time from board approval to implementation was approximately 174 days.

Stakeholder Quotes:

> *"Science moves fast and so if you wait 18 months to implement something the field may have already changed by that time."* – Transplantation professional

> *"We're presented with a process that takes longer than we're going to even serve on the committee, it's disheartening."* – Committee member

Alternatively, the goal for the timeframe for the entire SPPDF policy process, from idea submission to policy implementation, is approximately 262 to 292 days. The table below represents the expected duration of each phase of the SPPDF's policy development process. As the new process is documented and implemented, additional ways to reduce the time will be identified.

Table 18: Policy Development Duration Improvement

Phase	Description	Duration
Phase 0: Idea Generation and Strategic Alignment	Each new policy proposal would be reviewed within 30 days of submission.	30 days
Phase 1: Prioritization and Policy Selection	Each new policy proposal would be evaluated on a scoring rubric and prioritized within 30 days after Phase 0.	30 days

Phase	Description	Duration
Phase 2: Policy Design and Evidence Review	Each policy will undergo policy design and evidence review. A completed policy draft is prepared for public release.	42 days
Phase 3: Stakeholder Engagement and Public Comment	Each policy draft is prepped and released for public comment. Public comments are analyzed.	70 days (2weeks for prep, 6 weeks for public comment, 2 weeks for analysis)
Phase 4: Governance Approval	Each policy solution brief is revised, incorporating stakeholder feedback and public comments. BOD approval is obtained.	60-90 days
Phase 5: Implementation, Monitoring, and Feedback	Each policy is implemented according to the HHS/DoT-approved implementation plan.	30 days Ongoing monitoring will be conducted post-implementation

3.6 SPPDF Patient, Donor, and Family Engagement Opportunities

The SPPDF places recipient patients, registered and prospective organ donors, donor patients, and their families at the center of policy development, implementation, and evaluation. This inclusive approach ensures that the lived experiences and perspectives of those most directly impacted by organ procurement and transplantation policies are integral to shaping impartial, effective, and transparent outcomes.

Table 19: Sis-Phase Patient, Donor, Family Engagement Opportunities

Engagement Opportunities	Description
Active Participation in Policy Development	Recipient patients, registered and prospective organ donors, donor patients, and families are empowered to initiate change by submitting policy ideas that are documented, evaluated for strategic alignment, and developed into formal proposals. Every idea submission is tracked, and the submitter is informed of the idea's trajectory throughout the policy development process.
Representation in Policy Design Teams (PDTs)	Each PDT includes 1-2 members from the recipient and organ donor patient committees. Patient and donor representatives contribute to structuring review plans, interpreting data, and drafting policy solution briefs. Their involvement ensures the patient and donor voice is embedded in every stage of policy design.
Influence through Public Comment and Feedback	The SPPDF emphasizes transparency and public engagement. Patient and donor representatives review Policy Solution Briefs before they are finalized. Feedback collected during this phase is analyzed and used to revise proposals, ensuring that public input is meaningfully incorporated.

Engagement Opportunities	Description
Support During Implementation and Monitoring	Beyond policy approval, patients and donor representatives continue to play a vital role during implementation by shaping educational materials and engagement campaigns to ensure they are accessible and relevant. Their feedback is also critical in monitoring policy performance, identifying areas for improvements, and guiding iterative refinements.
Driving Accountability and Transparency	The OPTN community is kept informed of all policy decisions, including approvals, rejections, deferrals, and budget allocations. This transparency fosters trust and accountability, reinforcing the legitimacy of the policymaking process.

3.6.1.1 Future State Stakeholder Engagement

The figure below (figure 6) is a thumbnail of the Future State Stakeholder Engagement visual, which shows how a policy idea is developed into implemented, managed policy solutions and how patients, registered and prospective organ donors, and their families are centrally involved throughout the entire process. The chart below is described in detail by phase in Section 7.2.2 Sample of Policy Development Process.

Note: Re-engineering Report submission includes a Portable Document Format (PDF) of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view.

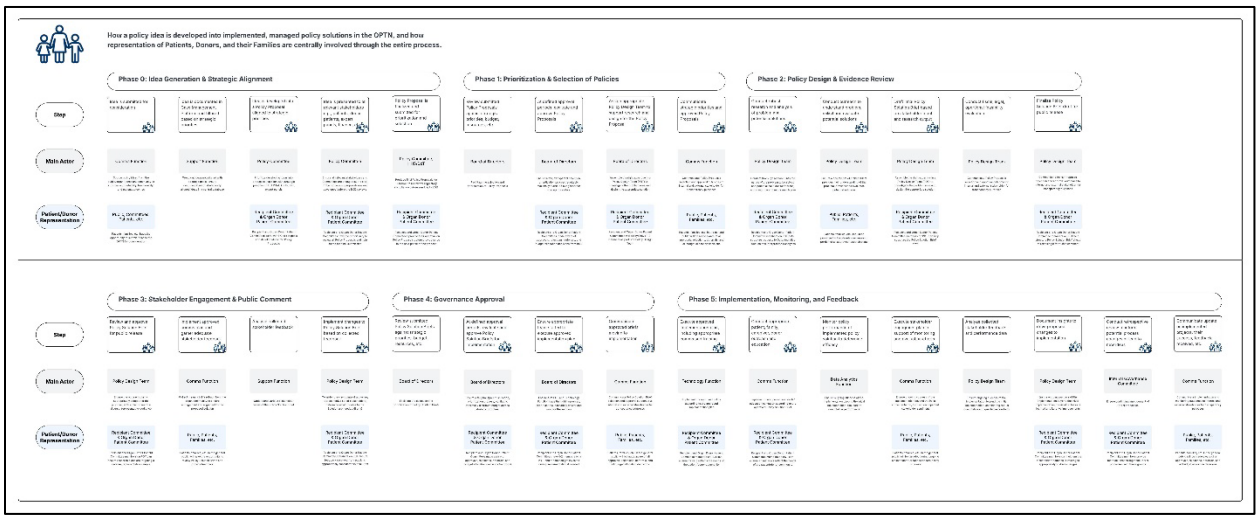

Figure 6: Future State Stakeholder Engagement

3.7 Key Components of the SPPDF

The key components of the SPPDF are outlined in the table below including stakeholders and their roles for each phase of the process and timeframe:

Table 20: Six-Phase Framework Key Components

Phase	Overview	Tasks
Phase 0: Idea Generation and Strategic Alignment	Policy ideas are sourced from the organ procurement and transplantation community and aligned with OPTN's strategic goals. Stakeholders across the network can submit ideas addressing the strategic priorities of the OPTN and issues pertaining to the needs of the organ procurement and transplantation community. Ideas are sourced and documented via public-facing website	• Conduct targeted engagement to source ideas that represent the organ procurement and transplantation community. • Evaluate each idea, score them on strategic priorities, and submit a policy proposal draft. • Review ideas on a regular cadence. • Collaborate with relevant stakeholders to develop proposals and necessary updates based on feedback. • HHS/DoT conducts review and approves policy proposals to ensure alignment with strategic priorities.
Phase 1: Prioritization and Policy Selection	Policy proposals that are moved to this phase will be scored on a rubric considering their feasibility, alignment with strategic priorities, costs, and other factors. They will be voted on and prioritized based on their score. The PDT is organized and given analysis assignment.	• BOD reviews and votes on policy proposals. • Information, including voting decisions, documented in case management system and communicated via a template • A facilitator will assist in identifying areas of consensus, when to proceed with a proposal, and manages BOD and committee meetings. • A budget is determined and allocated to each policy. • Approved policy proposals are communicated to internal and external stakeholders. • The PC designates members of the PDT with approval from BOD. • HHS/DoT approves policy proposals to advance to the next phase and approves the release communication.
Phase 2: Policy Design and Evidence Review	Approved policy proposals are subject to robust review, study, and analysis, including an evaluation of the policy's	• The PDT conducts a review, study, and analysis of the problem.

Phase	Overview	Tasks
	fiscal, legal, and operational feasibility. The outcome of this phase will be a completed policy draft for public release.	• Targeted engagement is sent to committees, organ-specific panels, and other relevant stakeholders to understand the problem and gathering feedback about the proposed solution is conducted. • The PDT team will review the brief for fiscal, legal, and operational feasibility, consulting with SMEs as needed. • Stakeholder feedback is analyzed. • The PDT lead determines when analysis is complete, and the brief is ready for review. • Review and the final policy solution brief are documented in the case management system, including information regarding the length of the Public Comment period and metrics to measure the policy's success.
Phase 3: Stakeholder Engagement and Public Comment	The draft of the policy solution brief is reviewed and submitted for public comment. Analysis of public comments is conducted. A final policy solution brief, incorporating desk review, public comment analysis, and an implementation and monitoring plan, is documented in the case management system.	• A communications plan, including ways to engage a diverse representation of stakeholders in the public comment period is developed. • Diverse representation of stakeholders in the public comment period is developed. • Policy proposals are published online for feedback. • A public comment period is announced for completed policy drafts. • Stakeholders are notified that policies are ready for public comment. • Stakeholder feedback will be supplemented by live webinars and regional meetings with question-and-answer sessions. • Stakeholder feedback is collected and analyzed.

Phase	Overview	Tasks
		• Feedback is incorporated into the proposal. • The final policy solution brief, incorporating desk review and public comment analysis, is documented in the case management system. • The final policy solution brief also includes an implementation and monitoring plan.
Phase 4: Governance Approval	A completed policy solutions brief, incorporating public feedback analysis, will be submitted to the BOD for approval. The BOD will provide a list of approved projects that will be documented in the case management tool. Information is communicated to internal and external stakeholders via a communications template. A team is assembled to facilitate the successful execution of the policy and is assigned a policy in the case management system.	• A completed policy solutions brief, incorporating public feedback analysis, is submitted to the BOD for approval. • The scoring rubric and budget allocation are included in the discussion and votes. • The BOD votes on submitted policy briefs and ensures that HHS/DoT and finance are aligned with direction. • The BOD's vote and feedback is documented in the case management system. • Documentation will include justification for the vote as determined by the policy's impact on strategic priorities, feasibility, and policy constraints. • HHS/DoT approves release of the policy solution brief and implementation plan. • The public and OPTN stakeholders are informed of the BOD's vote, public feedback, and other projects being reviewed. • The Policy Committee (PC) assigns internal and external staff to the implementation team for the next phase.
Phase 5: Implementation, Monitoring and Feedback	Policy implementation and performance monitoring using established frameworks and implementation plans. Data collection and analysis are conducted based on	• The policy is implemented according to the implementation plan, which includes documenting policy changes, a training plan, and necessary communications. Status

Phase	Overview	Tasks
	established frameworks and documented in the case management system. Findings from this phase are communicated to internal and external stakeholders. A retrospective analysis is conducted to determine where policy implementation succeeded and any areas for improvement. Next steps will be determined based on data gleaned from the implementation phase. This could include the submission of new ideas, continued monitoring, and evaluation, or a change in implementation.	updates to the appropriate oversight authorities will be provided. • The engagement and education campaign will be delivered to the public and stakeholders according to the communication plan. • Performance data will be collected and analyzed based on stakeholder feedback and performance metrics and documented on the monitoring and evaluation template. • Retrospective analysis will be conducted to determine if any processes need to be revised. • The communications template will be completed for public dissemination after obtaining HHS/DoT approval. PDT analyzes data from implementation and determines next steps (e.g., continued monitoring, new implementation plan or new idea). • Ongoing updates will be provided to the public and OPTN stakeholders on a quarterly basis.

3.8 Six-Phase Policy Development Framework Implementation and Change Management Plan

3.8.1.1 Phased Implementation

3.8.1.1.1 Implementation Steps & Activities

The new policy development framework will be implemented in four agile stages with a phased pilot testing of each of the new framework's six phases. This approach helps reduce risks, allows for controlled and incremental release, and enables real-time adjustments prior to final roll-out. The implementation plan focuses on initiation, planning, piloting, evaluation, and full-scale adoption. Below details the core implementation steps and associated activities.

- Implementation Activities by Phase:
    - **Stage 1:** Initiation & Infrastructure Setup (Months 1-3)
        - Hire/Onboard core implementation team (project lead, analysts, liaisons)

- Develop and finalize templates, tools, and resources (modules, handbooks, rubrics, authority matrix, etc.) aligned with the framework and its phases
- Develop a communications strategy for integration
- Develop and pilot trainings, webinars, and other learning opportunities for all relevant OPTN stakeholders to foster integration of the new framework

- **Stage 2:** Pilot Testing & Evaluation (Months 4-6)
  - Conduct pilot testing with OPTN stakeholders using active or emerging topics
  - Apply all six phases of the framework, being sure to capture any Key Performance Indicators (KPIs) that illuminate how the process went (ex: time in each phase, public comment process, stakeholder participation, stakeholder self-efficacy)
  - Offer live training sessions and technical assistance for committees and policy teams
  - Collect qualitative and quantitative feedback from participants
  - Refine framework tools and processes based on evaluation findings
- **Stage 3:** Implementation/Rollout (Months 7-8)
  - Integrate framework into OPTN workflows
  - Finalize all Standard Operating Procedures (SOP), guidance documents, and scoring criteria and rubrics
  - Upload asynchronous training modules for staff and stakeholders
  - Use previous evaluation indicators for ongoing performance monitoring
- **Stage 4:** Maintenance, Continuous Improvement (Months 9-12)
  - Once the new framework has been put in place, ongoing monitoring will commence in month 9. The tasks below will be ongoing once the framework has been implemented
  - Conduct bi-annual evaluations using RE-AIM informed indicators
  - Ensure framework is included in any oversight annual reviews by HHS/DoT
  - Host ongoing learning sessions about the framework for both internal and external stakeholders

3.8.1.1.2 Timeline & Milestones

The implementation of the SPPDF will follow a 12-month timeline with key milestones tied to the successful completion of tasks within each stage. These milestones serve as means of collaboration with HHS/DoT and stakeholders through pilot interactions and training and are indicators of readiness, ongoing improvements, adoption, and system-wide integration of the new approach.

Table 21: Six-Phase Timelines & Milestones

Phase/Timelines	Milestone
Stage 1: Initiation (Months 1-3)	• Project kick-off and orientation with contractor staff, OPTN volunteers, and HHS/DoT • Finalize guidance documents and draft SOPs

Stage 2: Pilot Testing (months 4-6)	• Pilot Phase 0-2 components in 1-2 committees • Conduct Training and provide Technical Assistance • Gather and analyze pilot feedback • Finalize SOPs
Stage 3: Implementation/Roll out (Months 7-8)	• Phase 3-5 piloted with public comment and governance pathway testing • Adjust Phase 0-6 based on pilot feedback • Prepare for full roll-out • Final framework launch across all OPTN policy activities
Stage 4: Maintenance/Continuous Improvement (Months 9-12)	• One-year evaluation with stakeholder interviews • Address feedback based on pilot feedback

3.8.1.2 Resource Planning

3.8.1.2.1 Roles and Responsibilities

Implementing the SPPDF requires targeted investment in human capital and technology infrastructure. Successful integration of the new policy development framework requires clear role definition across HHS/DoT, the OPTN contractor(s), internal and external OPTN stakeholders, and analysis staff and workgroups. Key roles include an implementation team to coordinate efforts, SMEs to guide technical execution within each phase, and communication leads to oversee the dissemination of information about the new framework, ensuring alignment with the overall vision and adherence to regulatory compliance.

Table 22: Six-Phase Roles and Responsibilities

Role	Responsibility
HHS/DoT Liaison	Serves as the federal oversight body, ensuring regulatory compliance, providing strategic direction, and facilitating coordination across stakeholders throughout the implementation process
OPTN BOD	Approves and monitors the modernization process and ensures that the policy process reflects the cultural values of the community
Implementation Team	• Coordinates day-to-day rollout activities and manages pilot • Conducts training of staff and pilot participants • Establishes metrics to track process compliance and adherence to OPTN strategic goals • Provides Technical assistance
Data Transparency & Analytics Committee	Tracks implementation metrics and provides support for RE-AIM-informed evaluation of pilot
Communications	Manages messaging with stakeholders and public comment material

Technology and Infrastructure	Builds onboarding materials and facilitate trainings

HHS/DoT will determine how to operationalize the SPPDF.

Key operational support functions necessary to implement the SPPDF include:

- **Technology and Infrastructure:** Develop, manage, and maintain OPTN's technical infrastructure. This includes databases, system architecture, matching algorithms, Application Programming Interfaces (API), and a Case Management Platform.
- **Organ Logistics & Tracking:** Provide real-time organ tracking and optimize logistics chains from donor to recipient.
- **Data Analytics:** Perform advanced analytics, reporting, and predictive modeling that are distinct from the analyses conducted by Scientific Registry of Transplant Recipients (SRTR), focusing instead on evaluating internal OPTN operations and supporting the policy development process.
- **Communication and Education:** Lead public education, stakeholder engagement, connection, digital engagement, manage community feedback, publication of stakeholder-facing materials, and ensure transparency in policy development.
- **Support:** Provide critical administrative support to the OPTN and the policymaking process, including facilitating key decision meetings, ensuring the efficiency and structure of policy-development meetings to drive timely, action-oriented decisions, preparing meeting materials before and after those meetings, vetting ideas submitted, and providing capacity support to the PDT.
- **Compliance and Auditing:** Monitor adherence to vendor contracts and the governance structure, conduct continuous evaluations of policy workflow and governance adherence to identify and address bottlenecks or inefficiencies early, identify and monitor patient safety issues.

3.8.1.2.2 Resource Allocation

Integrating the framework will require investment in personnel, technology, and associated tools. The best practice approach to identifying tools that will best meet the OPTN needs, functionality and budget is to conduct an Analysis of Alternatives (AoA) to evaluate technology solutions.

The AoA approach follows this process:

- Define the objective and validate the requirements for the tools
- Establish a common set of evaluation criteria to be utilized to evaluate the tool(s)
- Analyze and identify the list of alternatives
- Collect Data and evaluate alternatives
- Compare and rank alternatives
- Make recommendations (includes cost and schedule)

For staff estimation, a team is being proposed that possesses the skillset needed to conduct the AoA and may be utilized, once an alternative is chosen, to implement an agile approach to development, testing

and roll-out. If additional or different personnel are required for implementation, this will be identified as part of the AoA process.

- Resource Requirements
    - Implementation Team: responsible for managing implementation.
        - Project Manager: Works with vendors and staff to assist with streamlining the implementation of the new framework.
        - Policy Analysts from PC: facilitates framework application, evidence review, coordination with committees.
        - Data Analyst from Data Transparency and Analytics Committee: track metrics, support evaluation and feedback; works with Implementation Team to analyze processes, gathers requirements, and translates them into technical specifications to support system development, improvement, or integration.
        - Communications and Training Specialists: Develop training materials, webinars, and any e-learning content, facilitate stakeholder messaging around framework implementation. Also assess learning needs, creates instructional materials, and ensures learners can apply the knowledge effectively in their roles.
            - Technical Writer: Support drafting SOPs, policy templates, and training materials.
        - IT/Web Developer from Technology and Infrastructure: experts skilled at reviewing and optimizing the current OPTN dashboards to prioritize patient centricity.
    - Technology:
        - Case management system to document policy solution briefs including comments and updated information.
        - Tracking dashboards/system
        - Central health repository, or "data lake," to integrate all healthcare data from transplant centers and OPOs.
        - Knowledge management platforms for document storage
            - SharePoint

Table 23: Six-Phase Resource Allocation (Based on labor rates as of May 2025 – FTE hours = 1920)

Investment Category	Line Item (#)	Per Unit Cost	Total Cost
Sample Staffing – can be used for AoA and agile development	Project Manager	$74.37	$142,790.40
	Implementation Manager	$51.35	$98,592.00
	Policy Analyst (3)	$41.25	$237,600.00
	Data Analyst (3)	$41.25	$237,600.00
	Tech Writer (2)	$35.75	$137,280.00
	Business Analyst (3)	$56.49	$325,382.40

Investment Category	Line Item (#)	Per Unit Cost	Total Cost
	Comm & Train Specialist (3)	$48.57	$279,763.20
	Web Developer (3)	$50.31	$289,785.60
	Total		**$1,748,793.60**
Sample Technology Initiatives (Conduct AoA)			
Case Management AoA (90 Days – 480 hours)	Project Manager Data Analyst (2) Business Analyst (2) Tech Writer (1) Web Developer (2)	$74.37 $41.25 $56.49 $35.75 $50.31	$22,737.60 $39,600.00 $54,230.40 $17,160.00 $48,297.60
	Total		**$182,025.60**
Tracking/Dashboard AoA (90 Days)	Project Manager Data Analyst (2) Business Analyst (3) Tech Writer (1) Comm/Training Specialist (1) Web Developer (2)	$74.37 $41.25 $56.49 $35.75 $48.57 $50.31	$22,737.60 $39,600.00 $81,345.60 $17,160.00 $23,313.60 $48,297.60
	Total		**$232,454.40**
Health Repository AoA (90 Days)	Project Manager Data Analyst (2) Business Analyst (2) Tech Writer (1) Web Developer (3)	$74.37 $41.25 $56.49 $35.75 $50.31	$22,737.60 $39,600.00 $54,230.40 $17,160.00 $86,846.40
	Total		**$220,574.40**
Knowledge Management AoA (90 Days)	Project Manager Data Analyst (2) Business Analyst (2) Tech Writer (1) Comm/Training Specialist (2) Web Developer (2)	$74.37 $41.25 $56.49 $35.75 $48.57 $50.31	$22,737.60 $39,600.00 $54,230.40 $17,160.00 $46,627.20 $48,297.60
	Total		**$228,652.80**

3.8.1.2.3 Training and Support

Comprehensive training and technical support will be provided to ensure that staff across all work streams (OPTN, HHS/DoT, committees, etc.) understand and can apply the new framework. This will include workshops, reference guides, training, live sessions tailored to the phases of the framework, and access to technical assistance teams. Training will also be focused on operationalizing new tools (prioritization rubrics, dashboards, etc.), building long-term capacity for iterative policy development.

- Training Components
    - Foundational Training Modules

    - Overview of new framework
    - Tools for implementing (scoring tools and rubrics)
    - Best Practices
  - Role Specific Toolkits
    - For committee chairs, leadership, analysts, etc.
    - Delineate roles across each phase of implementation
  - Delivery Format:
    - Asynchronous modules
    - Live webinars
    - Office hours
    - Implementation Handbook with case studies and step-by-step guides

3.8.1.3 Change Management & Stakeholder Engagement

The integration of the SPPDF will be guided by Kotter's 8-Step Change Model, a widely recognized best practice for managing complex organizational change. It is suited for large, federal systems like OPTN because of its focus on stakeholder buy-in and long-term cultural alignment. By using this model, HHS/DoT and the OPTN vendors can navigate internal resistance change, establish communication channels, and track short-term wins that help build trust in the new process and aid in long-term progress. This model ensure that process improvements are matched with organizational readiness and leadership support necessary for successful, long-term integration.

- Based on Kotter's 8-step Change Model adapted for federal implementation

  - **Create Urgency**: Share data from current state review to show bottlenecks in policy cycles, delays in approval, or gaps in fairness-driven and policy outcomes in line with the needs of the organ procurement and transplantation community.
  - **Build Coalition**: Identify early adopters or key stakeholders across OPTN committees, HHS/DoT, and contractor staff.
  - **Define visions and communicate it often**: Use visual aids and briefing decks to explain and showcase framework benefits.
  - **Empower action**: Provide tools and training that make the framework easy to adopt.
  - **Generate wins**: Pilot success stories in framework implementation, track early metrics, and highlight improvements in transparency or engagement internally or externally.
  - **Consolidate gains**: Embed feedback loops to maintain an iterative refinement process
  - **Anchor in culture:** Align overall charters, bylaws and other governance documents with new framework.

- Implementation Steps

  - **Goal: build awareness, secure buy-in, and prepare infrastructure for policy cycle**
  - **Tasks:**

- Stakeholder mapping & engagement: identify key internal and external stakeholders
- Communicate toolkit for launch: Frequently Asked Questions (FAQ), webinar series, tailored briefing packets and sessions
- Technical Infrastructure Assistance: begin review and repurposing of technical tools such as existing dashboards, tracking Request for Proposals (RFP), and survey collection
- Develop idea generation strategy: draft SOP and timeline for solicitating and reviewing policy proposals
- Training committee members: create focused modules for busy professionals
- Pilot test on 1 policy: apply policy cycle to a single policy for evaluation

- **Timeline**
  - Month 1-2: stakeholder engagement, communicate launch, prepare technical infrastructure
  - Month 2-3: Committee training, RFP template created/finalized, pilot testing begins
  - Month 4: First formal RFP released, and proposal selected
  - Month 5-9: follow timeline of Policy process from Phase 1-5
  - Month 10: review and make improvements

3.8.1.4 Pilot Testing

Testing for the new framework will begin with only 1-2 committees and the selection of a small number of proposals to be input into the process. Formal proposal drafts will be selected and moved through each phase. Committee members, support staff and the contractor will constantly review and make improvements as needed. The purpose of the pilot is to evaluate how well each phase, from idea submission to implementation, functions in practice. Process metrics (e.g., time per phase) and outcome metrics (e.g. stakeholder satisfaction) will be monitored. The RE-AIM framework will guide how we assess adoption and implementation fidelity. The pilot phase is anticipated to last 9 months. Based on insights from the implementation process, a full rollout will include updates to bylaws, new SOPs, and formal onboarding for all. The staged approach ensures a responsive and user informed system-wide adoption.

3.8.1.5 Feedback Loop

The feedback loop is critical for the framework's integration and is designed to capture real-time insights and ensure continuous improvement. The pilot testing phase is assessed through debrief sessions, surveys, and retrospective reviews from policy staff, committee members, and key stakeholders. These inputs will be used to refine tools, clarify guidance, and address implementation issues. A centralized tracker can be populated to monitor recurring themes, while quarterly reviews can assess progress and prioritize updates. The tracker can log refinement recommendations and workflow improvement. This

iterative process ensures that the framework remains dynamic, adaptable, and responsive to user experience and evolving needs.

- Activities:
    - Launch bi-monthly feedback sessions with implementation staff, committee members, and external stakeholders
    - Disseminate short surveys and pulse checks after each phase is completed the policy cycle
    - Conduct retrospective meetings and focus groups post-policy approval (Phase 4) to assess what worked and what didn't work
    - Maintain a centralized tracker of recurring issues and adaptation made in response to feedback

3.8.1.6 Full Rollout

Full rollout will be marked by the formal integration of the SPPDF into the OPTN policy process. After pilot testing, the framework will be scaled across all committees and policy work. Training will be provided to ensure staff and governance readiness. There will be a digital repository to house all templates, guidance, and FAQs to support ongoing use by OPTN and its vendors. Rollout success will be monitored through adoption metrics, user satisfaction, and policy development efficacy. The full transition aims to embed the framework into OPTN operations as the new standard for transparent and evidence-based policy development.

- **Success Metrics**
    - **Framework Adoption KPIs**
        - Percentage of new policy proposals moving through all phases of the framework
        - Number of members who successfully completed training on the framework
        - Compliance with updates SOPs and templates
        - Alignment of policy objectives with public health principles (fairness, access, transparency)
    - **Feedback Loop KPIs**
        - Frequency of feedback loop activities (e.g., retrospective meetings, stakeholder surveys)
        - Time between issue identification and resolution
        - Number of framework/revisions resulting from pilot testing

4 Governance Structure Overview

This Report provides comprehensive recommendations to improve efficiency and effectiveness of the OPTN policy development and oversight process and governance structure based on evidence gathered during the development of the Mapping Report.

4.1 Background: (Current Limitations and Drivers for Change)

The OPTN, established in 1984, is undergoing significant scrutiny and reform due to longstanding concerns over transparency, efficiency, and equitable outcomes.

Until 2023, the original OPTN model was largely centralized under a single nonprofit vendor, UNOS, leading to multiple COIs and program underperformance and inefficiency. One of the key limitations of the system was its monopolistic structure, which stifled innovation, especially in the development and use of evolving technology. The lack of vendor performance metrics and accountability mechanisms, coupled with low patient engagement and lack of system-wide transparency, resulted in decreased public trust in the original model with issues cited such as inconsistent public comment periods, limited information about policy status and implementation, member performance, or system-wide outcomes.

The OPTN Final Rule outlines requirements for the size and composition of the BOD. It requires that the BOD have at least 34 but not more than 42 voting directors. The OPTN Bylaws allow the BOD to meet only twice a year and permit the Executive Committee (EC), comprised of only 12 individuals, to continue the work of the BOD throughout the year without needing to convene the entire BOD.

The EC and the Policy Oversight Committee (POC) can determine which policy proposals move forward without a full BOD review, resulting in a relatively small group exerting substantial influence over policy prioritization and development.

Provider-heavy committees can also influence which projects the POC approves. Because of providers' technical expertise, alignment with OPTN's clinical goals, and understanding of the nuances required to move policies through the process, they are often able to promote and/or defend policies effectively.

While expert perspectives are essential to the OPTN policy-making process, the current committee and BOD structure fails to adequately balance clinical viewpoints with patient and family perspectives. Providers often approach problems from a medical or operational standpoint, which can lead to the unintentional neglect of patient and family perspectives. To develop effective solutions, it is essential to include diverse viewpoints and gather feedback from all relevant stakeholders when examining issues and formulating solutions.

4.2 Transition to Modernization

In 2023, bipartisan legislation identified the need to review and update the governance model and the OPTN overall to facilitate system modernization. In response, HHS/DoT initiated the OPTN Modernization Initiative, leading to changes including the establishment of a new OPTN BOD, a new contract structure with fourteen diversified vendors, and expanded HHS/DoT staff support. Despite these changes, the current BOD structure does not lend itself to the action needed to modernize the OPTN.

HHS/DoT serves as the federal agency responsible for oversight of the OPTN, ensuring accountability and effectiveness. This oversight includes:

- Safeguarding against fraud, waste, and abuse
- Identifying and correcting errors affecting donor patients, waitlist patients, and recipient patients
- Monitoring patient safety and public health

- Ensuring that OPTN operations fulfill their intended objectives

Before launching the OPTN Modernization Initiative, Health Resources and Services Administration (HRSA), (now HHS/DoT) had already taken steps to strengthen OPTN accountability by strengthening contract requirements and oversight. The efforts included:

- Establishing stricter security and performance standards for the OPTN
- Soliciting expert and community input to improve transparency, accountability, and operational performance
- Holding a conference with patients and families to refine performance measures
- Partnering with technology experts to upgrade the OPTN's IT systems
- Working with Centers for Medicare & Medicaid Services (CMS) and other HHS agencies to enhance federal oversight, alignment, and support of the OPTN

Since March 2023, HHS/DoT has prioritized oversight and support for the OPTN by:

- Reinforcing its commitment to patients, donors, and their families
- Introducing a new process for reporting misconduct related to organ procurement and transplantation
- Leveraging the Critical Comment Process outlined in the OPTN Final Rule
- Fostering stakeholder involvement through OPTN Regional Meetings
- Supporting a conflict-free and independent BOD

HHS/DoT informs the OPTN community about ongoing OPTN Modernization efforts through its public-facing website: Organ Procurement and Transplantation Network (OPTN) Modernization Initiative.

4.3 Description of New Governance Structure:

The expanded PPP governance model restructures and strengthens the OPTN's current governance system by creating a functionally distributed, modular governance framework in which HHS/DoT staff work collaboratively with the OPTN BOD, and ten committees to inform and manage strategic projects implemented by a multi-functional team of experts.

A smaller BOD remains in place and retains many existing key responsibilities. The BOD is supported by ten Committees, which strengthens OPTN functions and governance, improves the policy development process, and enhances stakeholder engagement, with special focus on patients, their families and caretakers, and registered and prospective organ donors. To ensure the system is guided by expertise in organ procurement and transplantation, ad hoc working groups may be established, to include organ-specific knowledge, and implement other policy recommendations and governance standards.

This governance model (Figure 7 below) streamlines the committee structure, fosters cross-committee collaboration, and enables the OPTN to engage required operational and subject matter experts fostering innovation and accountability.

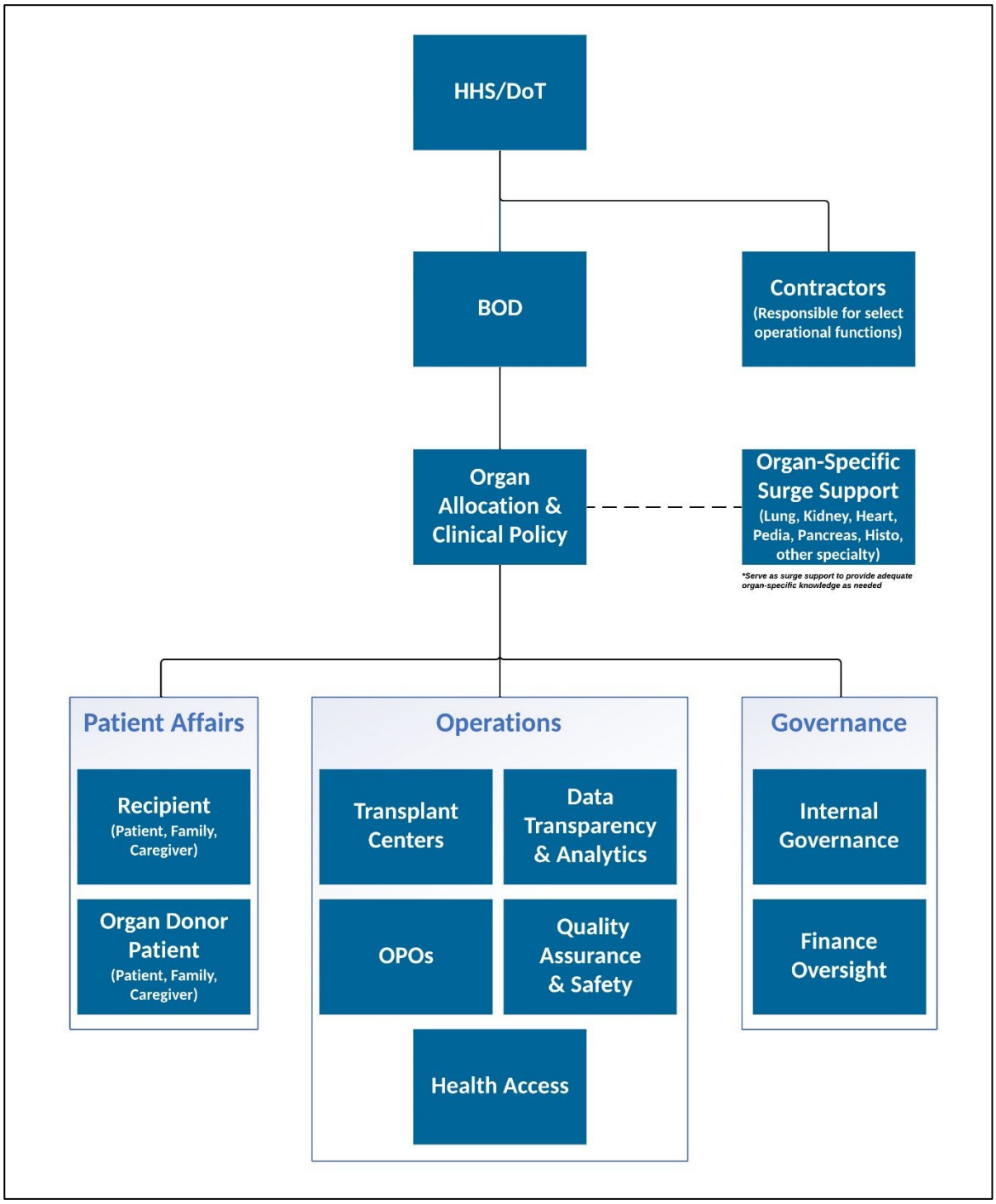

Figure 7: Restructured Governance and Committees Framework

Refer to Section 4.7 for more details on the key components of the PPP, which include the roles and functions illustrated in Figure 7 (above).

4.4 Objective of New Governance Structure:

The proposed PPP model separates strategic oversight from day-to-day operations, grouping governance, operations, and patient affairs functions, to improve accountability, transparency, and performance across the OPTN system. Compared to the original centralized structure, this enables greater innovation and efficiency because governance is managed by independent committees and implemented by vendors selected based on strong capabilities and past performance. This collaborative PPP structure leverages the private sector's diverse expertise, strengthens public oversight and expands stakeholder engagement to foster transparency and innovation.

The proposed PPP model:

- Reinforces and strengthens HHS/DoT's federal oversight role.
- Improves accountability, transparency, and performance across the OPTN system.
- Encourages innovation and efficiency.
- Establishes and enforces standards across the OPTN policy development and oversight process.
- Builds public trust by increasing transparency through increased registered and prospective organ donor, donor patient, and recipient patient voices in governance and policymaking.
- Improves performance by establishing a modular committee structure that facilitates cross-committee collaboration.

4.5 Rationale for Choosing the Expanded PPP Governance Model Over the Commission Model

Adopting an expanded PPP model for the OPTN is a strategic solution to the system's longstanding challenges. This model reduces the number of individuals on the BOD, restructures the Committees into a modular, functionally distributed governance framework, and enables a wide array of private vendor partners to bring their specialized expertise to various aspects of organ procurement and transplantation. It introduces modularity into the OPTN which enables cross committee collaboration and committee transitions without disrupting the entire process. Alternative models considered included a centralized Independent Regulatory Commission (IRC) and a federated regional model. The expanded PPP framework was eventually selected, narrowly outperforming the IRC model inspired by the Securities and Exchange Commission (SEC) which was strongest in addressing COIs. In the IRC model five to seven dedicated, paid commissioners would fall under HHS/DoT's administrative oversight but remain operationally independent. The IRC would require legislative, budgetary, and organizational changes that were ultimately deemed unfeasible. The federated regional model was evaluated as the least likely to result in achieving the objectives of OPTN modernization.

The PPP governance model represents a modern, accountable, and transparent approach to managing a critical national health ecosystem. By aligning technical, ethical, and administrative responsibilities with organizations best equipped to handle them in conjunction with HHS/DoT's enhanced oversight, OPTN can achieve its long-deferred promise of fairness, efficiency, and public trust in the organ procurement and transplantation system.

1. Flexibility and Scalability

The PPP model allows for more flexible governance, contractual oversight, and specialized vendor engagement, which are essential for managing the complex, evolving needs of the OPTN. Through structured partnerships with multiple vendors (e.g., IT, logistics, data, education, and compliance vendors), this model can scale capacity and incorporate innovation more effectively than an IRC.

2. Incentivized Performance and Competition

The PPP model can be structured to include performance-based contracts, allowing HHS/DoT to set clear metrics, benchmarks, and accountability structures for third-party entities. The additional functions, such as technology, analytics, and communication, refer to capabilities not currently performed by the SRTR. These functions are focused on supporting and evaluating internal OPTN operations, specifically the policy development process. By competitively bidding out services like IT infrastructure or data analytics, the PPP model promotes innovation and cost-effective benefits that may be more difficult to achieve under a fully federal commission structure.

3. Continuity with Reform Momentum

The current modernization efforts led by HHS/DoT emphasize reengineering the existing system rather than dismantling it. The PPP model builds upon this by incorporating reform without the significant legal, bureaucratic, and budgetary hurdles associated with creating a new federal commission.

4. Stakeholder Representation and Multi-Vendor Oversight

The PPP governance structure allows for increased stakeholder engagement through organ-specific panels and transparent policy development processes. Contractual segmentation by function (e.g., technological, communications, compliance) enables better checks and balances and mitigates risks that arise when one vendor (e.g., UNOS) controls multiple verticals.

Addressing Potential Challenges (COI, Inefficiency, and Lack of Accountability)

Even within an expanded PPP model, challenges such as COIs, lack of transparency, and inefficiency may persist. To address these:

- Independent compliance vendors should audit performance and financial operations.
- COI policies must be modernized and enforced, particularly regarding BOD composition and vendor selection.
- Stakeholder input mechanisms such as adherence to new BOD and Committee composition requirements, public dashboards, regional meetings, and public comment periods as well as open calls must be institutionalized.

4.6 Advantages and Expected Benefits of the PPP Model

The reimagined PPP Governance Model represents a reasonable and scalable approach to modernizing the OPTN, one that maintains existing reform momentum and fosters innovation through multi-vendor engagement.

- **Transparency:** Robust and impartial oversight supported by contracts prevents COI, fraud, waste, abuse, and stakeholder confusion.
- **Efficiency:** Specialization improves the speed and quality of services.
- **Adaptability:** Modular design allows easier replacement or upgrading of underperforming components.
- **Stakeholder Trust:** Structured engagement builds public and professional confidence.

The PPP model is designed to deliver many benefits across the OPTN and the wider organ procurement and transplantation ecosystem. With a distributed governance framework through a smaller BOD and restructured functionally grouped committees, supported by a flexible, decentralized vendor pool, the model aims to significantly enhance stakeholder engagement and process efficiency. The resulting improvements in policy and operational data infrastructure will support better system-wide decision-making, stakeholder engagement, and ultimately lead to improved patient outcomes.

4.7 Key Components of the PPP Governance Model

4.7.1 HHS/DoT

The new governance structure requires HHS/DoT to strengthen its role in the OPTN as a strategic, impartial regulatory and oversight body, ensuring reforms remain aligned with national public health goals, equity standards (as defined by NOTA and the OPTN Final Rule), and evidence-based policymaking. HHS/DoT will play a vital role in supporting the implementation of PPP governance, ensuring adequate OPTN oversight. Through its involvement with the BOD and committees, HHS/DoT will enhance member engagement and oversee modernization activities such as data standardization, safety monitoring and enhancement, and best practices dissemination among stakeholders.

As the OPTN federal oversight authority, HHS/DoT is essential in guiding the transition to an expanded PPP governance structure. Its comprehensive ecosystem, management, engagement and transparency will be critical in harmonizing the activities of vendors, fostering member and public trust, and monitoring, implementing, and advising on evolving regulations and governance structures.

Note: "Equity" the word as used in the paragraph above and throughout this document references the statutory requirement and definition as defined by NOTA and the Final Rule.

Table 24: PPP Role of HHS/DoT in Implementing the Reimagined OPTN

Role of HHS/DoT in the new OPTN	Description	Relevance
Informed Advisory Role	HHS/DoT provides expert, multidisciplinary recommendations to the Secretary of HHS on organ procurement, transplantation, and system oversight. This is especially critical as the PPP model introduces new vendors and governance complexities that require continuous guidance and monitoring rooted in clinical, ethical, and operational expertise.	HHS/DoT ensures policy reforms align with regulations and remain patient-centered and ethically sound amidst system restructuring
Alignment with HHS/DoT Strategic Oversight	Under the PPP model, the federal government retains oversight of the organ procurement and transplantation system in close coordination with the OPTN BOD while absorbing (as appropriate) and outsourcing operations. HHS/DoT ensures alignment with federal priorities and operational standards.	Supports strategic alignment, collaboration, and guards against fragmentation
Governance and Policy Evaluation Support	As OPTN adopts a modular governance system, HHS/DoT implements governance and policy changes, ensuring consistency, fairness, and accountability across OPTN BOD and Committees and vendors—especially related to: • COI policies • Transparency and community input • Performance metrics	Provides oversight integrity and coherence across modules
Central Program Manager	HHS/DoT oversees contracting, coordination, and management of vendors performing essential OPTN functions. They ensure structured oversight of these vendors, which includes regular reporting requirements and performance evaluations. HHS/DoT will: • Award contracts with multiple vendors • Define performance metrics • Conduct periodic performance evaluations • Review financial and technical reports • Ensure compliance with federal regulations • Coordinate collaboration among vendors • Manage vendor accountability • Enforce corrective actions • Monitor system-wide integration • Oversee use of federal funds	Manages multiple vendors to enhance OPTN operations

Role of HHS/DoT in the new OPTN	Description	Relevance
Support for Continuous Quality Improvement (CQI)	HHS/DoT's role is to improve the performance, quality, safety, and outcomes of the organ procurement and transplantation system. HHS/DoT's oversight will be crucial during: • Pilot phases of PPP implementation • Scaling up new technologies or allocation methods • Reviewing data analytics and outcomes • All phases of the policy development process	Strengthens accountability and continuous improvement

4.7.2 BOD and Committee Structure

Internal governance will be restructured to include a smaller BOD operating under HHS/DoT oversight. While preserving a traditional vertical hierarchy for governance, the BOD will be responsible for setting national standards and strategic priorities, reviewing and advising on HHS/DoT designated vendor performance metrics, reviewing and approving policy proposals, allocating budget equitably across strategic priorities, and ensuring fairness, transparency, and the protection of public interest in close collaboration with HHS/DoT. Reflecting best practices from high-performing nonprofit and private-sector boards, the new BOD will be significantly smaller to ensure more efficient decision-making and better member engagement, consisting of 15 to 20 members serving staggered terms to ensure continuity. Led by a Chair and a Vice-Chair, the BOD will have clearly defined composition requirements. The final composition requirements will be established by HHS/DoT to represent diverse, balanced stakeholder perspectives and promote equitable participation and governance. An example of balanced stakeholder composition is as follows:

Four individuals from each of the following five categories:

- Transplant physicians or surgeons, including transplant coordinators, and transplant hospitals
- Individuals representing OPOs or histocompatibility labs
- Regional councillors
- Individuals served by the OPTN, including transplant candidates, recipients, registered and prospective organ donors, and their family members
- Non-transplant professionals, including professionals from law, ethics, healthcare financing, public health, systems management, and data/technology

The current committee structure will be streamlined as external vendors take on many operational tasks for the OPTN. Each committee will consist of 15 to 20 members to align with best practices for maintaining effective and engaged committees. To maximize efficiency while ensuring sufficient representation from stakeholders, each committee should include:

At least two individuals from each of the following five categories. Additional committee members should represent a variety of perspectives relevant to the committee:

- Transplant physicians or surgeons, including transplant coordinators, and transplant hospitals
- Individuals representing OPOs or histocompatibility labs
- Regional councillors
- Individuals served by the OPTN, including transplant candidates, recipients, registered and prospective organ donors, and their family members
- Individuals with committee-specific expertise such as professionals from analytics, law, ethics, healthcare financing, logistics, public health, systems management, and data/technology

Ad hoc committees with organ-specific or operational expertise can be formed as needed to support the PC in setting organ and operational-specific goals and metrics to enhance policy development.

The composition of the BOD and committees should reflect the demographics of its stakeholder population and include at least one pediatric specialist. The OPTN Final Rule and the OPTN Bylaws will require revisions to reflect these changes to the OPTN BOD and committee composition.

The table below shows the new committee structure and aligns current and future committees:

Table 25: PPP Proposed Committees and Functions

Proposed Future State Committee	Roles and Responsibilities	Corresponding Current State Committee
Organ Allocation & Clinical Policy ("Policy Committee")	• Understands strategic goals of the OPTN and co-develops actionable, measurable goals with the support of organ-specific panels • Develops and revises organ allocation policies • Reviews and prioritizes new policy ideas aligned with strategic priorities • Develops and implements policy review plans • Ensures solutions are evidence-based and aligned with current clinical practice and stakeholder needs • Develops and disseminates comprehensive Policy Solution Briefs • Facilitates stakeholder engagement throughout the process • Partners with the vendor in charge of implementation to ensure successful delivery	Policy Oversight

Proposed Future State Committee	Roles and Responsibilities	Corresponding Current State Committee
Data Transparency & Analytics	• Provides additional supporting innovative technology analytics that are non-SRTR related functions • Non-SRTR software development and maintenance support • Monitors organ procurement and transplant databases and platforms • Ensures that policy decisions are informed by insights through data visualization & reporting	BOD Network Operations Oversight Data Advisory
Organ Donor Patient Committee	• Advocates for the needs of registered and prospective organ donors, living donors, and donor families • Facilitates civic engagement/awareness of OPTN and potential for donation • Actively develops/studies/innovates ways to engage more donors	Living Donor Patient Affairs Committee (PAC)
Finance Oversight	• Creates annual budgets aligned with OPTN's strategic goals • Ensures resource allocation reflects strategic priorities • Tracks the financial performance of strategic initiatives • Forecasts long-term financial viability and needs • Oversees annual audits • Develops financial reports that summarize annual activity for stakeholder review	BOD Finance
Health Access	• Addresses disparities in access to organ procurement and transplantation services, including disparities in race, ethnicity, geography, socioeconomic status, and other key demographics • Recommends policy changes that promote equitable access • Engages with historically underserved stakeholders to ensure that priorities are informed by community input	Minority Affairs

Proposed Future State Committee	Roles and Responsibilities	Corresponding Current State Committee
Internal Governance	• Supports the development of internal processes and policies and evaluates their success to ensure transparency and accountability within the OPTN • Defines member roles and responsibilities • Defines term limits • Oversees regular assessments/audits of the new BOD and other committees with support from external vendor(s) • Facilitates onboarding and training for BOD and committee members • Ensures compliance with federal statutes and regulations • Facilitates inter-committee collaboration • Evaluates the implementation of the policy development process	BOD Nominating Membership and Professional Standards Ethics Operations and Safety (also some aspects in Quality & Safety)
OPO Operations	• Monitors and supports the performance of Organ Procurement Organizations (OPOs) • Addresses operational challenges faced by OPOs • Develops standardized operational practices across diverse OPO settings • Identifies and improves systemic barriers to organ procurement • Serves as liaison between OPOs and OPTN leadership, and CMS and HHS/DoT staff	OPO
Recipient Committee (includes patients, family, caregivers)	• Advocates for the needs of patients, families, and caregivers • Facilitates collaboration between OPTN governance, OPOs, transplant centers, patients, families, caregivers, and advocacy groups	Patient Affairs
Transplant Center Operations	• Addresses operational challenges faced by transplant centers • Develops best practices and guidance to support operations across diverse (size, location, etc.) transplant center settings • Serves as a liaison between transplant centers and OPTN leadership, and CMS and HHS/DoT staff	Transplant Administrators Transplant Coordinators
Quality Assurance & Safety	• Coordinates rapid response efforts during public health crises (e.g., COVID) • Monitors safety data to detect emerging risks	Operations and Safety (some aspects of Internal Governance)

Proposed Future State Committee	Roles and Responsibilities	Corresponding Current State Committee
	• Investigates system failures • Develops national safety protocols for donor evaluation, organ transport, etc.	Ad Hoc Disease Transmission Advisory
Organ-specific Panels	• Ad hoc or surge teams convened by the PC to provide organ-specific guidance and support for OPTN policy decisions • Understands strategic goals of the OPTN and co-develops actionable and measurable goals with the PC • Reviews developed Policy Proposals and Policy Solution Briefs to ensure alignment with their expertise area's goals • Serves on PDTs, helping the PC to study ideas and develop them into meaningful Policy Proposals, then into detailed Policy Solution Briefs • Provides SME guidance to the PC and the OPTN BOD • Submits ideas for potential policy proposals that contribute to their area's goals	Heart Transplantation Histocompatibility Kidney Liver & Intestinal Organ Lung Pancreas Pediatrics Vascularized Composite Allograft International Relations Committee Multi-Organ Transplantation Committee
PDTs	• Ad hoc or surge teams convened by the BOD and the PC to manage a proposal idea through all phases of the policy development process • Composed of PC members, organ-specific panel members, and BOD and committee members with relevant expertise • Develops an idea into a Policy Proposal by analyzing and defining the problem, reviewing stakeholder feedback and developing solutions • Oversees the implementation, monitoring, and evaluation process • Solicits support from other committees, organ-specific panels, and vendors, as appropriate	All Committees that previously proposed and advanced policy ideas

4.7.3 BOD and Committee Nomination and Selection Process

The nomination process for the new BOD will use a mixed selection model aimed at promoting transparency and incorporating a variety of expertise. For key stakeholder groups, including transplant centers, OPOs, technology experts, and bioethicists, nominations will be gathered through an open public call. This approach will allow submissions from professional societies, advocacy organizations, and individuals via self-nomination.

Representatives with recipient patient, registered and prospective organ donor, donor patient, and family backgrounds will be selected through a public application process, ensuring that a wide range of lived experiences is represented at the board level of the OPTN. The BOD will elect its own chair and vice chair from among its current members, with terms that can be renewed every two to three years.

Each committee will undertake its own open application and nomination process, which will be overseen by HHS/DoT, the Internal Governance Committee, and the BOD. Members may be nominated by professional societies, colleagues, or institutions, or they can apply directly, allowing for both grassroots and institutional participation. The Governing Board will appoint committee chairs and vice chairs, who will serve staggered terms of two to three years to ensure continuity and foster leadership development across the network.

After all nominations have been received and reviewed, the proposed slate for both the BOD and committees must receive approval from HHS/DoT before proceeding to a vote. The election will utilize a hybrid model that includes both public voting and votes from current board and committee members.

Stipends and travel reimbursements could be offered to BOD and committee members to support meaningful and inclusive participation. This approach would help lower barriers to entry, especially for patients, family members, and community-based participants.

4.7.4 Operational Support

A key aspect of the PPP governance model involves identifying core OPTN functions requiring specialized expertise. These recommendations are intended to address operational pain points identified during the current state assessment, including overreliance on volunteer members and the challenges associated with having one vendor or partner. The table below outlines operational functions the OPTN requires to increase efficiency, reduce COIs, and better align resources with operational demands. HHS/DoT will ultimately determine how these functions, as well as any future required functions, will be managed.

Table 26: PPP Recommended Operational Support

Operational Function	Tasks	Rationale	Potential Services
Technology and Infrastructure	Develop, manage, and maintain OPTN's technical infrastructure. This includes databases, system architecture, matching algorithms, API, and a Case Management Platform.	Current IT systems are outdated and pose risks to performance and security. A dedicated technology partner ensures up-to-date, secure, and scalable systems.	• Software development and maintenance • Create/update matching algorithm • System uptime and disaster recovery • Secure interoperability with transplant centers and OPOs • Implementation management

Operational Function	Tasks	Rationale	Potential Services
			• Implement and maintain the Case Management Platform
Organ Logistics & Tracking	Provide real-time organ tracking and optimize logistics chains from donor to recipient.	Delays and mismanagement in transportation reduce organ viability. Modern tracking (e.g., Global Positioning System (GPS) and Radio Frequency Identification (RFID)) has shown to reduce cold ischemia time.	• Organ transportation coordination • Real-time organ tracking systems • Emergency routing and delivery optimization
Data Analytics	Perform advanced analytics, reporting, and predictive modeling.	Improved decision-making and performance evaluation, particularly within internal OPTN operations related to the policy development process, rely on robust data science and machine learning (ML) applications.	• Policy modeling and simulations • Fairness and access dashboards • Performance evaluations and compliance insights
Communication and Education	Lead public education, stakeholder engagement, digital engagement, manage community feedback, and ensure transparency in policy development.	Public trust and registration depend on informed consent and transparency. Past Office of Inspector General (OIG) reports indicate that public education spending lacked oversight.	• National awareness campaigns • Culturally tailored education initiatives • Stakeholder newsletters, webinars, and consultations • Organize public comment forums and consensus workshops • Provide facilitation fools and user-centered design
Support	Provide critical administrative support to the OPTN and the policymaking process including facilitating key decision meetings, preparing notes before and after those	The OPTN depends on volunteer support for a lot of its critical functions. To ensure the OPTN can keep up with the rate of change required to manage	• Facilitate BOD and PC reviews of Policy Proposals and Policy Solution Briefs • Prepare discussion guides and serve as an objective facilitator for key decision

Operational Function	Tasks	Rationale	Potential Services
	meetings, vetting ideas submitted, and providing capacity support to the PDTs.	policy, additional capacity will be required.	meetings, like the BOD meetings • Vet all submitted ideas for alignment to strategic priorities and document ideas in the Case Management platform • Provide administrative support throughout the policymaking process, including notetaking and proposal drafting
Compliance and Auditing	Monitor adherence to vendor contracts and the governance structure.	Ensure vendors are producing the desired results against strategic priorities and resolve any COIs that may exist within the OPTN.	• Routine and unannounced audits • COI monitoring • Governance structure evaluation • Monitoring and evaluation of implemented policies

4.8 PPP Governance Model Implementation and Change Management Plan:

4.8.1 Implementation Steps and Activities

The proposed PPP governance model will be introduced using a four-phase approach, featuring a pilot test of the key governance entities within the OPTN. This phased implementation of the new PPP governance model enhances transparency, fosters stakeholder collaboration, and modernizes operational infrastructure while enabling a controlled and incremental rollout and supporting real-time refinement before full deployment. The following outlines the key implementation stages and the corresponding activities.

- **Phase 1: Planning and Preparation (6–12 months)**
  - Lay the groundwork for introducing a restructured OPTN under the new PPP governance model.
  - Establish a temporary transition task force composed of representatives from HHS/DoT, transplant centers, OPOs, patients, policy experts, and change management specialists to guide the process.
  - Finalize the structure and framework of the expanded PPP governance model.
- **Phase 2: Initial System Setup and Parallel Operations (6–12 months)**

- Begin establishing the new system while maintaining continuity of the existing structure to ensure uninterrupted operations.
- Appoint initial BOD members and begin forming core governance and advisory committees
- Develop and issue new contracts for key vendors, including IT infrastructure, data analytics, and communications services.
- Pilot the Finance Oversight Committee, the Organ Allocation and PC, the Quality Assurance and Safety Committee, and select organ-specific panels to evaluate functionality and gather early feedback for improvements.
    - This ensures long term viability, effectiveness, and patient safety are established early in the transition process.

- **Phase 3: Gradual Transition and System Activation (6–9 months)**
    - Begin the phased transition to the new structure and vendors, ensuring continuity through a carefully sequenced transfer of functions.
    - Migrate services in waves—starting with data systems, followed by IT infrastructure, and then policy operations—to manage risk and maintain stability.
    - Implement robust backup systems to prevent any disruption in organ matching, procurement, and transplantation coordination.
    - Provide comprehensive onboarding and training for OPOs, transplant centers, and committee members, supported by a dedicated help desk and transition team.
    - Launch real-time data sharing capabilities and public-facing reporting tools to promote transparency and performance monitoring.
- **Phase 4: Ongoing Monitoring and Continuous Improvement (No Fixed Timeline)**
    - Conduct regular independent evaluations of vendors, the governing board, and committee performance to ensure accountability and effectiveness.
    - Continuously gather feedback from patients, registered and prospective donors, families, caregivers, transplant centers, OPOs, and the public through surveys, town halls, and advisory groups, both online and in person, to recommend and implement improvements.
    - Maintain an adaptive policy framework with ongoing updates to promote innovation and responsiveness to emerging needs.

4.8.2 Resource Planning

4.8.2.1 Roles and Responsibilities

The successful implementation of the new PPP governance model for the OPTN depends on clearly defined roles, collaborative leadership, and shared accountability across all stakeholders. As the transition unfolds through each phase of the change management plan, specific individuals and groups will take on key responsibilities to ensure a smooth and transparent transformation.

Table 27: PPP Governance Implementation Roles and Responsibilities

Role	Responsibility
HHS/DoT	Serves as the federal oversight body, ensuring regulatory compliance, providing strategic direction, and facilitating coordination across stakeholders throughout the implementation process.
Temporary Transition Task Force	Leads initial planning efforts. Comprised of representatives from HHS/DoT, transplant centers, OPOs, patients, and policy and change management experts, this group will finalize the new governance framework and set the foundation for implementation.
BOD and Committee Members	Will review and re-establish governance structures, develop policies, and ensure financial and operational integrity. Key committees prioritized include Finance Oversight, Organ Allocation and Policy, and Quality Assurance and Safety.
Organ-specific Panel	Will be identified on an ad hoc basis as surge support to advise on the transition, providing guidance and feedback throughout the implementation process.
Vendors	Contracted to provide specialized services, such as IT systems, data analytics, and communications, etc. They will be responsible for delivering functional, secure, and scalable infrastructure to support internal operations of the OPTN.
Transplant Centers, OPOs, and Internal Governance	Participate in onboarding and training, transition support, and lead implementation at the operational level, providing feedback and recommendations to ensure new tools, protocols, and data systems are adopted.
Patients, Donors, Families, Caregivers, and the Public	Play a key role in continuous improvement of the governance structure by providing feedback through structured engagement channels such as surveys, and town halls.

4.8.2.2 Resource Allocation

Implementing a new PPP governance model for the OPTN will require a strategic approach to resource allocation, aligned with the objectives of each stage of the change management plan. In the earlier phases of the implementation of the PPP governance structure resources must be directed toward planning, stakeholder engagement, and planning. This includes funding for a temporary transition task force, composed of experts from across the OPTN, including HHS/DoT, transplant centers, OPOs, patients, and policy professionals. Investments in policy development support, legal consultation, and change management expertise will be essential to create a solid foundation for the governance structure.

As the new system is set up alongside the existing governance structure, resource demands will increase. Budgeting must account for the recruitment and onboarding of new BOD members, the formation of core governance committees, and the creation of organ-specific panels. Substantial funding will also be required for procuring and initiating contracts with vendors. Operational continuity will depend on sufficient support to maintain both systems simultaneously, while supporting iterative testing and refinements.

Ongoing monitoring of the PPP governance structure will require continued resources to manage the transition and sustain the implemented improvements. Phase 3 will necessitate allocation for phased system migrations, backups, comprehensive training programs for transplant centers and OPOs, and a fully staffed help desk to support onboarding. Phase 4 will require long-term investment in monitoring, evaluation, and stakeholder engagement tools, including survey platforms, town hall coordination, and performance dashboards.

4.8.2.3 Training and Support

Comprehensive training and support will be essential to ensure a successful transition to the new PPP governance model. As the new system is introduced, particularly in Phase 3, stakeholders; including OPO representatives, transplant center representatives, committee members, Organ-specific panel members, and vendor partners; will require role-specific onboarding. Training programs should cover the functionality of new IT systems, data reporting tools, allocation frameworks, and governance protocols. This effort will need to be coordinated and delivered through a combination of virtual modules, live workshops, and written resources to accommodate diverse schedules and learning preferences. Special attention should be given to organ-specific panels and newly formed committees, as their early engagement is critical to the function of the new system.

A strong support infrastructure must be in place to guide users through the transition and ensure long-term adoption. A dedicated help desk should be established to provide real-time technical assistance and policy clarification, particularly during the system migration in Phase 3. Transition support teams should also be available to offer one-on-one coaching and work through operational challenges as they arise. Ongoing education and refreshers will be important in Phase 4 to adapt to policy updates and stakeholder feedback.

4.8.3 Change Management and Stakeholder Engagement

4.8.3.1 PPP Governance Model Change Management Plan

To assist in the change management to move to a successful PPP transition, we recommend Kotter's 8-Step Change Model. It provides a step-by-step approach to successfully implementing change by focusing on communication and stakeholder engagement. It is useful for multi-stakeholder initiatives like restructuring the OPTN governance model, as it helps align multiple conflicting interests and sustain momentum over time.

Based on Kotter's 8-step change model adapted for federal implementation:

Create a Sense of Urgency: Highlight the need for change by emphasizing risks related to inefficiency and lack of transparency in organ allocation. Use data, patient stories, and expert

analysis to build momentum and create understanding amongst stakeholders that the current system must be changed.

Build a Guiding Coalition: Form a temporary transition task force with representatives from HHS/DoT, OPOs, transplant centers, patients, and policy experts. This team will guide the new PPP model and lead early planning and stakeholder engagement.

Develop a clear vision for the restructured PPP governance model, including improved transparency, accountability, innovation, and patient outcomes. Outline the phased implementation plan to help stakeholders understand the change.

Communicate the Vision: Engage voices from across the OPTN including clinicians, administrators, and patient advocates to help build grassroots support for the new governance system.

Enable Action: Address current obstacles such as unclear roles and outdated IT systems by investing in training, offering transition support, and clarifying communication channels.

Generate Short-Term Wins: Pilot the Finance Oversight, Organ Allocation and Policy, Quality Assurance and Safety Committees and several organ-specific panels to demonstrate early success. Publicly share metrics and positive feedback to reinforce momentum and validate the structure.

Build on early successes by expanding committee operations, fully transitioning services in waves (data, IT, policy), and maintaining open communication. Provide continuous training and support while scaling the new structure across all stakeholder groups.

Anchor Change: Embed the new PPP governance model into the OPTN by aligning policies, performance measures, and stakeholder engagement around transparency and innovation. Continue to gather feedback, conduct evaluations, and update systems and policies to adapt to future needs.

4.8.3.2 Key Stakeholders:

The implementation of the new PPP governance model for the OPTN relies on the active involvement and coordination of key stakeholders. HHS/DoT provides oversight, guides the strategic direction, ensures regulatory compliance, and facilitates alignment across the public and private partnership. Transplant centers, OPOs, and other clinical transplant professionals will be critical in adopting new systems. Recipient patients, registered and prospective organ donors, donor patients, and their families provide essential perspectives to shape equitable and transparent governance practices. Policy experts, legal advisors, and change management professionals will help design and execute the transition. Additionally, the vendors will be important in building the foundation for the new governance system.

4.8.4 Feedback Loops

During the implementation of a PPP governance model, feedback loops will play a critical role in ensuring transparency, adaptability, and continuous improvement. One primary feedback mechanism will be structured stakeholder engagement, which includes routine consultations with recipient patients, registered and prospective organ donors, donor patients, their families, OPOs, and transplant centers. These stakeholders will be invited to provide input through formal channels such as advisory committees and panels and public comment periods. Their feedback will be analyzed and used to adjust operational priorities, refine allocation policies, and evaluate the performance of vendors and participating institutions. The iterative nature of this engagement will ensure that governance decisions reflect evolving medical standards, ethical considerations, and community needs.

Another feedback loop will include data-driven performance monitoring. The PPP model will include real-time collection and analysis of metrics such as organ utilization rates, waitlist mortality, and equitable access across demographic groups. Independent audits will further validate these performance assessments. Results will be fed to the oversight structures and the vendors to drive policy creation and innovation.

5 Evaluation & Monitoring

Evaluation and monitoring are critical to successful transformation, serving to understand how the process is working, quantify and qualify consequences- both positive and negative- of changes made, and adjust when requirements and milestones are not completed as planned. Governance structures and policy development structures require different approaches to evaluation and monitoring. Both should be based on measurable outcomes grounded in the performance metrics such as those recommended below.

5.1 Performance Metrics – Policy Process

Performance metrics should also be used to evaluate the efficacy of the SPPDF framework and its impact on the organ procurement and transplantation community. Potential metrics to assess the efficacy of the SPPDF framework include:

- **Phase 0:** A targeted number of policy proposals should be submitted and address issues pertaining to broader patient and community needs. Policy ideas should be sourced from members reflecting the size and variety of the organ procurement and transplantation community.
    - **Metric:** Track and analyze policy sources to ensure balanced engagement from diverse stakeholder groups.
    - **Metric:** Proposal Intake - Number of proposals submitted, completeness rate, and average time to submission acceptance.

- **Phase 1:** Policy proposals will be scored and prioritized on a rubric. The rubric will serve as a basis for policy selection and prioritization and include factors such as budget, resources and feasibility. The City of Portland provides a framework for scoring project applications based on criteria like budget, organizational feasibility and economic and social benefits.
    - **Metric:** Develop a standard rubric for assessing all policy ideas based on clear criteria such as budget, impact, resources, and feasibility.
    - **Metric:** Community Connection – Number of stakeholders engaged and number of representations across stakeholder types of engagement sentiment score.
- **Phase 2:** Ensuring that diverse and representative stakeholder views are included in the studies.
    - **Metric:** Measure the amount and variety of stakeholder input, and the extent to which different perspectives are incorporated into the studies.
    - **Metric:** Review & Analysis - Number of proposals under analysis, fairness impact score, and cost-benefit ratio.
- **Phase 3:** Targeted engagement to all stakeholder groups, particularly recipient patients, registered and prospective organ donors, and underrepresented groups. How well this phase performs will be judged by the number and representativeness of stakeholders providing comments to the policy solution brief.
    - **Metric:** Evaluate the number and type of stakeholder(s) providing comments on the policy solution brief.
    - **Metric:** Feedback Integration - Feedback addressed, stakeholder agreement rating, and volume of feedback by topic.
- **Phase 4:** Governance Approval
    - **Metric:** Continuous tracking of policies aligned to strategic goals and legal compliance .
- **Phase 5:** Implementation is measured by the speed and costs of policy adoption across the network. Monitoring will measure the policy's fidelity to its original intent and whether it is achieving its desired result. Surveys can determine the success of implementation and the effectiveness of education in stakeholders' understanding of the policy.
    - **Metric**: Track the speed and cost of policy implementation and maintenance.
    - **Metric:** Implementation & Optimization - Number of policies implemented and average time
- **All Phases:** Performance of the SPPDF will be measured by the length of time from ideation to implementation and monitoring.

- **Metric:** Conduct ongoing monitoring of the SPPDF framework by evaluating time, cost, and resource utilization.

5.2 Performance Metrics – Governance Transformation

Evaluating the proposed governance structure is essential for ensuring its success and identifying areas for improvement. Performance metrics should be utilized to assess the efficiency and effectiveness of this new governance framework. Potential areas for measuring success include:

Composition and Variety:

- BOD/Committee Composition: Track the variety of members in terms of gender, ethnicity, geographic location, and expertise.
- Skills and Experience: Measure the range of skills and experience represented on the BOD and committees.
    - Submit profiles of members onto a project management platform
        - Dashboard or visuals showing member breakdown
    - Create learning and training programs

Recruitment and Retention:

- Applicant Profiles: Monitor the number and quality of applicants for BOD and committee positions.
    - Monitor how often BOD members exit before their term limit
    - Monitor accepted versus denied applications
    - Examine BOD qualifications (e.g., Industry experience in policy/healthcare)

Meeting Effectiveness:

- Attendance Rates: Track the attendance at meetings.
    - Use a Quick Response (QR) code for attendees to scan and confirm their attendance
- Engagement Levels: Measure participation in discussions and decision-making processes.
    - Track voting trends (for or against policies)
    - Utilize interactive surveys
- Meeting Duration: Compare the number of minutes spent in meetings to the number of policies or decisions produced.

Stakeholder Engagement:

- Satisfaction: Collect feedback from stakeholders on the new governance process and their satisfaction levels.
    - Utilize online survey tools (e.g., Survey monkey, Google forms, etc.)
- Communication Effectiveness: Measure the effectiveness of communication channels with stakeholders.
    - Through meeting outcomes and project metrics such as deadlines
    - Monitoring engagement: increased engagement can be a sign of effective communication

- Ensure changes, requirements, and updates are well documented, and accessible to all members

Compliance and Risk Management:

- Statutory and Regulatory Compliance: Monitor adherence to statutory and regulatory requirements.
  - Utilize compliance checklist
- Risk Management: Evaluate the effectiveness of risk management strategies and the BOD's responsiveness to emerging risks.
  - Predictive analytics can help track news, compliance and regulatory updates, market trends, and potential outcomes, emerging risks integrated into operational planning, timelines

Financial Performance:

- Budget Adherence: Track adherence to budgetary constraints and financial planning.
  - Review existing budget baselines, budget reviews and monitoring cashflows, predictive analytics or repurpose an existing patient centric dashboard to visualize trends and create alerts for potential over or underspending and revise as needed.
- Resource Allocation: Measure the efficiency of resource allocation and use.
  - Measure ROIs of resources, project delivery metrics such as time delivery rates, scope creep incidents

Strategic Outcomes:

- Goal Achievement: Assess the achievement of strategic goals and objectives.
  - Evaluate achievements using the SMART goals framework
- Public-Facing Performance: Policy transparency index, policies with accessible public dashboards, website traffic and engagement with policy tools, time to respond to public inquires/comments, and NPS (Net Promoter Score)/public trusting rate.
- Project Management & Workflow Health: Track the number of policies stuck in a phase beyond the identified threshold time, time-in-phase average (per phase and per proposal), track the number of overdue steps/tasks of workflows completed without escalation and the utilization of automated reminders and triggers.
- Impact Measurement: Evaluate the broader impact of governance decisions on the organization and its stakeholders.
  - Conduct gap analysis to identify changes needed within the policy

5.3 Regular Reviews

- Routinely measure and report outcome data to determine whether policies are achieving desired results. Audits should be regularly conducted to report on performance data and stakeholder feedback.
- Review should incorporate the Re-AIM framework into the SPPDF policy process to better evaluate and monitor policies after implementation. Re-AIM has mechanisms for tracking outcomes and long term viability and can evaluate if framework is faithful to its original intent.

- The tool helps to assess how well the new policy process is being delivered, adopted, and sustained, with particular attention to its impact on underrepresented groups and locations.

5.4 Stakeholder Feedback

- Feedback will be solicited from stakeholders using repurposed patient centric online dashboards where OPTN members can comment on the new framework and identify areas for improvement.
  - Committee members and support staff will regularly review efficacy of the SPPDF during pilot testing and after full implementation.
  - Customized tools like SmartReview, DocketScope or qualitative analysis tools like NVivo can aggregate public comment feedback for analysis of key insights and pain points.

6 Risk Assessment & Mitigation Strategies

Several potential risks inherent in the SPPDF have been identified. The following is a list of potential hurdles and strategies to mitigate them.

- **Volunteer-driven bias:** Ideas tend to reflect committee members' professional backgrounds rather than broader patient/community needs. Mitigation strategies include:
  - Targeted engagement to patients and the broader community to solicit ideas from these stakeholders and mitigate any bias in idea generation, policy analysis and public comment feedback.
- **Resource bottlenecks:** Insufficient capacity (staff/volunteers) to properly vet and rank all proposals. Mitigation strategies include:
  - Employ a sufficient number of staff within the HHS/DoT to execute the multiple phases of the process.
  - Engage vendors to perform tasks like internal data analytics and stakeholder engagement.
  - Utilize software to improve policy analysis and analyze important information.
- **Disjointed data systems:** Limited integration between transplant center, OPO, and waitlist data inhibits comprehensive implementation and outcome analyses. Mitigation strategies include:
  - Create a central repository, or "data lake," to integrate all OPTN system data.
  - Adopt APIs to automate data transfer, reducing lags in data integration and eliminating manual data entry errors.
- **Technical complexity barriers:** Complex draft policies may be hard for non-experts to review and comprehend easily. Mitigation strategies include:
  - Offer easily digestible memos outlining policy proposals and tailor them to non-medical and/or non-technical stakeholders.
- **COI risks:** BOD members may represent organizations affected by policies. Mitigation strategies include:

  - Implement comprehensive COI guidelines that prohibit members from voting on policies that may personally benefit them.
  - Change the composition of the BOD to incorporate a greater variety of stakeholders.
- **Fragmented implementation responsibilities:** Unclear division of roles between OPTN committees, vendors, and member organizations. Mitigation strategies include:
  - Clearly define accountabilities and responsibilities.
  - Define roles for committees, vendors and other stakeholders in each phase in the policy development process.
- **Low submission/lack of variety in policy submissions:** Mitigation strategies include:
  - Communication support to source and submit policy ideas from the organ procurement and transplantation community, particularly patients, the public and traditionally underrepresented groups.
  - Communicate about policy
  - Provide user-friendly website for policy ideas submission that is available to the public.
- **Too many idea submissions:** Step 0 requires all policy proposals be reviewed and prioritized. Mitigation strategies include:
  - Ideas are collected on a rolling basis and vetted on their alignment with strategic priorities using selection criteria or scoring rubric.
  - Engage vendors to assess and prioritize policy ideas.
- **Limited availability of committee members:** May lead to delays. Mitigation strategies include:
  - Provide support for related tasks such as study/review and writing.
- **Apprehension from members in adopting the new policy framework:** Mitigation strategies include:
  - Gradually implement the new framework, focusing on 1-2 initial proposals.
  - Increase the number of committees and proposals as adoption becomes more prevalent.
- **Favoritism in policy proposal process:** Mitigation strategies include:
  - Increase engagement by providing feedback to all submissions and explaining the reasons for not selecting some proposals.
  - Vendors will filter policy ideas and document information in case management system to improve transparency.

Transformation of system governance can introduce risks such as reduced engagement by some stakeholders or groups, challenges adapting to new roles, misalignment of accountability and level of support, and delays in the review of new policy proposals and other BOD and Committee tasks. Below is a list of risks and mitigation strategies to avoid and/or address them.

- **Loss of expertise and talent:** Due to changes in program management, position requirements, and committee composition, some staff and committee members will choose to leave or may no longer be eligible to remain in place. Mitigation strategies include:

  - Implement transition periods and facilitate content/project handover from SMEs.
  - Provide training and support to new SMEs.
  - Communicate about program changes, timelines, and expected benefits.
  - Recognize departing individuals' contributions and ask for their support for a modernized OPTN.
- **Change in composition of stakeholders:** As the BOD and committees reorganize and stakeholder engagement is enhanced, member and stakeholder number and composition are likely to change. Mitigation strategies include:
  - Communicate about program changes, timelines, and expected benefits.
  - Monitor stakeholder engagement to ensure balance and adjust connection and engagement strategies.
- **New role responsibilities:** As governance is reorganized, individuals will be stepping into new roles that may present new challenges. Mitigation strategies include:
  - Document clear accountabilities and responsibilities for roles.
  - Monitor performance and the need for support and resources to ensure success.
- **Insufficient internal support to execute new governance framework:** New Administration priorities may shift and reduce the staffing and funding support for OPTN modernization. Mitigation strategies include:
  - Identify changes to existing modernization plans and gaps related to staffing and resources created by shifting priorities.
  - Consider adjustments to modernization plans.
  - Communicate with stakeholders about changes in resources and plans.
- **Delays in BOD and Committee work:** During reorganization, new individuals will enter, and existing individuals will exit BOD and Committee positions causing potential delays due to elections and the need for orientation and training. Mitigation strategies include:
  - Anticipate and adjust schedules to allow transition and orientation.
  - Communicate with stakeholders about planned changes to OPTN governance structure and possible delays.

7 Documentation & Processes

7.1 Documentation

Process documentation provides clarity and transparency, facilitates knowledge transfer, acts as a valuable training tool, plays a crucial role in quality management and serves as a foundation for compliance and auditing purposes. This will lead to stakeholder satisfaction and engagement. Continuous improvement through regular reviews, communication, and process enhancement, will continue support change adaption to the new policy and governance models.

Governance documentation must clearly delineate the responsibilities, authority structures, and decision-making processes of each aspect of internal governance. This includes updated regulations,

bylaws, charters, policies, and guidelines that reflect the diversified and distributed nature of a modernized OPTN.

7.1.1 OPTN Final Rule Alignment Recommendations

The OPTN Final Rule will require modernization to ensure alignment with the SPPDF and the new governance structure. This modernization may involve revising current regulations to incorporate updated practices that enhance policy effectiveness, stakeholder engagement, and ongoing evaluation processes. Making these changes will empower HHS/DoT and the OPTN to consistently address OPTN challenges, ensure that OPTN processes are transparent to all stakeholders, and facilitate a more strategic approach to policy development that prioritizes effectiveness, efficiency, and positive outcomes. Updates to NOTA were also considered but deferred due to the extended timeline required to implement. The table below outlines recommended changes to the OPTN Final Rule for seamless implementation of the SPPDF and governance structure.

Table 28: OPTN Final Rule Alignment Recommendations

Current Constraint	Recommended Changes	Justification
The OPTN Final Rule lacks an explicit requirement for strategic priority alignment in early-stage idea generation. The Final Rule is also silent on continuous strategic planning and structured ideation beyond general ethical guidelines.	• Add a mandate for OPTN to periodically align its policy agenda with HHS/DoT strategic priorities (e.g., fairness, innovation, patient-centered outcomes). • Require OPTN and HHS/DoT to develop a five-year Strategic Policy Plan that guides policy idea generation. • Mandate a "Needs Assessment" every 3–5 years that identifies gaps in access, innovation, and fairness.	Incorporates patient voices, emerging technologies, and health fairness issues earlier into the policy pipeline.
Stakeholder feedback currently lacks formal procedural status.	Amend §121.4(b) to: • Require structured public comment periods for all major policies. • Mandate summary responses to public comments explaining accepted or rejected changes.	Improve transparency and accountability

Current Constraint	Recommended Changes	Justification
The OPTN Final Rule vaguely references responsibilities without quantitative performance standards.	Introduce Measurable Performance Standards KPIs. Amend §121.4 to identify a core set of KPIs to monitor OPTN performance	Enhance efficiency and accountability
The OPTN Final Rule includes BOD composition requirements that do not align with recommended governance structure	Amend the Final Rule to ensure consistency with the new governance structure	OPTN Modernization aims to establish a more transparent and accountable governance structure. The existing Final Rule does not adequately reflect the governance reforms now deemed necessary.

Note: "Equity" the word as used in the table above and throughout this document references the statutory requirement and definition as defined by NOTA and The Final Rule.

7.1.2 Contract Recommendations

HHS/DoT's OPTN Modernization Initiative (2023–2025) moves OPTN toward a modern PPP model — separating previously consolidated functions (IT, policy, evaluation) and requiring competitive contracts. This model requires changes to previous contract management strategies as described below.

The PPP governance model, where the federal government partners with private or nonprofit entities, enables stronger accountability, transparency, competition, COI management, and a focus on public benefit.

The PPP Governance Model emphasizes:

- Separation of governance from operational management
- Transparency and accountability
- Performance driven contracts
- Strong oversight and enforcement

Clear and effective contract language is essential for guaranteeing vendor accountability, promoting efficiency, and ensuring proper oversight. Effective contract language should:

- Define Clear Roles and Responsibilities: Clearly outlined terms reduce ambiguity by specifying who is responsible for each task.
- Establish Performance Expectations: Measurable deliverables, timelines, quality standards, and facilitate accountability for all parties involved.
- Describe Enforcement Mechanisms: Clearly specify consequences for non-compliance to ensure obligations are enforceable.

- Establish a Streamlined Process: Contracts should outline expected workflows, communication protocols, and decision-making procedures to minimize delays and confusion.
- Ensure Transparency: Clearly define requirements for regular reporting, audits, and data sharing to ensure effective oversight and monitoring.
- Delineate Review Mechanisms: Incorporate built-in checkpoints to allow for course corrections and continuous improvement.

The recommendations below provide rationale and further details for consideration when developing new OPTN contracts.

Table 29: OPTN Vendor Contract Language Recommendations

Recommended Change	Problem	Details
Specify Accountability Mechanisms for OPTN Contractor(s)	Need for performance consequences if a contractor underperforms.	Include contract language that: • Requires performance-based contracts tied to KPIs (e.g., fairness measures, waitlist time reduction, organ utilization rates). • Allow corrective action plans and contractor replacement based on poor performance.
Strengthen Oversight and Independent Audits	Currently, oversight depends largely on HRSA administrative discretion.	Include robust contractual oversight provisions: • Require independent external audits of OPTN contractor(s) every 3 years. Provide HHS/DoT with explicit authority to intervene, suspend, or terminate contracts for governance or performance failures.
Clarify Ownership and Control of Data	Ambiguity about who owns OPTN's data assets.	Ensure contract language regarding recordkeeping and reporting requirements includes: • Designating OPTN data as a federal public asset (this may require Congressional approval). • Require that data systems be vendor-independent and transferable if contracts change.
Introduce Measurable Performance Standards KPIs	Need clear performance measures to ensure contractor accountability	Include contract language that: • Sets specific KPIs for OPTN performance (e.g., regional variance in wait times, organ discards, organ procurement, and transplantation fairness metrics). • Tie contractor renewal and funding to achieving these KPIs.

7.2 Processes

Process development is crucial for establishing structured, repeatable systems. Effectively describing a process involves breaking it down into clear and logical steps while providing sufficient context for others to understand and replicate it.

7.2.1 Future State Service Blueprint

The figure below (figure 8) is a thumbnail of the Future State Service Blueprint which sets out the internal processes and workflows on how process/steps will be completed.

Note: Re-engineering Report submission includes a PDF of the Future State Service Blueprint as an attachment. Please refer to the PDF attachment for a detailed view.

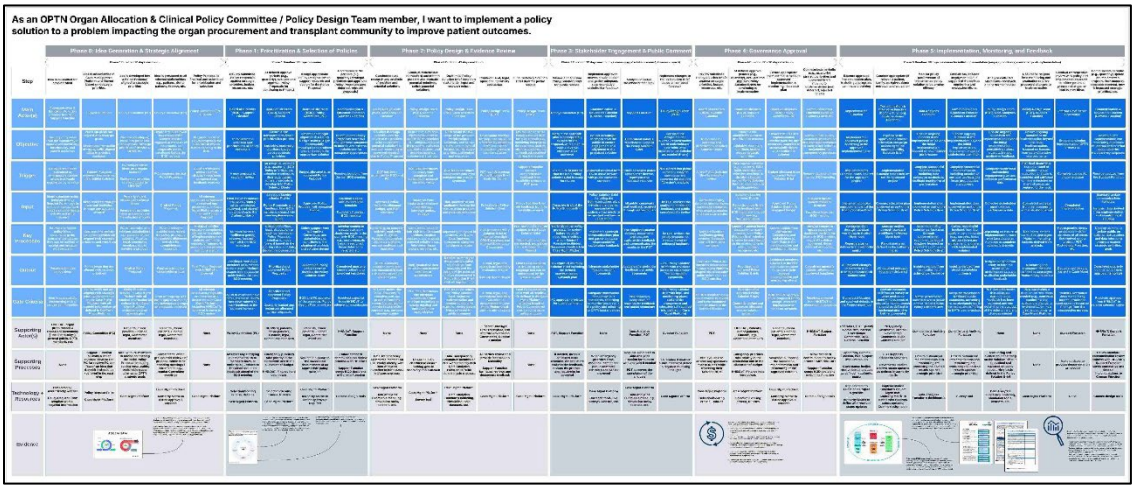

Figure 8: Future State Service Blueprint

7.2.2 Sample of Policy Development Process and Workflow

The narrative below offers a detailed description of each phase of the SPPDF and all the tasks that occur in those phases.

Each figure outlines how stakeholders will be involved during each phase.

Phase 0: Idea Generation & Strategic Alignment

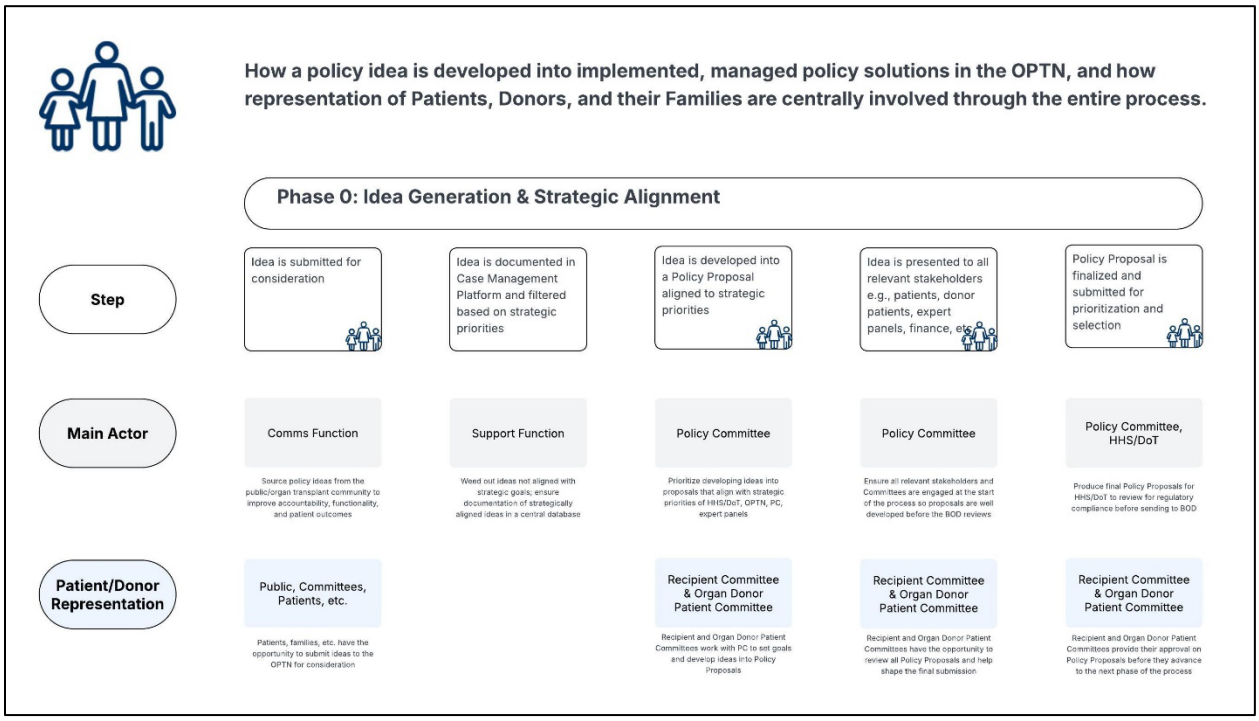

Figure 9: Phase 0: Idea Generation & Strategic Alignment

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 0.

Phase 0 of the recommended policy development framework is triggered by the identification of a policy gap, community concern, or regulatory issue within the organ procurement and transplantation ecosystem. Ideas can be generated by any stakeholder, may arise in response to a Congressional inquiry, or follow HHS secretarial direction to address a public health or patient safety concern. Once an idea is identified, whether a general policy or an emergency situation, it is submitted via the case management platform. This process provides access and engagement to more stakeholders.

Submissions are logged and assessed for strategic alignment, meaning they are elevated based on how well they match up with the key priorities outlined by HHS/DoT and the OPTN BOD. This ensures that invested resources are focused on proposals with the highest likelihood of success, addressing a previously identified issue with inefficient policy prioritization.

From here, the PC takes the lead in developing policy drafts, consulting with SMEs as needed about the best approach to shape the policy proposal, including setting measurable, actionable goals aligned with the strategic priorities.

The proposal is then shared with other key stakeholder constituencies, such as committees, recipient patients, registered and prospective organ donors, families, and OPOs/transplant centers, to gather more feedback, foster stakeholder engagement, and ensure that the most relevant proposals are made to the BOD. After feedback is incorporated, the PC finalizes the proposal and submits it for prioritization in Phase 1.

HHS/DoT's regulatory oversight is necessary to ensure that all policies align with strategic goals and funding priorities. After the PC has finalized the proposal, HHS/DoT will review to verify its compliance with NOTA and the OPTN Final Rule, providing guidance to incorporate statutory and regulatory considerations early in the policy development process. This oversight helps identify potential issues that may conflict with existing federal requirements. Additionally, HHS/DoT's role includes advising on the feasibility of implementing new policies, promoting transparency and consistency throughout the idea generation stage. This can aid in steering ideas into policies that comply with federal regulations and ensure alignment with strategic priorities while benefiting the organ procurement and transplantation community.

Phase 1: Prioritization and Selection of Policies

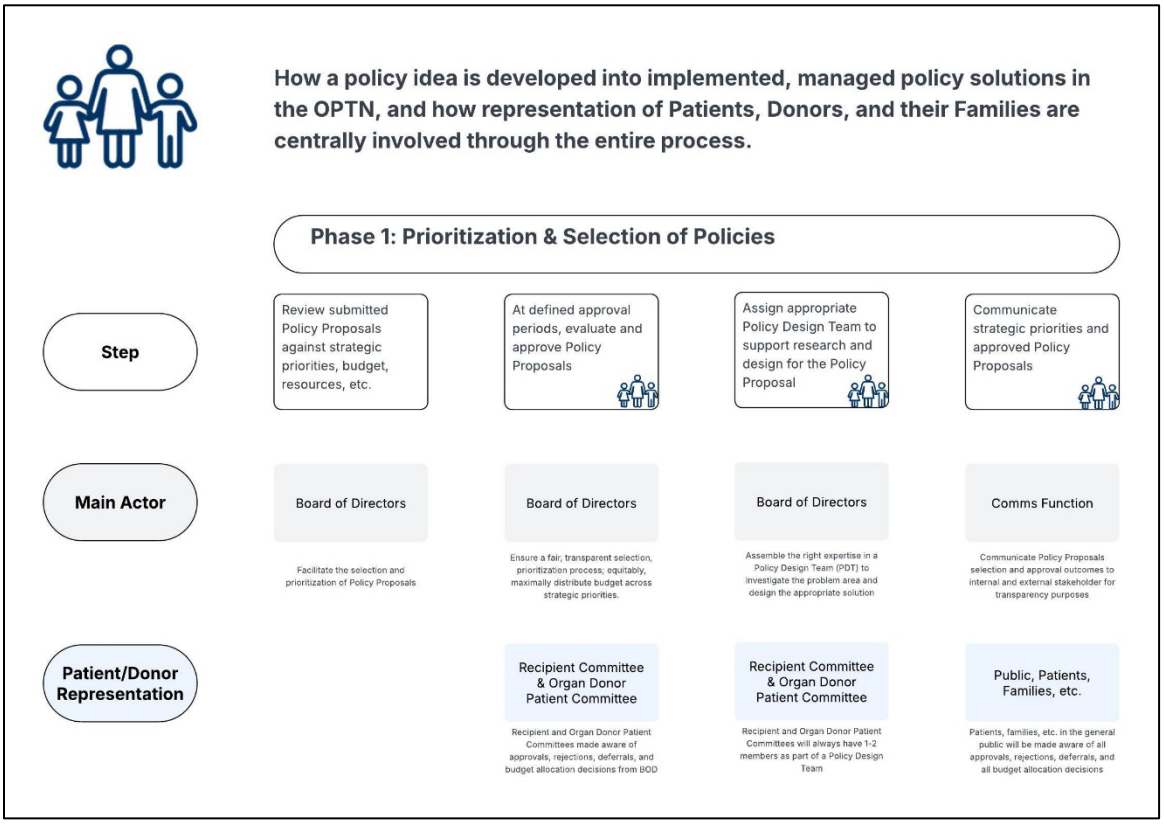

Figure 10: Phase 1: Prioritization & Selection of Policies

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 1.

Once a structured and well-supported proposal is ready, it moves into Phase 1: Prioritization and Policy Selection. Here policy proposals are voted on and move from idea to becoming a planned project. This phase begins when proposals are presented to the OPTN BOD for consideration, using selection criteria or a scoring rubric to measure important factors (e.g., alignment with strategic priorities, budget considerations, feasibility, resource allocation).

Based on results from the scoring rubric, approved proposals are prepared to move into Phase 2: Policy Design and Evidence Review. For each policy proposal, a PDT is assembled and tasked with successfully investigating the problem area and designing the appropriate solution (Policy Solution Brief). To maintain transparency during the process and show a commitment to engagement, each policy's proposal and approval outcome will be communicated to internal and external stakeholders.

Phase 1 involves both primary and supporting actors who ensure that policy proposals are reviewed promptly and fairly. They also share outcomes with the organ procurement and transplantation community, including the PC, HHS/DoT and the BOD.

Phase 2: Policy Design and Evidence Review

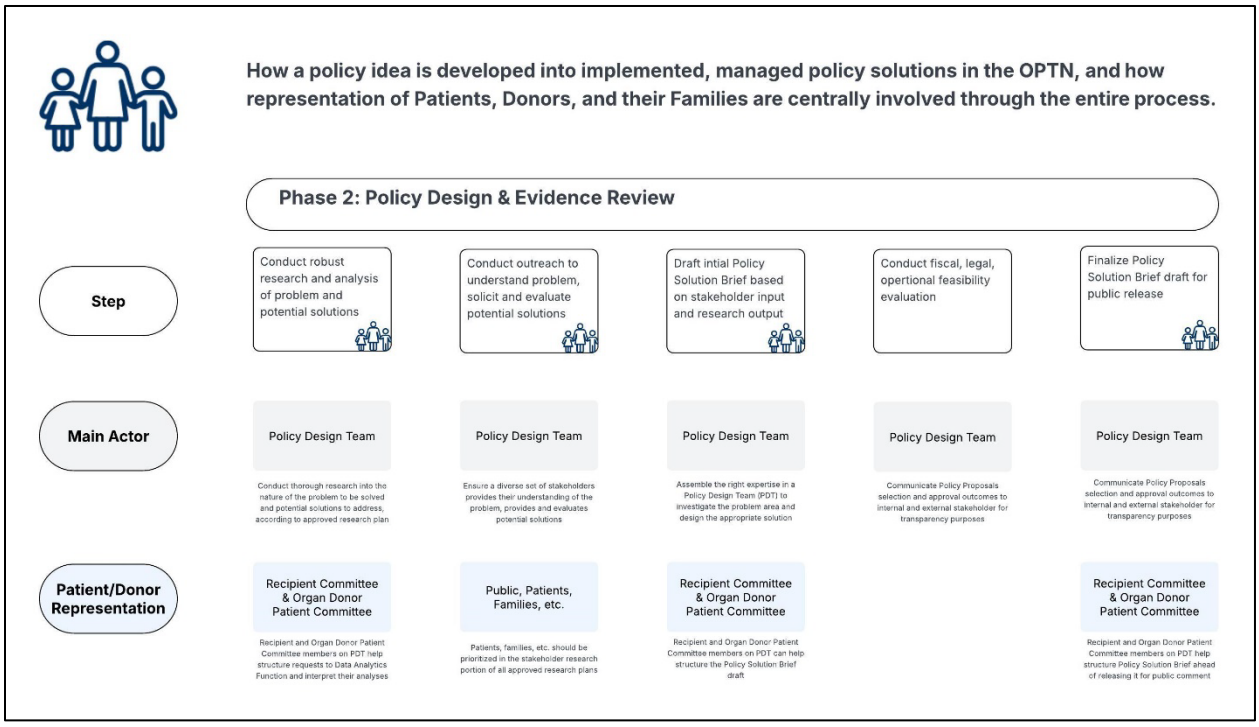

Figure 11: Phase 2: Policy Design and Evidence Review

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 2.

Phase 2 of the SPPDF centers on conducting a comprehensive review, study, and analysis to refine and validate proposed policies. This phase begins with a thorough investigation into the policy problem and potential solutions. The PDT will conduct an in-depth study/analysis into the nature of the problem and potential solutions according to an approved analysis plan. The team will complete the initial analysis. This includes gathering quantitative data, running models and simulations to understand the scope of the issue. All findings are carefully documented and uploaded to a case management platform that can be accessed by stakeholders. The result of this analysis will be a draft incorporating some early findings and analysis.

Next, stakeholders are engaged to further understand the policy problem and introduce solutions. Targeted efforts will be made to engage stakeholders through committees, ad hoc organ-specific panels, and other relevant stakeholders. Diverse perspectives will be gathered through interviews, focus groups, surveys, and other engagement methods to deepen the understanding of the problem. The PDT will analyze stakeholder feedback and determine when enough information has been collected.

After the stakeholder analysis and desk review are completed, a policy solution brief is drafted, incorporating an outline of the problem's scope, an analysis of findings, and preliminary solution strategies that align with the OPTN's strategic priorities.

The solution's practicality is then rigorously assessed through fiscal, legal, and operational feasibility studies. A collaborative review process will ensure that any potential barriers or concerns are resolved early in the process. The final step in this phase is preparing the final policy solution brief for public comment release.

Phase 3: Stakeholder Engagement and Public Comment

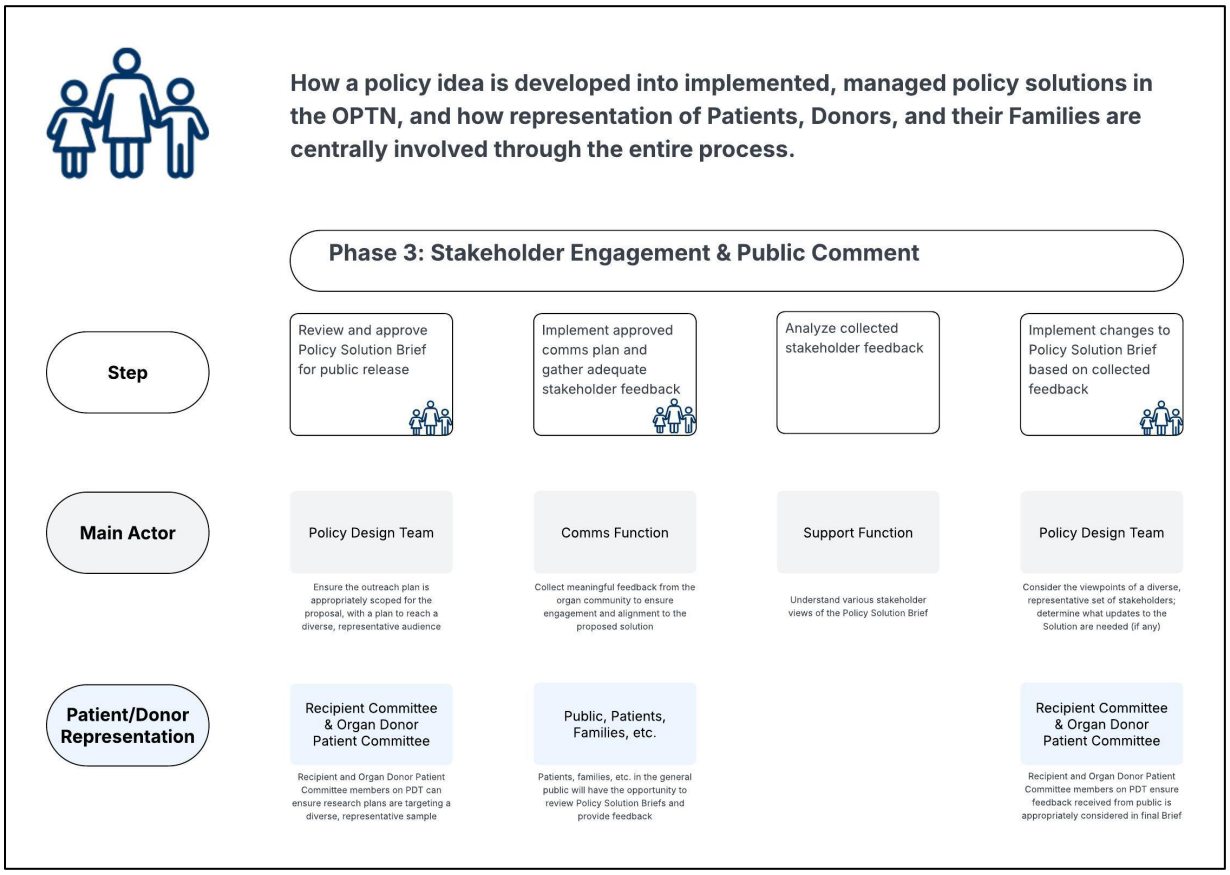

Figure 12: Phase 3: Stakeholder Engagement & Public Comment

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 3.

Phase 3, called Stakeholder Engagement and Public Comment, is designed to gather valuable feedback from the public and stakeholders across the OPTN

The phase begins with the PC reviewing the brief submitted by the PDT and evaluating its readiness score. If additional review or stakeholder feedback is required, additional feedback will be obtained, and revisions will be completed before resubmission to the PC for review prior to being sent out for a formal public comment period. An engagement plan will be used to notify and engage stakeholders from diverse demographics. Adequate public comments will be collected according to the metrics and goals established in the policy solution brief.

Analysis of stakeholder feedback will be conducted after it has been collected, documented, and carefully examined, looking for key insights and criticisms. Modeling and simulation tools will be utilized as needed to deepen analysis.

The policy solutions brief is revised based on the feedback received. The goal is to produce a final, polished policy document that considers diverse stakeholder input, along with a clear plan for implementing the policy across the organ procurement and transplantation community and a monitoring strategy to evaluate its effectiveness. A blueprint to educate and engage stakeholders on the policy will also be included in the final policy solutions brief.

Phase 4: Governance Approval

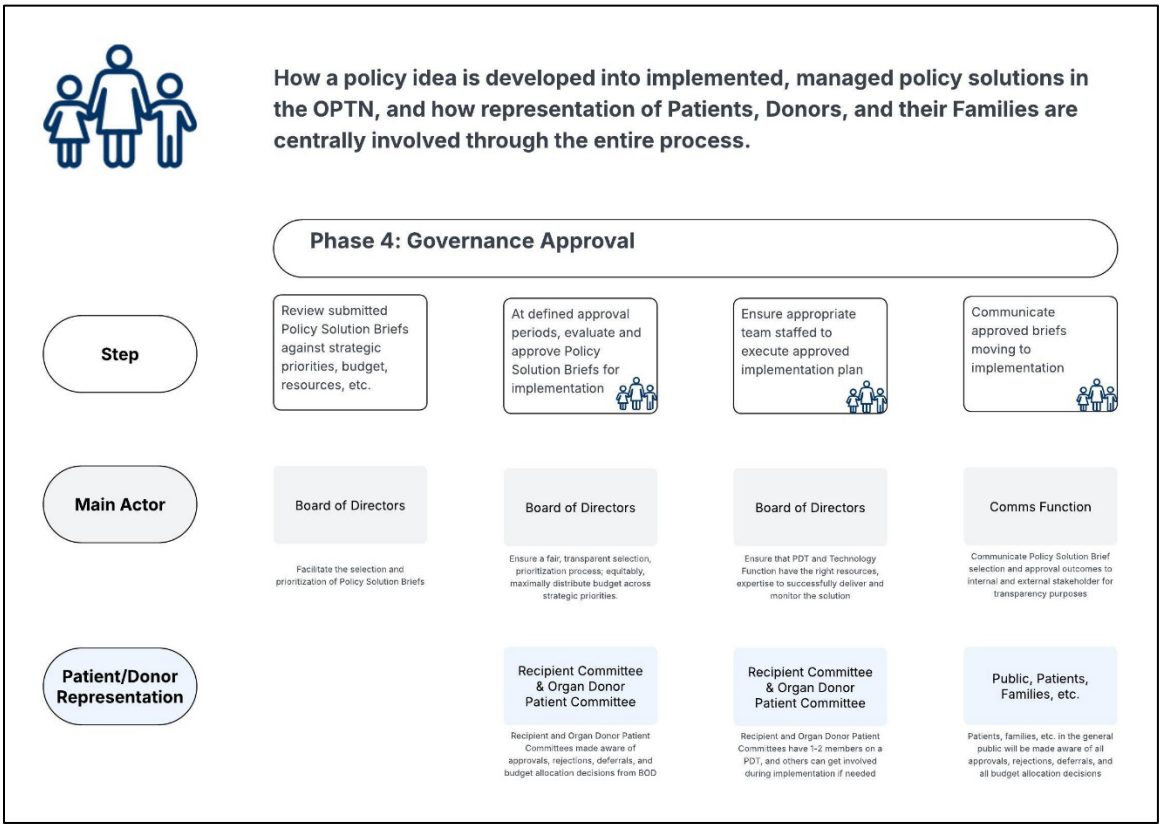

Figure 13: Phase 4: Governance Approval

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 4.

In Phase 4, the PC submits the final policy proposal, complete with a comprehensive implementation and monitoring plan, and a stakeholder engagement and education strategy to the BOD for review and final approval.

In conjunction with HHS/DoT, the BOD evaluates and votes on submitted policy solution briefs.

All voting decisions—whether approvals, deferments, rejections, or requests for revisions—will be documented in the case management system along with their justifications. For a proposal to advance, sufficient justification demonstrating its alignment with the strategic plan and feasibility across financial, legal, operational, and policy dimensions must be provided. Approved policies will be formally recorded, including voting outcomes and rationale, and will be shared publicly on the OPTN website after each meeting.

HHS/DoT a policy has been approved by the BOD, its status is updated to "approved" in the case management platform, and the PC assigns the appropriate combination of internal and external staff to support the implementation process. These assignments are documented in the case management platform. At this point, the focus shifts to ensuring transparency with the public and relevant stakeholders by communicating updates on strategic decisions made by OPTN. HHS/DoT approved updates are published using a combination of the case management platform and the OPTN's public-facing website and database. This ensures broad access to accurate and timely information across the organ procurement and transplantation ecosystem.

Phase 5: Implementation, Monitoring, and Feedback

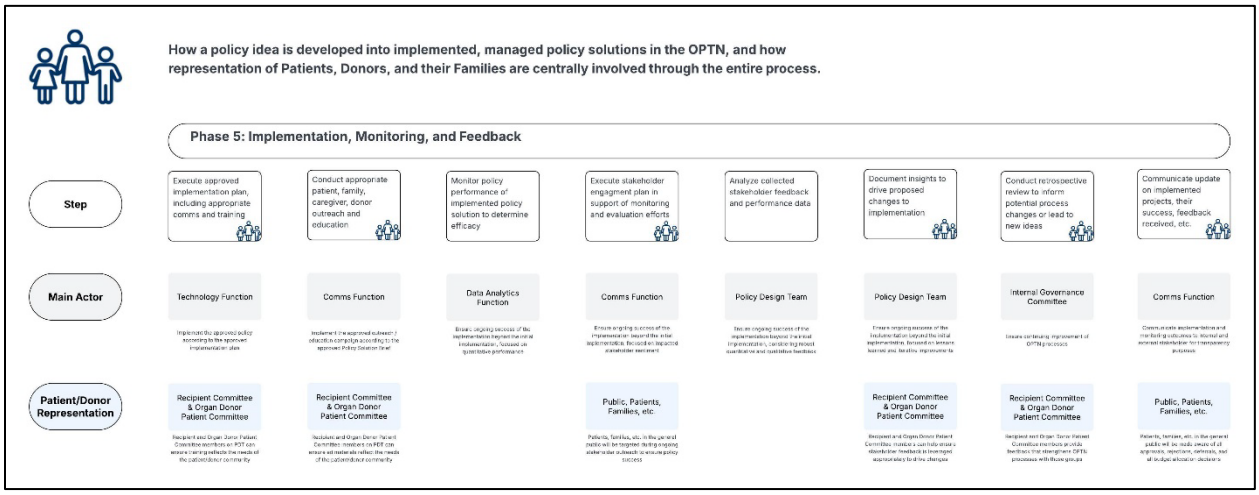

Figure 14: Phase 5: Monitoring, Evaluation, & Feedback

Note: Re-engineering Report submission includes a PDF of the Future State Stakeholder Engagement as an attachment. Please refer to the PDF attachment for a detailed view of Phase 5.

After a project receives approval, the implementation phase begins with a kickoff meeting. The goal is to execute the implementation plan, which includes delivering all necessary training and communicating essential information via an Engagement and Education campaign that adheres to the requirements outlined in the communications plan.

Following the successful completion of policy implementation, the focus shifts to evaluating the policy's effectiveness through data collection and performance tracking. The evaluation process will be guided by one of several implementation science frameworks, such as RE-AIM, EPIS, or the Pew framework.

Next, sustained impact is ensured through ongoing stakeholder engagement to maintain transparency. and support the long-term success of the policy. A rubric can be used to determine if implemented policies are targeting the correct demographics by linking multiple data sources for enhanced program evaluations. Analysis of findings inform future policy refinement and improvement to ensure the continued success of the policy beyond its initial implementation. Insights are captured to support the policy's ongoing success through continuous improvement. The case management platform remains the central technology used to store and manage these insights, ensuring they are accessible to guide future decision-making and governance efforts.

Upon successful completion of a policy implementation, a retrospective review is conducted to identify opportunities for process improvement and generate new ideas. Transparency is promoted by sharing periodic updates on implemented projects, including their outcomes, feedback received, lessons learned, new initiatives stemming from them, and their alignment with OPTN's strategic priorities.

Quarterly communications summarizing key policy updates will be developed. Before they are released, all communications must receive formal approval from HHS/DoT.

7.3 Communication Plans – Reporting Mechanisms

This Policy Communication Plan template will inform stakeholders about new or revised policies. It outlines what is required to ensure all relevant stakeholders understand the new, amended, or replaced policies.

Effective reporting mechanisms are essential to monitor performance and maintain public trust. Under the expanded PPP Governance model, reporting must capture standardized data on policy metrics such as the number of policy proposals received, selected, and drafted, public comments received and their outcomes, policies approved, implemented, and tracked. System-wide metrics such as organ recovery and utilization rates, waitlist times, organ procurement and transplant outcomes, geographic fairness, and system responsiveness must also be reported. These reports should be generated regularly and made accessible to all stakeholders in the OPTN ecosystem. Performance dashboards and quality assurance reports enable stakeholders to track trends, identify disparities, and intervene where systemic improvements are needed. By integrating real-time internal data analytics and stakeholder feedback the governance framework can remain responsive to evolving medical and social challenges. Transparent reporting also reinforces trust within the system, especially when paired with public engagement efforts and open channels for accountability.

Recognizing the stakeholders' training needs and requirements through effective reporting is also key. To enhance communication and transparency, the matrix table below serves as a tool for capturing training needs and addressing any task or procedure issues among identified stakeholders.

Table 30: Stakeholder Impact & Training Requirements

Impacted Stakeholders	Information Required	Key Message	Communication Type	Education Required	Responsible Party	Date
EX 1: Patient	Key changes to policy #	Date of change	Open Forum, email, website	Yes	Who will communicate?	By what date

This Policy Implementation Matrix (PIM), outlined in the table below, is a communication tool that illustrates how each item in a policy will be implemented in practice. It will also assist in evaluating the outcomes and success of that implementation.

Table 31: PIM of the New/Amended and/or Replacement Policies

Policy Information	Communication Framework
Policy Name	Framework for Developing Plan
Key Msg	What needs to be known about the policy
Stakeholders	Listing all key stakeholders
Time/Frequency	When?
Resources	Listing all identified resources to effectively implement this communication plan
Method/ Communications Channel	Listing communication types: website, forum, virtual meetings, etc.
Accountability	Who is responsible for communicating this policy information?
Desired Results	Expected outcome? EX: Transparency, Engagement
Responsible Party	*Contact information and role/responsibility

To ensure that policies are compliant with statutory, regulatory, or OPTN Bylaw and Policy requirements, demonstrate transparency, and document post-implementation review, the following template (table below) should also be completed.

Table 32: Compliance Monitoring

Compliance Requirements	Monitoring Activities	Procedure Required (if any)	Frequency	Training Material Required (if any)	Responsible Party	Date
Ex: Policy Regulation or Review	e.g., Stakeholder engagement, resource utilization	Detail procedure to be used	How often	Yes – list training materials	Who will communicate?	By what date

8 Technology Solution Recommendations

8.1 Project Management Tools

Project management tools aid in increasing transparency and accountability over the progress of policy development and implementation. These tools should support end-to-end tracking of policy proposals, workflow automation, team collaboration, deadline management, and visibility across the policy pipeline. Key features include task dependencies, alerts for bottlenecks, dashboards for leadership oversight, and real-time updates on progress.

Top tools:

- Systems with built-in policy case management workflows
- Platforms that support integrated patient centric dashboards and task routing
- Tools with automated reminders and progress tracking

Recommendation: Tools like Monday.com, Salesforce, or Microsoft Project can be tailored to track and manage policy progress across multiple teams.

Integration: To effectively manage the full lifecycle of policy development from idea intake to implementation, organizations should adopt a unified technology ecosystem that streamlines workflows, improves visibility, and ensures accountability. This includes systems with built-in case management workflows to track policy proposals through defined stages; platforms that integrate patient centric dashboards and task routing to centralize information and coordinate stakeholder actions in real time; and tools that offer automated reminders and progress tracking to prevent delays and ensure continuous forward movement. When combined, these capabilities create a seamless, transparent, and adaptive policy management process.

Table 33: Project Management Technology Solutions

Example Technology Solution	Description
Monday.com	Monday.com is a customizable Work Operating System (OS) that supports project management, workflow automation, and team collaboration. It uses visual boards to track tasks, deadlines, and dependencies in real time. It is best for organizations needing a flexible, user-friendly interface to manage projects from intake through execution with transparency and automation.
Salesforce	Salesforce is a cloud-based Customer Relationship Management (CRM) platform, widely used in both the private and public sectors. Its modular architecture allows teams to build custom solutions for case management, stakeholder engagement, and data tracking. It is best for larger organizations that need a scalable, enterprise-grade solution to manage complex policy workflows and stakeholder relationships.
Microsoft Project	Microsoft Project is a project management tool designed to handle detailed scheduling, task assignments, and resource management. It integrates well with other Microsoft 365 tools. It works well for project managers and policy teams

Example Technology Solution	Description
	needing structured, timeline-driven planning with in-depth task management and integration into the Microsoft ecosystem.

8.1.1.1 Process Mapping Tools (For example: Lucidchart, Visio)

Process mapping tools visualize the full policy lifecycle, identify pain points, and communicate workflows across teams. In addition to depicting the current state process, mapping tools can be leveraged to map an ideal future state. They are essential for designing and refining procedures that are consistent, scalable, and auditable.

Top tools:

- Cloud-based collaborative diagramming tools
- Platforms with decision-tree logic support
- Tools that integrate with project and document management systems

Recommendation: Lucidchart and Microsoft Visio offer intuitive, flexible solutions for process visualization.

Integration: To support clear, consistent policy planning and decision-making, organizations should implement an integrated suite of tools that enhances collaboration and structure. This includes cloud-based collaborative diagramming tools that allow teams to co-develop visual process maps in real time, platforms with decision-tree logic support to guide structured policy analysis and scenario planning, and tools that integrate with project and document management systems to ensure diagrams and decision models are aligned with broader organizational workflows and accessible across teams. Together, these solutions enable transparent, data informed policy development anchored in shared understanding and streamlined execution.

Table 34: Process Mapping Technology Solutions

Example Technology Solution	Description
Lucidchart	Lucidchart is a cloud-based visual collaboration tool that allows users to create diagrams, flowcharts, org charts, system maps, and process workflows. It is designed for real-time collaboration across teams and integrates easily with many common workplace tools. It works well for distributed teams needing a modern, intuitive, and real-time tool for process mapping and visualization.
Microsoft Visio	Microsoft Visio is a robust diagramming tool widely used in enterprise settings. It supports a wide range of professional diagrams including process flows, organizational charts, floor plans, and IT architecture diagrams. It is available as both a desktop and cloud application and integrates closely with Microsoft 365.

8.1.1.2 Data Analysis Tools

These tools support fairness assessments, impact evaluations, and cost-benefit analyses. They should allow integration of structured and unstructured data, statistical modeling, and visualization for decision-making.

Top tools:

- Platforms supporting data wrangling, modeling, and visualization
- Tools capable of ingesting stakeholder feedback for sentiment or trend analysis
- Environments supporting reproducible analysis, review, and audit trails

Recommendation: Salesforce, R, and Tableau provide a strong foundation for internal data analysis and visualization.

Integration: A modern, insight-driven policy process depends on a data infrastructure that can handle the full analytical lifecycle. Platforms supporting data wrangling, modeling, and visualization enable teams to transform raw data into actionable insights. Tools capable of ingesting stakeholder feedback for sentiment or trend analysis help surface public priorities and identify emerging issues in real time. Paired with environments that support reproducible review/analysis and maintain audit trails, this ecosystem ensures that findings are transparent, evidence-based, and ready for both internal review and public accountability.

Table 35: Data Analysis Technology Solutions

Example Technology Solution	Description
Salesforce	Salesforce is a highly configurable cloud-based platform originally built for CRM but now widely used for case management, workflow automation, and stakeholder engagement across sectors including public policy, healthcare, and nonprofit work. It is best for organizations needing an all-in-one platform for managing complex policy workflows, stakeholder communications, and performance metrics particularly when scalability and customization are priorities.
R	R is an open-source programming language and software environment widely used for statistical computing, data visualization, and predictive modeling. It is favored in analysis, academic, and public policy settings for its flexibility and analytical power. It is best for Policy analysts, data scientists, and analysts who need to run rigorous quantitative analyses, develop models, or generate insights from complex data sets in a transparent, reproducible way.

8.1.1.3 Technology Solution Metrics

Technology solutions metrics will assist in determining the value and efficiency of the process mapping and data analysis tools being recommended to track the policy development process.

Dashboard and Platform technology monitoring and evaluation will be crucial to ensure the proposed technology tools are tracking the policy development process effectively while meeting the users need and aiding in decision making for ongoing improvement throughout the policy development process.

Table 36: Technology Solution Metrics Table

Metric	Description
Executive/Leadership Dashboards	• Focus: Strategic outcomes and progress • Features: KPIs across all policy phases, risk flags, heatmaps, trend lines • Visuals: High-level scorecards, red-yellow-green (RYG) indicators
Policy Staff & Analysts Dashboards	• Focus: Operational tracking and insights • Features: Workflow status, bottleneck alerts, stakeholder feedback patterns, cost-benefit analysis • Visuals: Timelines, bar/line graphs, sentiment analysis charts
Public/Stakeholder-Facing Dashboards	• Focus: Transparency and engagement • Features: Policy status summaries, participation stats, feedback summaries • Visuals: Interactive charts, plain-language summaries, maps
Technology & Platform Utilization	• User adoption rate of dashboards and feedback tools • Anomaly Detection • System uptime and responsiveness • Integration score across platforms (data interoperability) • AI model accuracy (e.g., sentiment classification)

8.2 Training Solution Recommendations

Training systems are essential for onboarding stakeholders to new processes, gathering internal feedback, and reinforcing best practices throughout policy development.

Top tools:

- Learning Management Systems (LMS) with policy-specific training modules
- Platforms supporting on-demand video, quizzes, and certification
- Tools that provide usage analytics to identify training gaps

Recommendation: Moodle, or Microsoft Viva Learning are flexible platforms that support scalable training delivery.

Integration: To build policy literacy and ensure consistent understanding across stakeholders, organizations should implement a training ecosystem that is both flexible and data driven. LMS with policy-specific training modules deliver targeted education aligned to each phase of the policy process. Platforms supporting on-demand video, quizzes, and certification make learning engaging and accessible, while tools that provide usage analytics help identify participation trends and training gaps, enabling continuous improvement and strategic support where it is needed most.

Table 37: Training Solutions

Example Training Platform Solution	Description
Moodle	Moodle is an open-source LMS widely used by educational institutions and public sector organizations. It offers extensive flexibility, community support, and a strong ecosystem of plugins and integrations. It is best for organizations that need a customizable, robust training system with the ability to manage long-term or complex learning pathways—especially those with in-house IT capacity.
Microsoft Viva Learning	Microsoft Viva Learning is a component of the broader Microsoft Viva suite, designed to embed learning directly into the flow of work within Microsoft Teams. It connects learning content from various sources into a unified experience. It is best for organizations already using Microsoft 365 that want a seamless, embedded learning experience with minimal disruption to daily workflows.

Metrics for training solutions evaluate the effectiveness of programs, reflect the impact of stakeholder learning, and provide essential data for program improvement. The table below identifies potential metrics for evaluating training solutions.

Table 38: Training Solutions Metrics Table

Metric	Description
Training & Internal Capacity Building	• Completion rate of training modules • Average quiz or certification score • Number of training hours logged per staff member • Training gap identification (from usage analytics) • Employee confidence level in using policy tools (survey-based)

8.3 Artificial Intelligence/Machine Learning

Artificial Intelligence (AI)/ML tools can help streamline intake, cluster feedback, detect duplicate ideas, and predict which proposals are likely to stall. They enhance fairness analysis by identifying patterns in outcomes and stakeholder responses and can optimize workflows by flagging inefficiencies.

Top tools:

- Natural Language Processing (NLP)-based platforms for feedback classification and sentiment analysis
- Predictive modeling tools to assess policy impact or workflow delays
- ML tools integrated with repurposed existing OPTN dashboards to surface real-time insights

Recommendation: Azure AI, Google Cloud AutoML, and International Business Machines (IBM) Watson provide a range of customizable solutions that can be embedded into the policy review and implementation process.

Integration: To enhance decision-making and responsiveness in policy development, organizations should adopt intelligent systems that turn data into actionable insights. NLP-based platforms enable rapid classification of stakeholder feedback and sentiment, revealing common themes and concerns. Predictive modeling tools help forecast potential policy impacts and identify workflow bottlenecks before they occur. When paired with machine learning tools integrated into pre-existing OPTN dashboards, these technologies deliver real-time insights that empower teams to adapt quickly, optimize processes, and drive data-informed policy outcomes.

Table 39: AI/Machine Learning Solutions

Example AI/Machine Learning Solution	Description
Azure AI	Azure AI is Microsoft's suite of AI services available through the Azure cloud platform. It includes prebuilt AI models, customizable machine learning tools, and a robust environment for deploying intelligent applications. It is best for public sector teams already working within the Microsoft ecosystem who want secure, scalable AI tools that can integrate directly into existing data and collaboration platforms.
Google Cloud AutoML	Google Cloud AutoML is designed to help users with limited data science expertise build custom machine learning models using Google's advanced infrastructure. It is best for organizations needing fast, user-friendly access to advanced machine learning tools for text analysis, forecasting, and multilingual engagement.
IBM Watson	IBM Watson is an AI service and application that includes machine learning, NLP, speech recognition, and advanced decision support tools. It is particularly strong in regulated and analysis-heavy environments. It is best for government or policy organizations that require robust AI tools with advanced governance, especially when handling sensitive or large-scale datasets.

9 Gap Analysis of OPTN Policies and Bylaws:

Effective and comprehensive governance documents are crucial for clarifying responsibilities, defining processes, mitigating risks, and ensuring compliance with legal requirements. To support HHS/DoT's OPTN modernization efforts, it is necessary to update the existing OPTN governance documents. Current OPTN policies are disproportionately focused on transplant centers, with less clarity on OPO operations and responsibilities. A missing policy and bylaw gap analysis identified policies and bylaws that do not exist across the OPTN ecosystem and that will help define OPTN functions.

Please reference Appendix I: Missing Policies and Bylaws within OPTN for detailed information.

Writing an effective policy or bylaw means creating a document that is clear, practical, enforceable, and aligned with organizational goals and legal requirements.

Elements of an effective policy or bylaw include:

- A well-defined purpose and scope that clearly outlines the intent and applicability of the policy or bylaw
- Incorporation of legal frameworks, guidelines, or criteria that provide a foundation for the policy or bylaw
- A glossary of key terms and definitions relevant to the policy or bylaw
- A detailed, step-by-step procedure outlining how to comply with the policy or bylaw
- Supporting forms or documentation required to implement the procedure effectively
- Clearly assigned roles, responsibilities, and resources needed for implementation
- A structured process for monitoring, evaluation, and periodic review of the policy or bylaw
- Documented key dates, including implementation, review, and revision timelines
- Defined success metrics or evaluation criteria to measure the effectiveness of the policy or bylaw

An evaluation of OPTN's current policies and bylaws identified missing elements that should be included to enhance their effectiveness.

Please reference Appendix J: Incomplete Policies & Bylaws Within OPTN for detailed information.

Recommendations:

Develop Comprehensive Documentation: Create detailed policies and procedures outlining the nomination process, committee formation, and stakeholder engagement strategies to enhance transparency and inclusivity.
Establish a Formal Policy Management System: Implement an end-to-end tracking system for policy idea submissions, including clear guidelines on submission methods, review timelines, and communication protocols.
Clarify Roles and Responsibilities: Define the specific roles of the BOD, and HHS/DoT in the policy development process to ensure accountability and effective oversight.
Standardize Definitions and Criteria: Develop clear definitions for terms such as "emergent public health issue," "patient safety factor," and "non-controversial" to guide the categorization and prioritization of policy proposals.
Enhance Stakeholder Communication: Improve engagement and communication strategies to inform stakeholders about opportunities to participate in the policy development process and to submit proposals.

10 Limitations

Several constraints impacted the scope and depth of the analysis, including:

- **Data Access**: The inability to access specific datasets (e.g., the 'project forms' system, the SharePoint system) hindered detailed evaluations.
- **Documentation**: Delays in receiving documents (e.g., UNOS governance and operations plans, UNOS project management plans, UNOS progress reports, UNOS and OPTN policy development documents) hindered the breadth of understanding of certain processes and methodologies.
- **Interview Sample Size:** Due to the contract timeline and Paperwork Reduction Act clearance policy, we limited external interviews to fewer than ten people or groups.
- **Virtual meeting attendance:** The inability to attend committee and regional meetings in person limited analysis findings due to lack of direct observation of OPTN processes and face-to-face meetings with stakeholders.
- **Significant Project Delays:** Repeated requests for documents, data, feedback, and the global federal communication pause caused significant barriers to discovery resulting in project delays.
- **Significant program changes underway during project:** HHS/DoT initiated OPTN transformation in 2023 and taken significant action to alter the program management, structure, and reduce COI so the program continued to change and evolve during the development of the Mapping and Re-engineering Reports.
- **Change in Administration:** Shifting staffing and priorities during the development of this report required review and revision of prior Administration's actions causing delays.

11 Conclusions, Implementation Roadmap & Next Steps

Ensuring that OPTN's modernization addresses the challenges experienced by stakeholders will require major changes to the policy development process, governance, and stakeholder engagement followed by ongoing monitoring and continuous improvement to ensure that the system processes and technologies are always supported by best practices in health system and technology management.

A structured 12-month implementation roadmap with quarterly milestones and deliverables is provided to support implementation of HHS/DoT OPTN's re-engineered policy framework and governance model.

Quarter 1 (Months 1–3): Foundation & Planning

1. Governance Setup

- Finalize appointments to the new BOD and committees.
- Define roles, responsibilities, and terms of reference for each committee.
- Conduct onboarding and orientation sessions for all BOD and committee members.

2. Framework Alignment

- Review and validate the SPPDF with key stakeholders.
- Map existing policies to the new framework to identify gaps and overlaps.
- Develop a policy re-engineering charter and project plan.

3. Communication & Change Management

- Launch internal communications campaign to introduce the new governance and policy framework.
- Identify change champions across departments.

Quarter 2 (Months 4–6): Policy Audit & Design

4. Policy Audit
- Conduct a comprehensive audit of all existing policies.
- Categorize policies by relevance, compliance risk, and alignment with the new framework.

5. Policy Design (Phase 0-1)
- Begin drafting or revising policies under the first two phases of the framework.
- Engage relevant committees for review and feedback.
- Establish a policy style guide and standard templates.

6. Capacity Building
- Train policy owners and committee members on the new framework and policy development process.

Quarter 3 (Months 7–9): Implementation & Integration

7. Policy Development (Phases 2-3)
- Continue development and approval of policies under phases 3 and 4.
- Pilot test selected policies in departments to gather feedback.

8. Governance Integration
- Align committee workflows with policy review and approval cycles.
- Implement a digital policy management system (if applicable).

9. Stakeholder Engagement
- Conduct stakeholder consultations and feedback sessions.
- Refine policies based on input and lessons learned from pilot testing.

Quarter 4 (Months 10–12): Finalization & Long Term Viability

10. Policy Completion (Phases 4-5)
- Finalize and approve remaining policies.
- Ensure all policies are published and accessible.

11. Monitoring & Evaluation
- Establish KPIs and a monitoring framework for policy compliance and effectiveness.
- Schedule annual policy reviews and BOD evaluations.

12 Appendix A: Current-State Analysis Methodology

Appendix A describes methods used to analyze the current state of the OPTN policy development process.

12.1 Process Mapping

The current state analysis of the OPTN policy development process was developed through review of OPTN's processes, operations, and the resources required for OPTN policy development and oversight. The findings mirrored previous investigations into OPTN's current state, including:

- Ineffective policy prioritization
- Long timelines for policy implementation
- Failure to define systems and roles, leading to system inefficiencies
- Lack of transparency and role definition in the BOD and committees
- Data quality and availability challenges

- Failure to engage stakeholders.

12.2 Data Collection

The current-state mapping and assessment process was grounded in Service Design and HCD methodologies:

- **Service Design**: A holistic approach that focuses on creating seamless and efficient service experiences by understanding and addressing the needs of all stakeholders involved.

- **Human Centered Design**: A methodology that places the needs, behaviors, and experiences of people at the forefront of the design process, ensuring solutions are tailored to real-world contexts.

The primary service design artifact we used to guide the investigation methodology was the service blueprint highlighting the existing processes at incredible depth, to drive understanding of where challenges exist and create associated action plans to transform the experience for all stakeholders.

Investigation focused on identifying where the process was failing to deliver stronger patient outcomes and where functionality and accountability were insufficient to facilitate these outcomes. Investigation activities were narrowed down to those most critically impacting the defined process metric themes, uncovering the patient, family, caregiver, and community voices. The figure below (figure 15) shows a thumbnail of the completed current-state service blueprint, including the critical pain points explored in the mapping report. Please refer to PDF attachment to the Mapping Report for a detailed view of the Current State Mapping Service Blueprint.

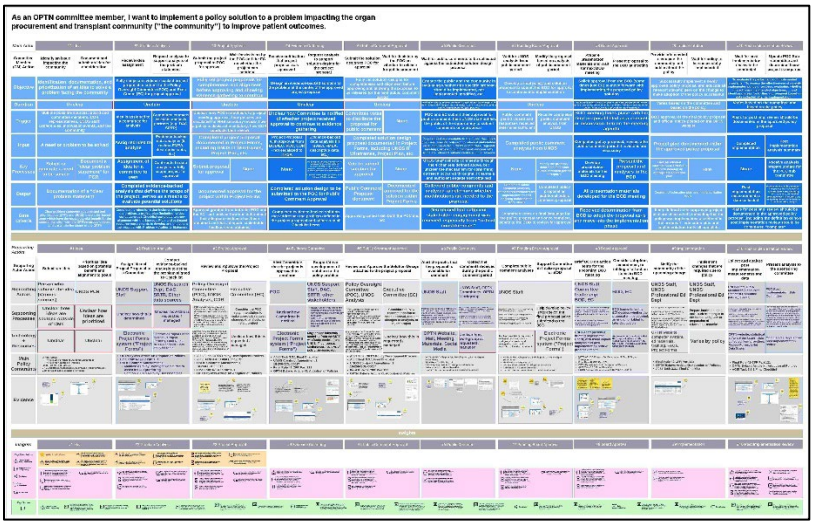

Figure 15: Current State Mapping Service Design Blueprint Icon

Note: Mapping Report submission included a PDF of the Current State Mapping Service Blueprint as an attachment. Please refer to the PDF for a detailed view.

Step 1: Baseline the Current Process

Investigate OPTN documentation to establish a baseline understanding of the current policymaking process. Documenting the end-to-end process in a service blueprint model, highlighting key stages, stakeholders, and the flow of activities.

Step 2: Gather Stakeholder Insights

Conduct desk review, stakeholder interviews, and attend committee and regional meetings to gain insights and fill in any gaps identified during the initial documentation providing a diverse perspective and experiences of those directly impacted by the OPTN policies.

Step 3: Analyze and Prioritize Findings

Analyze collected data to identify insights, the most critical and impactful challenges, then prioritize based on their presumed impact on the functionality and accountability of the process and enhanced patient outcomes.

Step 4: Re-engineering Phase

Reviewing evidence-based methods to reorient the process around patient outcomes and the patient experience. Order findings and recommendations into a future-state service blueprint mapping out the ideal policymaking process to addresses HHS/DoT's goals and prioritized success metrics.

12.3 Review

The current-state analysis included secondary review of peer-reviewed articles, case studies, reports, OPTN committee meeting summaries, and other published documents.

Interviews included stakeholders representing patients, families, and their associated community organizations; providers, including transplant and organ procurement professionals; and governance representatives, including OPTN committee members and HRSA regulatory SMEs (see Appendix E: Stakeholder Interview Participants). Observations were gathered through virtual attendance at committee meetings, all regional meetings, and the BOD meetings from November 2024 to present.

13 Appendix B: Current-State Mapping

Appendix B provides a step-by-step overview of the OPTN's processes for BOD and committee selection and policy development.

13.1 Preliminary Steps in BOD & Committee Selection Process

This section details the BOD and committee selection process for the OPTN, including who is responsible and how they coordinate tasks like identifying vacancies, posting calls for nominations, and ensuring federal requirements are met. It explains the annual composition reviews, Executive Director (ED) performance evaluations, and timelines for nominations and elections (e.g., posting open positions in August, meeting in October–November). The section also covers how committees are formed, from needs assessments and calls for nominations to final appointments and describes the Board Support facilitator's ongoing role in supporting the BOD and its committees (e.g., maintaining rosters, providing meeting materials, and adhering to federal regulations).

The BOD selection process involves both the Board Support role and the Nominating Committee. The Board Support Role tasks include annual composition reviews, ED performance evaluations, and public calls for nominations, while the Nominating Committee identifies upcoming vacancies, releases call for nominations, organizes elections, and ensures the BOD meets federal requirements and reflects diverse representation.

1. Open BOD Positions (August)
    a. Prior to the Nominating Committee's fall meetings, upcoming BOD positions are posted on the OPTN website.
    b. Regional councillors also notify members during regional meetings.
    c. The Committee solicits input and nominations from the entire OPTN membership.
2. Nominating Committee Meetings (October–November)
    a. The Nominating Committee convenes in October and November, ahead of the November BOD meeting, to propose a slate of nominees (directors and officers) for the BOD.
    b. In preparation for the annual meeting of members (usually in March), the form of proxy and ballot is sent to each OPTN member institution's representative.
    c. Candidates are elected by a majority vote of a quorum of the entire voting membership.

By following this timeline, the BOD selection process remains transparent, inclusive, and aligned with OPTN's mission and regulatory requirements.

Note: As of December 24, 2024, the former OPTN BOD has been renamed INVEST (Independent Network of Volunteers for Equitable and Safe Transplants). INVEST now serves as the OPTN BOD under HRSA's designation and oversight, in compliance with federal laws and regulations. Its bylaw now known as the Bylaws of Independent Network of Volunteers for Equitable and Safe Transplants, Inc., were most recently updated in December 2024.

13.1.1 Board Support Role Tasks

The Board Support Role Activity table summarizes the key tasks performed each year to manage the BOD—including annual composition reviews, ED performance evaluations, and developing public calls for nominations.

Table 40: Current State Mapping Board Support Role Activity

Board Support Role Activity	Key Tasks
Annual BOD Composition Review	• Five days after any changes in BOD or EC membership Ensures the BOD meets § 121.3 The OPTN BOD of the Part 121 - Organ Procurement and the Transplantation Network • Reviews the BOD's composition to confirm compliance with federal regulations. • Identifies any gaps in representation (e.g., missing professional roles or communities). • Considers how regional councillors are nominated and factors this into the overall composition review.

Board Support Role Activity	Key Tasks
ED Annual Performance Review	• Conducts a performance review of the ED. • Provides that performance review to the Contract Officer Representative (COR) before the BOD decides on re-appointment.
Reporting & Planning	• Provides a report on the findings of the annual composition review to the COR, by a date mutually agreed upon by the Contractor and COR. • Uses the annual composition review findings to develop an annual BOD recruiting plan targeting disparities in representation identified in the composition review. • Includes in the annual BOD recruiting plan recommendations or guidance to OPTN regions to encourage regional nominations that assist in targeting disparities. • Provides the annual BOD recruiting plan to the Nominating Committee to guide the annual BOD nominations process. • Submits the annual BOD recruiting plan to the COR for review twenty business days prior to the beginning of the annual BOD nominations process.
Support for Nominating Committee	• Uses the findings from the annual composition report to create an annual BOD recruiting plan aimed at closing representation gaps. • Includes recommendations or guidance for OPTN regions to help fill these gaps through regional nominations.
Nominations, Announcements, and Collections	• Gives the annual BOD recruiting plan to the Nominating Committee so they can guide the BOD nomination process. • Submits this plan to the COR 20 business days before BOD nominations begin. • Supports the Nominating Committee by finding candidates for open BOD positions. • Publicly announces the BOD nomination process annually, including on the OPTN website. • Asks for nominations from the OPTN and the public; collects and verifies nominee information. • Sends the final list of nominees to the COR within ten business days after nominations end.

Roster Updates	• Provides updated rosters to the COR:
	  • Within five days after the end of the Effective Date of Contract (EDOC), and/or
	  • Five days after any changes in BOD or EC membership.
	• Gives the COR a list of new BOD members and their qualifications after the yearly nominations and elections.

Board Support Role Activity	Key Tasks
	• Provides an analysis of how the new BOD makeup meets the composition requirements in the OPTN Final Rule.

13.1.2 Nominating Committee Tasks

The Nominating Committee Tasks table outlines the core responsibilities of the Nominating Committee, such as identifying BOD vacancies, releasing calls for nominations, and reviewing applicants to ensure compliance with the OPTN Final Rule.

Table 41: Current State Mapping Nominating Committee Tasks

Nominating Committee Activity	Key Tasks
Identifies Vacancies & Recruitment Needs	Following the volunteer needs assessment: • Reviews upcoming BOD vacancies and the OPTN Final Rule requirements. • Develops recommendations for recruiting new BOD members. • Reviews potential nominees recruited by Board Support Role contractor
Releases Call for Nominations	• Publishes the "Call for Nominations" each July. • Collects applications through September 15th.
Meetings & Selection	• Meets biweekly in September and November to review applications received in response to the Call for Nominations and nominees recruited by the Board Support Role contractor to ensure they meet the OPTN Final Rule requirements and the BOD's needs. • Presents proposed list of nominees at December BOD meeting. • Holds a national election in January; all eligible OPTN members may vote.

13.1.3 Committee Selection Process

The Committee Selection Process explains how committees are selected each year—from identifying which seats are open and asking for nominations, to reviewing candidates and finalizing appointments—so the right people fill each role. The selection process includes the following:

1. **Needs Assessment:**
    a. The nominating committee conducts an annual committee needs assessment.
    b. The nominating committee meets biweekly from March to April to perform a committee volunteer needs assessment.
    c. Reviews upcoming vacancies in conjunction with requirements of the OPTN Final Rule.
    d. Develops recruitment recommendations.
    e. Develops the annual "Call for Nominations."

2. **Call for Nominations:**
    a. A "Call for Nominations" is released to the public in July detailing each vacancy on the BOD and committees.
    b. All applicants must submit a biography form by September 15th to be considered for positions beginning July 1st the following year.
3. **Review & Recommendation:**
    a. Committee applicants for at-large positions are reviewed by the leadership of the BOD and Committees in conjunction with OPTN Final Rule requirements and the BOD's annual needs assessment.
    b. Committee applicants for regional representatives to committees are reviewed by the Region's nominating committee.
    c. Recommendations are made to the OPTN President-Elect.
4. **Appointment:**
    a. The OPTN President-Elect looks at the recommendations and makes final committee appointments.

13.1.4 Ongoing UNOS Committee-Related Tasks

UNOS's ongoing responsibilities for managing BOD committees—ensuring they follow federal regulations and providing administrative support—include:

- **Establish & Manage BOD Operating Committees:**
    - Provide agendas and meeting materials to the COR 10 business days prior to each operating committee meeting.
    - Provide rosters of all committee members to the COR one month prior to the beginning of new committee terms.
    - Identify individuals for each operating committee, the role of each member, and reasons for any simultaneous service on different groups.
    - Ensure that operating committee membership is consistent with the requirements of the OPTN Final Rule 42 Code of Federal Regulations (CFR) §121.3(a)(4).
    - Notify the COR in writing when members and chairs of governance groups change.
- **Compliance with OPTN Final Rule:**
    - Ensure each committee follows 42 CFR §121.3(a)(4) of the OPTN Final Rule.
    - Tell the COR in writing when committee members or chairs change.
- **Administrative & Logistical Support:**
    - Provides administrative and logistical support to the OPTN BOD and governance groups to perform their functions under the OPTN contract.
- **Establish Communication and Coordination**
    - Assist with communication and coordination among OPTN committees, subcommittees, and ad hoc groups during policy development.

The OPTN Policy Development Process, from initial idea generation (Step 1) to post-implementation review (Step 10), describes how new policy ideas are gathered, which committees and stakeholders analyze them, how public comments are incorporated, and how final approval and implementation occur. The appendix also points out gaps—like unclear timelines or responsibilities—and highlights key interactions among the POC, EC, and the BOD. Through this step-by-step breakdown, readers can see where decisions are made, who is involved, and how policies move from concept to adoption and ongoing review.

13.2 OPTN 10-Step Policy Development Process

The existing OPTN 10-Step Policy Development Process was analyzed to create a foundational understanding of how it operates. This involved a comprehensive review and documentation of OPTN's processes, operations, and the resources necessary for policy development and oversight. Key stages, involved stakeholders, and the flow of activities were highlighted throughout this review. This foundational step ensured a clear and thorough understanding of the current system was documented.

13.2.1 Step 1: Idea

Summary

The Idea step explains how new project and proposal policy ideas enter the system, what information they include, and how they are reviewed and prioritized.

Key Steps

1. **Submitting an Idea to UNOS:**
    a. According to the OPTN policy development process explanatory document, the Policy and Community Relations Department (PCR) logs incoming ideas—originating from a wide range of sources such as BOD and committee members, COR representatives, UNOS staff, transplant conferences, innovation events, the community, the HHS Secretary, Congress, and HRSA—into an electronic system called "project forms."
    b. The "project form" is created and updated in the electronic system by UNOS PCR staff.
2. **Information Included:**
    a. Each idea is required to have the source of the idea, the problem it aims to solve, and any potential solutions.
3. **Review & Prioritization:**
    a. PCR leadership and OPTN Committee leadership review ideas regularly to see which offers the most benefit to the organ procurement and transplantation community, aligns with support of OPTN's strategic goals, and fits under OPTN's scope.
    b. The problem/idea identified and prioritized in this step (Step 1: Idea) is assigned to a committee for analysis.
    c. If selected, the idea goes to an OPTN committee for further analysis.

13.2.2 Step 2: Problem Analysis

Summary

At the Problem Analysis step, committees analyze each approved idea in detail, define a clear problem statement, and confirm compliance with NOTA and the OPTN Final Rule. However, there are gaps in how ideas transition from Step 1 and unclear guidelines about timing and responsibilities.

Key Steps

1. **Define & Analyze the Problem:**
    a. Committees clarify the scope of the problem and create a written problem statement.
    b. UNOS collects evidence and analyzes the problem in depth through an "evidence-based problem analysis."
2. **Update the Project Form:**
    a. UNOS attaches the evidence, a project plan (including a stakeholder collaboration plan), alignment with the Strategic Plan, and estimated resources.
    b. UNOS develops meeting materials (using the updated project form, evidence, and any authority statements) to support the POC when evaluating and recommending the proposal in the next step.
3. **Create an Authority Statement:**
    a. UNOS references the NOTA/Final Rule Checklist—deciding if each requirement is "Applicable" or "Not applicable"—but this process happens behind the scenes, offering limited visibility into how these determinations are reached or documented.
    b. The authority statement documents compliance with NOTA and the OPTN Final Rule. It is unclear where this is documented.
    c. Staff consult with UNOS counsel and HRSA if alignment issues with NOTA and the OPTN Final Rule come up.
4. **Formalizing the Problem Statement:**
    a. The Problem Statement is a statement that describes the problem the policy proposal or project is trying to solve. This is documented on the project form.
    b. This step concludes when UNOS staff updates the project form with a written problem statement.

13.2.3 Step 3: Project Approval

Summary

The Project Approval step shows how project proposals move through the approval process—first through the POC and EC, then the COR—and highlights missing details about timelines, HHS Secretary review, and who is responsible at each step.

Key Steps

1. **POC Evaluation:**
    a. The POC checks if the project aligns with strategic goals, has the right collaborators, and whether potential risks and costs have been considered.
        i. Alignment with the Strategic Plan and Policy Priorities
        ii. Involvement of relevant collaborating committees
        iii. Project sequencing within committee and overall OPTN efforts
        iv. Measurability of the intended effects and identification of key metric(s)
        v. Potential risks or unintended consequences
        vi. Technical implementation resources required
        vii. Overall assessment of cost and benefit
2. **Checklist Analysis:**
    a. A UNOS analyst analyzes the proposed model against the checklist.
    b. If concerns are identified, staff discuss them with the sponsoring committee and HRSA.
    c. A summary of the analysis is included in the public comment proposal.
3. **COR Review:**
    a. Any changes to policies or bylaws must be reviewed by the COR before going to the full BOD. However, the steps for ensuring that COR review occurs and is documented are not clear.
4. **EC Review:**
    a. The EC reviews the POC's recommendation and decides if the project can move forward.
5. **HHS Review:**
    a. All proposed policies require HHS Secretary review and approval prior to public comment.

13.2.4 Step 4: Evidence Gathering

Summary

The Evidence Gathering step focuses on gathering detailed evidence, consulting relevant experts, and checking each policy proposal against NOTA and the OPTN Final Rule—though the process lacks clarity on exactly when committees begin gathering evidence, how long it should take, and how much input is required.

Key Steps

1. **Committee Analysis:**
    a. Committee members assigned to the policy proposal gather evidence and build potential solutions.
    b. Committee members may use data analysis, inferential modeling from SRTR, wireframe models from UNOS information technology (IT), review policy language, or hold conferences.

2. **Stakeholder Input:**
    a. UNOS staff seek feedback from other OPTN committees or community members who have relevant expertise.
    b. If more expertise is needed, they may bring additional SME onto the committee.
    c. HRSA and general counsel are consulted if issues arise.
3. **Check Against NOTA and the OPTN Final Rule:**
    a. UNOS staff use a checklist to ensure each policy proposal meets all legal requirements. The HHS Office of General Counsel can override the contractor's interpretation of alignment with NOTA and the OPTN Final Rule.

13.2.5 Step 5: Public Comment Approval

Summary

In the Public Comment Approval step, the committee's final policy proposal goes to the POC and EC to confirm it is ready for public comment—though it is unclear who manages the review process, how long each review should take, and exactly when evidence gathering ends and public comment approval begins.

Key Steps

1. **Committee Vote:**
    a. Sponsoring committee members, with support from UNOS, draft the public comment policy proposal—including the policy language and a summary of the analysis.
    b. The committee finalizes its solution and votes to send it out for public comment.
2. **POC & EC Review:**
    a. The POC and the EC review the policy proposal again against the same factors required for approval in Step 3 (Project Approval) as well as checking that it had enough stakeholder input, that the proposed solution is aligned to the problem, and that the solution meets fiscal requirements.
        i. Whether ample stakeholder engagement occurred
        ii. Whether the solution is tailored to the problem
        iii. Whether the project meets high-level fiscal implications
        iv. All factors from Step 3 (Project Approval)**:**
            1. Alignment with Strategic Plan and Policy Priorities
            2. Involvement of relevant collaborating committees
            3. Project sequencing within committee and overall OPTN efforts
            4. Measurability of intended effects and identification of key metric(s)
            5. Potential risks or unintended consequences
            6. Technical implementation resources required
            7. Overall assessment of cost and benefit
3. **Public Comment Decision:**

a. If the POC and EC vote to approve it, the policy proposal can be distributed to the public for comment.
b. After the POC and EC approve for public comment, the UNOS Communication Department notifies the public (through the OPTN website, social media, mailings, etc.).

13.2.6 Step 6: Public Comment

Summary

At the Public Comment step, the policy proposal is published for public feedback—UNOS staff notify stakeholders, gather comments, and coordinate a fiscal impact review—though it is unclear how each type of feedback is tracked and evaluated, who decides whether comments change the policy proposal, and how long the entire public comment process should last.

Key Steps

1. **Notifications:**
    a. UNOS staff,
        i. Posts a notice on the Public Comment OPTN website.
        ii. Posts notification at regional meetings and committee meetings.
        iii. Emails all OPTN members and uses additional tools—such as social media or targeted mail—to notify relevant stakeholder organizations, including both transplant and procurement professionals and patient groups. This approach varies based on the specific policy under review and aims to ensure all affected stakeholders receive timely information.
    b. Performs targeted communication to specific stakeholder groups based on specific policy.
    c. OPTN requests public comments at least twice per year.
2. **Collects & Review Comments:**
    a. UNOS staff record comments in an electronic system and check for any that might violate set principles outlined in the OPTN policy development document.
    b. Applicable OPTN committees also review comments and provide feedback (including SMEs like ethics, minority, pediatrics, and patient affairs).
    c. An OPTN workgroup reviews fiscal impacts and shares their analysis with the committee and the BOD.
3. **Public Comment Timing:**
    a. Public comment periods are usually 45 days, but this can vary (such as 55 or 56 days for certain cycles).
4. **Some Policy Proposals Do Not Require Public Comment**, including:
    a. Proposals that clarify or correct existing policy without changing its intent.
    b. Proposals that reflect administrative or other non-substantive procedural changes.

c. Emergency Policy Changes: Approved and enacted prior to public comment but must be submitted for public comment within six months of approval and for at least 30 days.
d. Expedited Policy Changes: May take effect after a 30-day comment period, unless a threshold number of objections is received

13.2.7 Step 7: Pending BOD Approval

Summary

UNOS staff will analyze and summarize public comment feedback, which will be provided to the sponsoring committee and the POC along with the collected data. Based on this analysis, the committee may adjust the policy proposal to meet policy proposal goals and, if necessary, resubmit it for further public comment before voting to send the updated policy proposal to the BOD.

Key Steps

- **Public Comment Analysis:**
  - UNOS reviews each set of public comments, organizes the feedback, and then shares it primarily with the sponsoring committee, the group that originally proposed the policy. Other relevant committees may also be involved, depending on the policy proposal's focus (e.g., specific organs, safety issues, or ethical considerations). After examining UNOS's analysis, the sponsoring committee determines whether the policy aligns with broader OPTN goals and available evidence, deciding if any revisions are necessary before moving forward.
- **Committee Review of Public Comments:**
  - The sponsoring committee examines the feedback/analysis of public comments from UNOS and considers how stakeholder input may affect or transform the proposed policy.
  - The sponsoring committee reviews the final policy proposal, ensuring it meets all necessary criteria and addresses identified issues.
- **Approval or Revision:**
  - The relevant committee votes on the updated policy language—which incorporates findings from the public comment analysis—and, if approved, sends it to the BOD for final approval. If the policy proposal does not meet required standards or needs further changes, the committee may request revisions or even reject it.

13.2.8 Step 8: BOD Approval

Summary

BOD Approval involves final approval by the BOD after reviewing the completed policy proposal, public comment feedback, and any necessary revisions. BOD's approval is required for the policy proposal to be formally adopted and implemented, ensuring that it aligns with the organizational goals and adhering to legal and regulatory standards.

Key Steps

1. **Policy Proposal Final Review:**
    a. The BOD conducts a review of the finalized policy proposal, incorporating any revisions based on public comments, committee feedback, and data analysis.
    b. The BOD discusses the proposed policy in detail, ensuring it meets all relevant legal, clinical, and ethical standards.
2. **Policy Proposal Approval or Rejection:**
    a. The BOD votes on the policy proposal.
        i. If approved, then the policy proposal moves forward to be implemented.
        ii. If rejected, then the policy proposal will be sent back for further revisions or even reconsideration.
    b. The decision, along with the rationale for approval or rejection, is documented and made publicly available under recent updates of the Policies page on the OPTN website.
3. **Post-Approval Implementation Planning:**
    a. Once the BOD approves the policy proposal, preparations for implementation begin, including any necessary training, system updates, and stakeholder communication.

13.2.9 Step 9: Implementation

Summary

Implementation of the approved policy is rolled out. This step involves updating systems, training stakeholders, and ensuring that all parties involved are informed and prepared to follow the new policy guidelines.

Key Steps

- **Engagement with Transplant Centers, OPOs, and Other Key Groups**
    - Transplant centers, OPOs, and other involved parties are notified about the new policy and provided with detailed information on how it will affect their operations.
- **Training and Education for Transplant Personnel and Procurement Professionals:**
    - Training sessions and educational resources are provided for relevant personnel to ensure they understand the policy's requirements and are equipped to apply them.
- **OPTN Data System Updates:**
    - UNOS staff make necessary updates to OPTN data systems, tools, and infrastructure to accommodate the new policy and ensure it can be effectively executed.

13.2.10 Step 10: Post-Implementation Review

Summary

Post-Implementation Review involves the evaluation of the effectiveness of the newly implemented policy. This stage includes gathering feedback, analyzing data on policy outcomes, and identifying any areas that require further adjustments or enhancements to ensure the policy is meeting its objectives.

Key Steps

- **Data and Feedback Collection:**
  - Gathering data on the policy's performance, including any challenges, successes, and impacts on organ procurement and transplant outcomes and operations.
  - Collecting feedback from transplant centers, patients, families, caregivers, and OPOs to assess how the policy is functioning in practice.
- **Evaluating Policy Proposal Effectiveness:**
  - Analyzing the gathered data and feedback to determine whether the policy is achieving its intended goals, such as transforming patient outcomes or optimizing organ allocation.
  - Identifying any unintended consequences or barriers to successful implementation, including operational or logistical challenges.
- **Reporting and Recommendations:**
  - Documenting the results of the review and communicating any changes or next steps to transplant centers, patients, families, caregivers, and OPOs, ensuring transparency and continued alignment with policy objectives.
  - Based on the results review, making recommendations for necessary adjustments, revisions, or updates to the policy to address any identified issues and enhance its effectiveness.

14 Appendix C: Current-State Assessment

Appendix C represents our analysis and assessment of the OPTN's current state based on our five process metric themes. Across these themes, the most frequently cited, overarching gaps and challenges were:

- Lack of clear documentation of criteria and processes
- Lack of transparency and engagement
- Lack of data standardization, collection, and analysis
- Lack of timeliness and efficiency

These gaps and challenges, identified in stakeholder interviews, desk review, and meeting attendance, are discussed by theme below.

Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritization.

14.1 Theme 1: Committee & BOD Composition

14.1.1 Interviews Assessments

Note on Reporting Language

Interview findings are reported when at least three separate participants noted a similar response. Each finding includes a mix of stakeholders unless otherwise noted. Reporting language includes "a few" (n=3-4), "some" (n=5-8), "half" (n=9), "more than half" (n=10–13), "most" (n=14–17), "all" (n=18).

Some stakeholders cited BOD member COI with corporate or clinical interests as one of the key challenges with the overall policy development process. A few stakeholders felt the BOD and committee selection process is not opaque or understandable.

Interview Insights

> *"And they have OPTN and BOD and policymaking people that are just on the take from medical device companies."* – Patient Advocacy Organization

> *"There are certain committees that really benefit from certain representation and that those committees actually work to make sure that's maintained. It's well done in the background. I just don't think people realize it happens."* – Committee Member

Half of the interview participants cited lack of patient participation as a challenge to committee and BOD composition. Others felt the number of people, size of the committees, and BOD were ineffective, with a few pointing to too many people on the BOD and a few others to too many committees.

Interview Insight

> *"When you have a board or group that's making decisions or coming up with policies and procedures. And you have everyone with the same background. You want to get the same responses."* – Community Donation Education Program

Strengths

As a counterpoint, some interview participants reported that the mix of participation was a key strength to the overall process, which extends to the committee and BOD composition. When specifically asked about composition, some found the committee composition and a few separately the BOD composition

to be adequate. They cited the mix of different types of participants in the process, including providers and patients.

Interview Insight

> *"So, we were intentional during the next period when we were given a slate of potential candidates to make sure that we were filling those voices and that we stay balanced. And I'm sure all of the other committee leaders are doing the same as making sure that you have the right expertise in your committee to be able to move forward good work."* – Current Committee Co-Chair

14.1.2 Desk Review Assessment

The OPTN BOD establishes and maintains transplant and procurement policies, bylaws, and management and membership policies that govern OPTN. Committees work to address concerns of the organ procurement and transplantation community. Ensuring that the OPTN governance structure is comprised of a diverse group of experts and stakeholders who are free of COIs is essential for maintaining strategically focused and efficient decision-making. However, several issues contribute to failures within the BOD and committee selection process.

Unclear regulations arise because both NOTA and the OPTN Final Rule are silent in terms of the process for soliciting nominations for the OPTN BOD and committees.

Another concern is the lack of direct HRSA oversight of committee appointments, as HRSA does not formally review or approve committee composition or appointments. Additionally, there is a lack of consensus in the OPTN Vice President's committee selection process. Under the "OPTN Management and Management Policies" (updated March 6th, 2025), the OPTN Vice President independently selects committee members from a list of candidates, rather than holding a formal vote. This lack of a consensus-based process raises concerns about potential limited stakeholder input in determining committee composition.

Unclear annual timelines and scheduling further complicate matters. While August is identified as the month when upcoming BOD positions are posted, and October–November is set for Nominating Committee meetings, it remains unclear how other key tasks fit into the overall timeline. Specifically, there is no mention of when the annual composition review or the ED performance review begin, nor how long each task takes. It is also unclear whether the BOD selection process has a consistent annual kickoff or how the annual BOD recruiting plan aligns with the posting of open positions and committee meetings.

Public solicitations for committee nominations remain unclear, aside from posting a 2024–2025 "Call for Nominations" on the OPTN website, there is no formal mechanism to keep the general public informed

of new nomination opportunities. While potential sources for publicizing these calls (e.g., Federal Register notices, professional societies like the American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of OPOs (AOPO), or transplant forums such as TransplantPro or TransplantConnect) could broaden communication and engagement, there is no definitive evidence these channels are routinely used to reach a wider audience. It remains unclear how individuals are nominated for committees and how individuals can request to join. There is an informal "let us know" or recommendation-based system, raising concerns about public availability and transparency. In some cases, UNOS proactively contacts candidates to encourage them to apply, but there is no evident, standardized approach for meeting composition requirements or informing interested individuals.

Another gap concerns the storage of preliminary BOD and committee selection documents, as it remains unclear where or how these documents are maintained. There is also no accessible database of past, present, and nominated members, leaving stakeholders unable to view changes in membership overtime. Finally, unclear committee appointment deadlines and approvals pose yet another challenge, since there is no clear mention of time requirements (i.e., firm deadlines) for committee appointments.

The OPTN Final Rule outlines requirements for the size and composition of the BOD. The OPTN Final Rule requires that the BOD have at least 34 but not more than 42 voting directors. The OPTN Bylaws allow the BOD to only meet twice a year and permit the EC, comprised of only 12 individuals, to continue the work of the BOD throughout the year without needing to convene the entire BOD. Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritization. Provider-heavy committees can also influence which projects the POC approves, given their technical expertise, alignment with OPTN's clinical goals, and understanding of the nuances required to move policies through the process.

While expert perspectives are essential to the OPTN policy-making process, the current committee and BOD structure fails to adequately balance clinical viewpoints with patient and family perspectives. Providers often approach problems from a medical or operational standpoint, which can lead to the unintentional neglect of patient and family perspectives. To develop effective solutions, it is essential to include diverse viewpoints and gather feedback from all relevant stakeholders when examining issues and formulating solutions.

Providers—such as doctors, investigators, organ procurement and transplant professionals—have a strong presence in the OPTN's policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories. Since providers dominate in representation on the BOD, committees, and conference participation, they submit more ideas than patients or donors.

Ideally, there should be a balance of people involved in proposing ideas. However, this can be difficult for people who do not have a formal medical education and can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. Additionally, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the OPTN. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Additionally, neither NOTA, the OPTN Final Rule, nor the OPTN Bylaws delineate the number of individuals required for minority and gender representation or whether a single person can count as representation for multiple groups (e.g., a Black female transplant surgeon). It is important to ensure each distinct perspective is represented by a separate voice, potentially undermining the goal of genuine variability.

A lack of role and structure definition also contributes to failures throughout the policy-making process. The BOD and committee members must be clear on their roles and responsibilities to work effectively. However, OPTN fails to train new BOD and committee members about the policy-making process, including strategies for proposing ideas, how and when to access available/required resources, and requirements for moving policies through all stages of the process. Adequate training is essential for informing committee and BOD members how to contribute their diverse viewpoints to ensure that all stakeholder voices are heard throughout the process and to avoid delays in a policy's progression.

Clearly defined roles also contribute to ensuring a policy moves forward as expected. However, the OPTN policy development process documents fail to fully define the roles and responsibilities at each step of the process. For example, in Steps 2 (Problem Analysis) and 4 (Evidence Gathering) of the policy-development process, when data collection is required, committee members need to know the kinds of data that can be requested, the amount budgeted for the request, and how to submit the request. However, newly onboarded committee members are not consistently informed about the requirements for this process.

Additionally, during Steps 2 and 4, the UNOS liaison coordinates resources and logistics by notifying relevant resources (such as SRTR, UNOS IT, and the UNOS Research Department). Liaisons also manage schedules, set meeting agendas, and oversee workgroup progress. However, it remains unclear who informs committee members of the liaison's responsibilities and who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track.

There is also no clearly defined responsibility for the data collation necessary in Steps 2, 4, 7 (Pending BOD Approval), and 10 (Post-Implementation). Although meeting minutes capture the discussion points and issues raised, it remains unclear who specifically compiles and organizes the data once it is collected. There appears to be no formal process to determine who consolidates these findings into a cohesive format, leaving an ambiguity around how data is integrated and documented.

Because of variations in committee makeup and the types of policies they approve, there is no standardized methodology for policy implementation (Step 9), including requirements for stakeholder notification of new policy rollouts and post-implementation monitoring (Step 10). There is no clear

mechanism for how UNOS staff inform all relevant stakeholders—beyond general announcements—about new policy requirements, leaving it uncertain whether key parties receive timely and accurate updates.

14.1.3 Meetings Notes Assessment

Meeting Notes Assessment
During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to BOD composition and size, and committee composition and size within the policy development cycle.

Table 42: Current State Assessment Theme 1: Committee/BOD Composition & Size

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
BOD Composition	Region 1 attendees pointed out the crucial representation of donor families on the BOD for more compassionate and effective organ allocation practices.	Regional Meeting Notes
BOD Composition	Region 2 attendees stressed the importance of ensuring patient advocacy groups have a role and adequate representation on the BOD.	Regional Meeting Notes
BOD Composition	Region 1 and 2 attendees highlighted the importance of regional and OPO representation on the BOD to ensure diverse perspectives in policy development. They noted that it is disproportionately high physician and surgeon representation; low OPO representation.	Regional Meeting Notes
BOD Composition	Region 6 attendees pointed out the need for regional representation on the BOD for underrepresented groups like pediatrics and rural populations. Decisions on allocation have disparate impacts on different parts of the country and densely populated regions might be disproportionately impacted by allocation changes. They stressed the importance of focusing on patient experience and equitable organ allocation.	Regional Meeting Notes
BOD Composition	Region 6 attendees shared that there's great value in having association representation to complement regional representation because of the complexity of how states and regions have different population,	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
	geographic, and logistical challenges. And those association perspectives can often highlight either disparities or strengthen ties to policy.	
BOD Composition	Presenter of Region 9 emphasized the importance of getting true leaders who understand the OPTN and who understand the community so that they can help influence modernization in a positive way.	Regional Meeting Notes
BOD Composition	Region 9 Patient Representative in the BOD expressed the importance of maintaining patient and donor family representation on the BOD and raised concerns about the impact of 100% turnover of the BOD.	Regional Meeting Notes
BOD Composition	Region 9 attendees raised concerns on the lack of pediatric representation on the Transitional Nominating Committee and the need for adequate representation on the BOD.	Regional Meeting Notes
BOD Composition	Region 10 attendees supported the involvement of committee leadership and SMEs in BOD discussions to provide inputs and clarity on certain specialty subjects. They will just be on an advisory capacity and non-voting members. The attendees also highlighted the importance of ensuring that stakeholders' inputs are heard and considered in BOD decisions.	Regional Meeting Notes
BOD Size	Regions 1 and 3 attendees expressed that a larger BOD provides greater safeguards in policy development.	Regional Meeting Notes
BOD Size	PAC Presenter of Region 2 suggested that a manageable BOD size is 10-15 members and should have diverse representation including patients, donors, PAC members, lawyers, finance, and IT professionals. He also suggested incorporating a Patient Bill of Rights into the Final Rule, or wherever appropriate and must include, among other things, patients' rights pre-transplant on the waitlist.	Regional Meeting Notes
BOD Size	Regions 5 and 11 attendees considered current BOD as too large, which consists primarily of	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
	physicians/surgeons/providers who are very busy, leading to inefficiencies.	
BOD Size	Majority of attendees in Region 10 believed that the BOD appears to be unwieldy because it's fairly large but also admitted not knowing the correct size. For them the size is meaningful, but perhaps secondary. What matters is optimizing representation of patients, donor families, and relevant stakeholders as well as ensuring better interaction and communication between the BOD and the committees. They also emphasized that the BOD's size should reflect its function and the priority of representing the organ procurement and transplantation community.	Regional Meeting Notes
BOD Size	Regions 9 and 10 attendees expressed caution about significantly reducing the size of the BOD, fearing that it could limit the voice of patients, donor families, and the broader community.	Regional Meeting Notes
BOD Size	During the PAC meetings in early 2025, members expressed concerns about the large size of the BOD, questioning its ability to be agile and responsive to changing times.	PAC Meeting Notes
Committee Composition	PAC Presenters believed that PAC is well represented and consists of diverse members including living donors, recipients of various organs, and family caregivers.	Regional Meeting Notes
Committee Composition	Region 1 attendees stressed the need for more voices and perspectives in committees, especially for out-of-sequence organ allocation.	Regional Meeting Notes
Committee Composition	Region 2 attendees raised concerns on regional representation and suggested having a rotating ability to sub-in individuals with relevant expertise across specialties. They also emphasized the importance of representing diverse areas within the region to avoid having everyone from the same place.	Regional Meeting Notes
Committee Composition	Region 2, 3, and 8 attendees emphasized the need for at least one PAC member or patient and donor	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
	representatives on OPTN organ-specific committees to provide patient perspectives in policymaking and enhance engagement.	
Committee Composition	Region 5 attendees highlighted the need for sub-committees dedicated to vulnerable and underrepresented populations (e.g., pediatrics, rural folks).	Regional Meeting Notes
Committee Composition	Region 6 attendee expressed concerns about geographic imbalances in committee representation, particularly noting the lack of West Coast representation on the Pancreas Committee. Other attendees supported the need for adequate regional representation to ensure diverse perspectives in policy discussions.	Regional Meeting Notes
Committee Composition	Region 9 attendee suggested the need for membership category for certain groups within the Membership & Professional Standards Committee (MPSC) to hold them accountable.	Regional Meeting Notes
Committee Composition	Region 9 and 10 attendees emphasized the importance of patient, donor family, and community representation in committees and also their participation in policy discussions.	Regional Meeting Notes
Committee Composition	Region 10 and 11 attendees suggested a reevaluation of regional representation in light of continuous distribution allocation system. They expressed the need for representation from all regions and stakeholders to ensure all voices are heard.	Regional Meeting Notes
Committee Composition	Region 5 and 6 attendees noted that committee size is reasonable, but not all regions are equitably represented. Some regions are less well-represented and there is less of a voice compared to others.	Regional Meeting Notes
Committee Composition	During an Operations and Safety Committee meeting on 02/20/2025, members discussed the roles and expertise of key personnel involved in the Normothermic Regional Perfusion (NRP) process, highlighting the importance of including trained	Operations and Safety Committee Meeting Notes

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
	recovery surgeons and Advanced Practice Providers (APP) in the guidance document.	

14.2 Theme 2: Engagement & Transparency Assessment

14.2.1 Interviews Assessments

More than half of interview participants cited lack of patient awareness or engagement as the key pain point of the overall process. When specifically asked about engagement and transparency, participants cited the key issues as: lack of patient awareness and engagement in the process, lack of transparency throughout the process, loud voices advancing personal agendas and crafting outcomes, and roles being misaligned with skills.

Half of stakeholders felt that general public patients, families, and caregivers are not aware of how to get involved in the policy development process. Even if they do become involved, such as sitting on a committee, their voice is not valued as highly as other stakeholders. Some felt this was exasperated by health literacy barriers like complex medical terminology.

Interview Insights

> *"Like if you're just like an independent patient that's not involved with TRIO or you're not with the American Kidney Foundation, you may not be getting any information at all. So, what policies and procedures are being made? How do how do we get that point of view from that patient to voice their opinion? So, it's there. But how do I know it's there?"* – Donor education organization

> *"They use patients just as like mascots that they don't listen to."* – Patient advocacy organization

Some felt that a select few "loudest voices" were driving the policy making process and drowning out the voices of others. Some others felt that those savvy to the process tried to control the process to produce their desired outcomes.

Interview Insights

> *"...this singular expert on the committee who has a large voice, you know, particularly if they are the loud voice in the room. You know what they say usually goes and it's not as much of a robust discussion."* – Transplant professional

> *"And so, when I see and interact with members on the BOD, and I can't speak to the BOD when I get to go to the BOD meetings twice a year as [redacted], I'm not allowed to speak at those meetings. What you just see is sort of something that to me looks choreographed because I've been around business long enough to know when I'm going to get turned down for a bank loan. That decision has already been made well in advance of me going in the door." – Committee member*

Some thought that there was role misalignment between the responsibilities of individuals in the process and their expertise. Examples included physicians making policy decisions and patients being expected to know how to participate in the policy development process. Some identified a need for training to better fulfill their roles, while others saw a need for a better facilitator role to drive policy forward. Additionally, some found a lack of collaboration avenues both between committees and with external stakeholders, causing missed opportunities for efficient and effective problem solving.

Interview Insights

> *"But really sometimes federal agency officials, with all due respect to HRSA, and medical professionals, with all due respect to their professions and their terminal degrees, it's not a deep well of people that implement policy."* – Patient advocate organization

> *"But as it's currently structured, I don't know of a whole lot of conscious effort to inform the community. I think there's probably a general expectation that people have some literacy about that when they're coming into the discussion."* – Transplantation professional

> *"It's hard to keep track of what's going on and making cohesive policy decisions without knowing what the different organ groups or the different other groups are going on. And it would be nice if there were a way where a topic could be early identification of relevant stakeholders, because I have had experience where different committees are kind of working on something related without information."* – Committee member

And finally, many thought that there was a lack of systems in place to hold the contractor (UNOS) accountable for their work.

Interview Insight

> *They didn't feel comfortable bringing it to UNOS because they thought this would just get buried, they'd face retaliation, and I can't say people's names but a lot of people*

that brought a complaint to UNOS got run out of industry. – Patient Advocacy organization

Strengths

Some felt there was adequate representation of stakeholders in the policy development process.

- Some pointed to OPTN committee and BOD members commitment to contribution, dedicating time and effort into the policy development process
- A few thought there was transparency in the process with stakeholders and the public.

14.2.2 Desk Review Assessment

One major issue is the lack of documented criteria for evaluating proposed projects found in Step 3 (Project Approval). There are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there clear guidelines for evaluating the measurability of outcomes, potential risks, technical resource needs, costs, or overall benefits. Without these standards, it is unclear how proposals are judged before moving forward.

A related concern involves no defined measures for stakeholder involvement in Steps 2, 3, 4, and 6. There is no documented process for measuring how stakeholders, including recipient patients, registered and prospective organ donors, donor patients, families, and other underrepresented groups, are included in Step 2 (Problem Analysis). Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. In addition, there is no clear guidance on how committees formalize or execute collaboration strategies with stakeholders.

Another gap centers on defining "enough" evidence in Step 4 (Evidence Gathering). Documents do not specify how much stakeholder input or review is required before moving on to the next step. This creates ambiguity about when a committee can confidently transition from information gathering to proposal development.

Further, there is a shortfall in quality standards in Step 5 (Public Comment Approval), as there are no official criteria for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Compounding this, the process lacks metrics to measure stakeholder engagement (also in Step 5). There are no clear measures for how well Step 5 involves recipient patients, registered and prospective organ donors, donor patients, families, and the underrepresented, or how effectively it communicates transparency.

Finally, there is a persistent issue of lacking metrics to measure stakeholder engagement and transparency in Step 6 (Public Comment). OPTN solicits public comments twice per year but does not provide any metric to gauge the proper level of engagement. There is a goal to increase participation from recipient patients, registered and prospective organ donors, donor patients, donors,

and families at regional meetings and in online public comments—for example, a member from the PAC suggested that a public comment question be "designed to ensure the living donor perspective is represented." The POC wants more pediatric patient families to share their views as well, but there is no official measure of how much feedback is considered "enough." Without metrics or best practices for measuring engagement and transparency at the public comment stages, it is difficult to gauge whether the policy development process is truly inclusive. Reports highlight the disproportionate participation of providers at regional meetings and through the online public comment forum. With no specific metrics or practices established by the OPTN, measuring successful engagement and transparency remains a challenge throughout policy development.

Submitting an idea is an unclear process in Step 1 (Idea). Although regional meetings include open mic sessions where attendees can speak directly with OPTN BOD members, there is no formal online form or clearly advertised process for public idea submissions. Moreover, there appears to be no known annual call for ideas, leaving the public uncertain about how—or even whether—they may officially submit proposals for consideration. There is no documented system or formal instructions letting OPTN stakeholders know if or how they may submit new policy ideas. Anyone who is not already "in the know" has no clear path to propose ideas, and it remains unclear whether any submissions go through OPTN or directly to UNOS. This lack of transparency leaves many potential contributors unaware that they can even offer suggestions. The OPTN does not appear to offer a public-facing submission process—such as an annual call for ideas or a Federal Register notice—beyond open-mic sessions at regional meetings. Consequently, it remains unclear how (or whether) suggestions submitted via email, fax, mail, or phone are formally evaluated and tracked.

A lack of ideas from diverse sources in Step 1 further compounds these challenges. Ideally, there should be a variability of people involved in proposing ideas. However, this can be difficult for people who do not have a formal medical education. Since providers dominate in representation on the BOD, committees, and participation in conferences, they will submit more ideas than patient or donor representatives.

Some OPTN members have asked for more perspectives from people who are not typically involved or who represent overlooked problems. POC meeting notes show that proposals—especially in the early "idea" phase—need more diverse viewpoints and "recommended more patient feedback and involvement." Meanwhile, committees such as the MPSC focus on transplant success metrics and do not measure how well they engage the public or share information openly. The OPTN has no set process or metric to ensure that recipient patients, registered and prospective organ donors, donor patients, families, or other underrepresented groups have a voice early on. Without official guidelines or measures of engagement, it is hard to know if the process is truly transparent or successfully inviting all relevant perspectives.

Providers—such as doctors, reviewers, and transplant professionals—have a strong presence in the OPTN's policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories.

Because providers make up so many committees, they tend to submit the majority of new policy proposal ideas. However, this can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. In addition, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the organ procurement and transplantation system. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Provider-heavy committees can influence which projects the POC approves, given their technical expertise and alignment with OPTN's clinical goals.

No central oversight or tracking for idea submissions in Step 1 remains a barrier, since there is no documented process for collecting, reviewing, and entering them into the system. Additionally, there is no established mechanism or oversight to ensure that every idea is logged, processed, and followed up on, which raises concerns about potential gaps in capturing stakeholder input. While a policy-related Tableau dashboard (owned by UNOS) exists, there is no known comprehensive system for logging, monitoring, and following up on new proposals. Although the PCR logs ideas into the "project forms" system, there is no standardized form or procedure to ensure each idea is submitted with the necessary details (such as the source of the idea, the problem it aims to solve, and potential solutions). It remains unclear who in PCR gathers this information or how consistently those requirements are met—leaving many proposals without the crucial data needed for proper evaluation.

Ambiguous criteria for expedited action in Step 1 is yet another issue. There is no clear, standardized definition of what constitutes an "emergent public health issue" or "patient safety factor." Instead, HRSA and the OPTN exercise broad discretion in determining when expedited action is warranted—for example, issuing an advisory on NRP after patient safety concerns arose. It remains unclear whether the BOD formally defines these criteria or how alternate pathways are chosen. Additionally, HRSA issued a directive for OPTN to improve allocation policy requirements and policy definitions in response to a critical comment letter concerning the activities related to "expedited" allocation of organs.

Similarly, an expedited variance process lacks transparency in Step 1. There is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked. The problem is compounded by the subjective definition of "non-controversial" proposals in Step 1, since no formal or consistently applied criteria exist for classifying a proposal as "non-controversial." It appears to be a subjective term without a clear, written definition—underscoring the need to investigate if any official guidance on this designation is provided.

Unclear roles and responsibilities affect the entire 10-step policy development process. From Step 1 to Step 2, the process does not clarify how an idea transitions from initial submission to being formally assigned to a specific committee. It is also unclear who determines which committee will sponsor and address the problem, leaving a gap in transparency and responsibility at this critical handoff. It is not spelled out who does each task, when, or what level of analysis is required (e.g., literature review, formal study, etc.). Moving from Step 3 (Project Approval) to Step 4 (Evidence Gathering), the process does not clearly define how the committee is informed that a project is approved and can start collecting evidence. During Step 4, staff liaisons coordinate resources and logistics once a proposal is

approved for evidence gathering. The staff liaison—not the volunteer committee members—typically notifies relevant resources (such as SRTR, UNOS IT, and the UNOS Research Department), manages schedules, sets meeting agendas, and oversees workgroup progress. However, it remains unclear who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track.

In terms of the HHS Secretary review in Step 3, it is unclear whether committees designate a policy as "mandatory" versus "non-mandatory" at this step, when policies are sent to the HHS Secretary for review, how that gets done, or how long it takes. Further complicating matters is the lack of documented criteria for evaluating proposed projects in Step 3. There are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there clear guidelines for evaluating the measurability of outcomes, potential risks, technical resource needs, costs, or overall benefits. Without these standards, it is unclear how proposals are judged before moving forward.

No defined measures for stakeholder involvement in Steps 2, 3, 4, 6 adds another layer of complexity. There is no documented process for measuring how stakeholders, including recipient patients, registered and prospective organ donors, donor patients, families, and other underrepresented groups, are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. No clear guidance on how committees formalize or execute collaboration strategies with stakeholders. This intersects with defining "enough" evidence in Step 4, where documents do not specify how much stakeholder input or investigation is required before moving on to the next step. The NOTA/OPTN Final Rule Checklist Used Behind the Scenes in Step 4 further complicates things: while the NOTA/OPTN Final Rule checklist states that proposals move forward if no concerns are raised about compliance with its requirements, the checklist does not fully define the steps for this analysis. However, UNOS process documents indicate that a spreadsheet is used to document whether the authority and/or applicability of one or more requirements is not clearly established or there are different interpretations as to applicability. The process documents fail to indicate when and by whom the spreadsheet is implemented.

At Step 5, quality standards remain undefined. No official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Step 5 also lacks metrics to measure stakeholder engagement, providing no clear measures for how well to involve recipient patients, registered and prospective organ donors, donor patients, families, and the underrepresented, or communicate transparency. Meanwhile, Step 6, which lacks metrics to measure stakeholder engagement and transparency, is equally problematic. OPTN solicits public comments twice per year but does not provide any metric to gauge the proper level of engagement. There is a goal to increase participation from recipient patients, registered and prospective organ donors, donor patients, and families at regional meetings and in online public comments. A lack of metrics and best practices to measuring engagement and transparency, particularly at the public comment stages. Reports have highlighted the disproportionate participation of providers during regional meetings and through the online public comment forum. Without any specific metrics or practices by the OPTN, it is difficult to measure successful engagement and transparency during policy development.

Step 6 further illustrates these weaknesses as there is no clear monitoring or responsibility for public notifications. While the Public Comment OPTN website posts public comment announcements and staff or committee liaisons may share them via email or newsletters, it remains unclear how or whether social media channels are used. Moreover, there appears to be no formal process to verify that these notifications reach all stakeholders or to confirm that the step has been completed. Public comment details (also Step 6) are likewise undefined, as the OPTN policy process documents do not explain step-by-step how each kind of feedback (online, in-person, email) is gathered and tracked to ensure that every comment is included in the public comment analysis. The policy process documents also do not clarify who decides if comments can alter the proposal or how that decision is made. OPTN requests public comments at least twice per year and may also hold special comment periods for various reasons but currently lacks a metric to gauge whether participation is sufficient.

Virtual meetings and public comment engagement in Step 6 shows some promise. A study by Ernst & Young found that attendance at winter regional meetings between 2020-2021 increased by 37% and 106% for patients, families, and caregivers when they could participate virtually indicating a possible path to more balanced engagement. The Ernst & Young study indicated that virtual meetings provided more proportional representation during these regional meetings; transplant hospitals and other medical professionals tend to drive public comments online and at meetings. There was a noted tendency to cast votes through multiple forums, skewing perceptions for or against a policy proposal. Virtual meetings increased participation among patients, families and caregivers, and a further study by an OPTN committee provided a potential baseline for the appropriate amount of participation among stakeholders. Yet, without any specific metrics or best practices by the OPTN, it is difficult to measure successful engagement and transparency during policy development. This lack of metrics and defined targets, particularly at the public comment stage, further hinders the ability to ensure consistent and thorough stakeholder involvement. Reports have highlighted the disproportionate participation of providers during virtual regional meetings and through the online public comment forum. It was noted that regional meeting engagement did skew towards providers relative to patients, families, and caregivers. The Ernst & Young report specified that transplant hospitals tended to dominate these discussions over other groups including OPOs and labs. A transition to hosting virtual regional meetings increased participation among all groups. However, there is a lack of metrics and defined targets to measuring engagement and transparency, including at the public comment stage. The policy development process tends to be tailored to medical professionals, making it difficult for patients, families, and caregivers to fully engage with the ideas being discussed. This creates a burden for physicians trying to properly educate their patients. At a Kidney Transplantation Meeting discussing statistics from the SRTR, one member remarked that the "Committee and community may need to hear this information a few times in order to fully appreciate the nuances."

Provider Dominance in Public Comment in Step 6 is a recurring theme, as many public comments come from medical professionals, overshadowing the recipient patient, registered and prospective organ donor, and the donor patient's viewpoint. There were recommendations to include more representatives from OPOs and pediatrics. Many OPTN providers also tend to be older and more established in their fields and come from urban areas.

Concerns about the limited impact of public feedback in Step 7 (Pending BOD Approval) then arise. While public comments are reviewed, there may be instances where stakeholder input does not significantly alter the final policy proposal, leading to concerns that the process could be more responsive to public support, suggestions, and concerns. This raises the question about potential bias in donor, patient, family, advocacy, and small organization representation where clinical perspectives outweigh patient voices. During the public comment period, medical professionals and clinicians may exert greater influence than patients, donors, families, or advocacy groups. This imbalance can lead to concerns that clinical viewpoints are prioritized over the firsthand experiences of those most directly affected by organ procurement and transplantation policies.

An unclear comment review and tracking process in Step 7 exacerbates the issue. It remains unknown who specifically reviews each public comment for compliance with OPTN public comment principles and how any potentially violative comments are escalated to UNOS leadership. There is no documented process detailing who tracks these reviews, how follow-up occurs, or whether comments are returned to the general queue. Neither HRSA's role in this screening nor the UNOS's or BOD's exact responsibilities are clearly defined, leaving a major gap in transparency and accountability. No formal process for incorporating public comment concerns pre-BOD approval in Step 7 makes it unclear how—or even whether—feedback from the public comment period is systematically addressed before proposals reach the BOD. There is no documented mechanism to ensure that stakeholder concerns are resolved, leaving uncertainty as to whether significant objections or suggestions are truly considered or merely set aside. Additionally, influence of larger organizations in Step 7 arises because larger transplant centers and well-funded institutions may have more resources to devote to policy discussions, thereby overshadowing smaller transplant centers or community-based organizations. This disparity can create an uneven playing field, potentially affecting the variability and balance of input that shapes final policy outcomes.

Finally, resource and implementation concerns appear in the later steps. Limited resources in Step 9 (Implementation) are an issue for some OPTN transplant centers, smaller transplant centers, and community-based organizations may lack the resources (such as funding, staff, time, etc.) to fully comply with the new policy proposal, potentially leading to unequal implementation across the system. Ongoing monitoring of policy proposal rollout (in Steps 9 and 10) is unclear, making it difficult to determine how the implementation process is tracked and potentially affecting early detection of issues. This lack of clarity can hinder a policy's successful rollout. Additionally, there is no documented process for stakeholder notification of new policy implementation. No clear mechanism for how UNOS staff consistently informs all relevant stakeholders—beyond general announcements—about new policy requirements, leaving it uncertain whether key parties receive timely and accurate updates. Finally, insufficient long-term data in Step 10 (Post-Implementation) completes the picture of missing elements. Some policies may require more time to fully assess their long-term impact, and post-implementation reviews may not always account for the full range of effects over time. The UNOS secure transplant network system (UNet) is closed, so it is difficult to understand the methods of analysis that are being conducted, and qualitative data is often overlooked in favor of quantitative data. These gaps collectively illustrate the complexities and shortcomings within the OPTN's 10-step policy development process,

highlighting the need for more transparent guidelines, robust stakeholder engagement, and clear accountability measures across all 10-steps.

14.2.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to engagement and transparency within the policy development cycle.

Table 43: Current State Assessment Theme 2: Engagement & Transparency

Engagement & Transparency Sub-Theme	Evidence	Source
Regular Engagement and Updates	Region 1 and 8 attendees expressed the need for regular engagement and more comprehensive updates with recipient patients, registered and prospective organ donors, donor patients, and family members.	Regional Meeting Notes
Communication Channels and Feedback	Region 2 and 5 attendees shared the need for better communication among members within the region and suggested creating a listserv or moderated forum for interregional and intraregional communication. Other communication channels like community town halls, national public campaigns, grassroots engagement through local OPOs and transplant centers were suggested to foster better engagement and transparency.	Regional Meeting Notes
Communication Channels and Feedback	Region 4 attendees discussed the need for better communication and feedback across transplant centers. They also pointed out the importance of involving the community in discussing policy outcomes and identifying impacted groups.	Regional Meeting Notes
Communication Channels and Feedback	Region 5 and 7 attendees recommended keeping virtual options for those who cannot attend in-person meetings to enhance engagement. They also encouraged transplant and procurement professionals to promote OPTN volunteering opportunities.	Regional Meeting Notes
Transparency in Decision-Making	Region 3 attendees questioned how effectively public comments were integrated into final policy decisions, expressing a need for greater transparency in how feedback influences outcomes. There were also concerns on whether all stakeholders, including smaller transplant	Regional Meeting Notes

Engagement & Transparency Sub-Theme	Evidence	Source
	centers and OPOs, had equal access to the public comment process.	
Transparency in Decision-Making	Region 5 attendees suggested the use of the OPTN safety portal in reporting unexpected disease transmission events and to incorporate standardized national guidelines into hospital protocols. They also emphasized the need for clear, uniform processes across OPOs and transplant centers to promote transparency, consistency and fairness.	Regional Meeting Notes
Transparency in Decision-Making	A Region 6 attendee wanted some clarifications on how one measures whether the BOD or the committee is achieving the goals of the OPTN and how these goals can become part of the metric of effective operation of either the BOD or the committee.	Regional Meeting Notes
Transparency in Decision-Making	Region 8 and 9 attendees raised concerns about transparency in OPTN leadership activities despite the creation of new COI policies.	Regional Meeting Notes
Transparency in Decision-Making	A Region 9 attendee expressed feelings of deception and disrespect regarding the temporary nature of BOD appointments, highlighting the lack of transparency in the communication process regarding OPTN Modernization. Other attendees also expressed concerns that patients are not well informed about changes in policies and how these changes might affect them. They stressed the importance of transparent communication and education for patients.	Regional Meeting Notes
Transparency in Decision-Making	During the PAC meetings in early 2025, members raised concerns about the transparency of the transition process, with some feeling that there has been a lack of clear communication and involvement in critical discussions.	PAC Meeting Notes
Transparency in Decision-Making	A PAC member said there is a lack of transparency around policy projects and how sponsoring committees incorporate feedback from other committees into their policies.	PAC Meeting Notes
Community Involvement and Representation	Attendees from Regions 3, 4, 8, and 9 emphasized the importance of ensuring patient	Regional Meeting Notes

Engagement & Transparency Sub-Theme	Evidence	Source
	voices and experiences are heard by the BOD and committees. They also raised the need for patients' involvement in the decision-making process as well as receiving comprehensive updates from OPTN leaders.	
Community Involvement and Representation	A Region 9 attendee pointed out the need for balanced representation and transparency in congressional hearings related to OPTN Modernization.	Regional Meeting Notes
Community Involvement and Representation	Region 10 attendees emphasized the value of regional breakout meetings for understanding policy impacts and ensuring regional representatives are well-informed. They also stressed the importance of elevating alternate voices to ensure all perspectives are heard, especially those outside the mainstream conversation. The attendees also suggested including content experts as non-voting members in BOD discussions to ensure informed decision-making.	Regional Meeting Notes
Community Involvement and Representation	Region 11 attendees pointed out the importance of transparency and formalizing allocation practices to maintain public trust, highlighting the need for community input.	Regional Meeting Notes
Best Practices and Information Sharing	During an MPSC meeting on 02/21/2025, members highlighted the need for transparency for candidates regarding the updated notification requirements, noting that the retrospective notification process could be burdensome on transplant programs.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During an MPSC meeting on 02/21/2025, members stressed the importance of sharing best practices and engaging the PAC to ensure the process works best for both programs and patients.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During an MPSC meeting on 02/06/2025, members highlighted the importance of sharing effective practices between OPOs and ensuring that performance measures are complementary to CMS metrics to aid in identifying opportunities for enhancement.	Membership & Professional Standards Committee Meeting Notes

Engagement & Transparency Sub-Theme	Evidence	Source
Best Practices and Information Sharing	During an MPSC meeting on 12/13/2024, members highlighted the importance of providing clear information for programs about the performance enhancement zone, as feedback from previous processes indicated confusion among some members.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During Living Donor Committee (LDC) meetings in the month of March 2025, members highlighted the importance of clarifying options and adding definitions to the forms to ensure transparency and comprehensiveness in capturing relevant data.	Living Donor Committee Meeting Notes
Best Practices and Information Sharing	During an LDC meeting on 03/06/2025, members highlighted the importance of providing clear information to programs about the data collection process, as feedback indicated confusion among some members.	Living Donor Committee Meeting Notes
Best Practices and Information Sharing	During a Minority Affairs Committee (MAC) meeting on 12/16/2024, members emphasized the importance of updating the Equity in Access dashboard with a rolling 10-year window for better availability and transparency for the public and other OPTN Committees.	Minority Affairs Committee Meeting Notes
Best Practices and Information Sharing	During a MAC meeting on 11/18/2024, members emphasized the importance of including the requirement for all candidates registered on or after January 4, 2024, to receive proposed education, eligibility, and outcome notifications in the public comment proposal to ensure transparency and community feedback.	Minority Affairs Committee Meeting Notes
Best Practices and Information Sharing	During a MAC meeting on 10/16/2024, members emphasized the importance of including what constitutes a notification in the evaluation plan to ensure clarity and transparency for transplant programs.	Minority Affairs Committee Meeting Notes
Best Practices and Information Sharing	During an Operations and Safety Committee meeting on 02/20/2025, members highlighted challenges in engagement and transparency, emphasizing the importance of involving all key personnel in pre-procurement huddles to ensure clear communication and decision-making.	Operations and Safety Committee Meeting Notes

14.3 Theme 3: Timeliness Assessment

14.3.1 Interviews Assessments

Some felt the overall policy-making process was too long. Most feedback was about the length of the overall process, a few specifically identified the amount of time to receive data and the length of public comment as two bottlenecks. Although there was a consensus the process was too long, many also mentioned that length was necessary to get through all the important steps in the process.

Interview Insights

> *"Are you out of your minds that you're going to crawl along a 10-step process that's multiple years when literally people are dying?"* – Committee member

> *"I think that if it were a more streamlined process, you might be able to get even more engagement from experts knowing that their impact has more direct, expedited effect, because I know that's been a frustration for others as well, so just one thing I would emphasize as well."* – Organ Procurement professional

> *"Science moves fast and so if you wait 18 months to implement something the field may have already changed by that time."* – Transplantation professional

Strengths

A few pointed out that there have been times when the policy process moved fast, such as during the COVID pandemic or when there was a high priority directive.

Interview Insight

> *When it's a little more focused and HRSA and OPTN are very interested in making things happen quickly, they do.* – Committee member

14.3.2 Desk Review Assessments

Delays and various extraneous factors affect timeliness throughout the 10-step process.

Submitting an idea is an unclear process in Step 1 (Idea). Although regional meetings include open mic sessions where attendees can speak directly with OPTN BOD members, there is no formal online form or clearly advertised process for public idea submissions. Moreover, there appears to be no known annual call for ideas, leaving the public uncertain about how—or even whether—they may officially submit proposals for consideration. There is no documented system or formal instructions informing OPTN

stakeholders if or how they may submit new policy proposal ideas. Anyone who is not already "in the know" has no clear path to propose ideas, and it remains unclear whether any submissions go through OPTN or directly to UNOS. This lack of transparency leaves many potential contributors unaware that they can even offer suggestions. The methods for submitting an idea to OPTN are unclear. Consequently, it is unknown how (or whether) email, fax, mail, or phone submissions are formally logged, evaluated, and tracked.

No central oversight or tracking for idea submissions in Step 1 also poses a significant gap. There is no documented process for collecting, reviewing, and entering them into the system. Additionally, there is no established mechanism or oversight to ensure that every idea is logged, processed, and followed up on, which raises concerns about potential gaps in capturing stakeholder input. While a policy-related Tableau dashboard (owned by UNOS) exists, there is no known comprehensive system for logging, monitoring, and following up on new proposals. Although the PCR logs ideas into the "project forms" system, there is no standardized form or procedure to ensure each idea is submitted with the necessary details (such as the source of the idea, the problem it aims to solve, and potential solutions). It remains unclear who in PCR gathers this information or how consistently those requirements are met—leaving many proposals without the crucial data needed for proper evaluation.

No formal process for revisiting unprioritized policy proposals in Step 1 further complicates matters. Although the POC should periodically re-evaluate previously submitted ideas, prioritize them, and communicate any updates to the original submitters, there is no evidence that this happens. The absence of a defined schedule or clear feedback loop leaves the fate of unselected proposals in a "black box," making it unclear if they are ever reviewed again.

No standardized process for committee assignments in Step 1 adds another layer of inconsistency.

Decisions about which committee handles a given policy proposal appear to rest largely with the POC, which has the discretion to create ad hoc committees as needed. There is no consistent, documented approach for similar proposals, resulting in variability and a lack of transparency in how assignments are made. Meanwhile, the expedited variance process lacks transparency in Step 1 (also seen in Theme 2: Engagement & Transparency), given that there is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked. Additionally, there is no formal definition for "critical constituency" involvement in Step 1 (again, also seen in Theme 2: Engagement and Transparency). It remains unclear who designates a "critical constituency" for a given policy proposal and how those groups are formally brought into the process. While it appears the POC chair may play a key role in identifying these stakeholders, there is no documented procedure governing their selection or engagement.

A gap between Step 1 and Step 2 (Problem Analysis) underscores the problem of unclear transitions. The process does not clarify how an idea moves from initial submission to formal assignment within a specific committee. It is also unclear who determines which committee will sponsor and address the problem, leaving a gap in transparency and responsibility at a critical handoff. Unclear timing in Step 2

remains an issue, as there is no standard timeframe for turning an approved idea into a complete problem statement and updated project form.

Inconsistent data standards in Steps 2, 4,7, 9, and 10 is another obstacle as inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements.

Unclear roles and responsibilities in the entire 10-steps and specifically Step 2 further hinder efficient progress. It is not spelled out who does each task, when, or what level of analysis is required (e.g., literature review, formal study, etc.). This lack of clarity extends to complexities in SRTR Data Requests and Resource Allocation in Steps 2 and 4. Committee members cannot make data requests to SRTR directly; requests must go through UNOS staff or potentially involve HHS/DoT as an intermediary. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues.

No clear process for determining required resources in Step 2 and Step 4 (Evidence Gathering) compounds these delays. It remains unclear how committees decide what resources, financial, technical, or expertise—are needed for developing and implementing a proposal. UNOS often guide methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise. This creates a risk that committees receive solutions shaped more by the UNOS' understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed.

No formal guidance on problem analysis tools and timeframes in Steps 2 and 4 highlights another gap. It remains unclear which tools or resources committees use to analyze a problem, or how members are informed of their availability. There is no documented process specifying a timeframe for completing an analysis or guidelines for documenting and reviewing the results, leaving committee members uncertain about best practices and next steps. Likewise, there are no defined measures for stakeholder Involvement in Steps 2, 4, and 6. There is no documented process for measuring how stakeholders, including recipient patients, registered and prospective organ donors, donor patients, families, and other underrepresented groups are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. Similarly, no clear guidance on how committees formalize or execute collaboration strategies with stakeholders.

The unclear processes in Step 3 (Project Approval) also contribute to timeline failures because there is no documented process or monitoring system to ensure all reviews occur as required or to prevent

projects from getting stuck in any review stage. It remains unclear who is responsible for each step or how much time is required for each review. Moreover, the HHS Secretary review is not well defined in Step 3. It is not clear which policies must be sent to the HHS Secretary for review, how that gets done, or how long it takes. It is unclear whether committees designate a policy as "mandatory" versus "non-mandatory" at this step and whether this is the step that requires mandatory policies to undergo review by the HHS Secretary.

COR Involvement in Step 3 lacks transparency as well since the contract says the COR reviews changes first, but the public OPTN documents do not mention how or when this occurs. Moving forward, there is no standard timeline in Step 4 to guide how long evidence gathering should take, and transition from Step 3 to Step 4 is not clearly defined in terms of how the committee is informed that a project is approved and can start collecting evidence. The timeframe from project approval to completion of evidence gathering is unclear. There are no guidelines for how long evidence gathering should take. The timeframe between committee vote, and POC feedback in Step 4 similarly remains unclear, as it largely depends on the POC's meeting schedule and can be affected by requests for additional information or documentation. Further, defining "enough" evidence in Step 4 is an unresolved issue, given that documents do not specify how much stakeholder input or review is necessary before advancing to the next step. This leads to a highly variable timeframe for evidence gathering in Step 4: if a proposal requires minimal deliberation, the committee may proceed quickly, while more complex cases can significantly prolong this stage. Further, it is unclear if drafting the proposal is considered part of Step 4 or Step 5 (Public Comment Approval).

Staff liaisons coordinate resources and logistics in Step 4 by notifying relevant resources such as SRTR, UNOS IT, and the UNOS Research Department. Liaisons also manage schedules, set meeting agendas, and oversee workgroup progress. However, it remains unclear who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track. There is a need for clarity in Step 4. The boundary between finishing evidence gathering and drafting the public comment proposal is not clearly defined.

Focusing on roles and timeframes in Step 5 reveals that it is unclear how long the POC and EC each have to complete their review. Once the POC is notified of a policy's readiness, the vote can occur at its next meeting, which varies from a few weeks to a couple of months. After the POC approves a proposal, the BOD typically considers it in the following meeting cycle. The typical timeframe for drafting and releasing public comment proposals in Step 5 is also subject to batching cycles that occur two to four times a year, making the scheduling neither fixed nor transparent.

Varying timelines in Step 6 (Public Comment) reflect the exact length of the public comment window differs and is not strictly documented, and some policy changes (e.g., emergency or expedited) skip or shorten this phase. Variable timeframes and no formal Federal Register Notice in Step 6 further highlight how OPTN relies on general announcements via email blasts, newsletters, regional meetings, and mailing list signups, rather than a standard Federal Register Notice. The public comment window itself typically lasts 45 to 60 days, though it can vary depending on interest or other factors, without a single fixed duration. This lack of formal structure can lead to concerns about time regarding how long the

entire process takes (weeks or months) and Step 7 (Pending BOD Approval) similarly offers no specific guidance on analyzing public comments in a timely manner, particularly comments that criticize the OPTN policy development process.

An implementation gap in Step 8 (BOD Approval) arises when the time required for policy proposal review and approval creates a lag between approval and actual implementation, potentially affecting the timely adoption of crucial changes. Finally, the lack of standardization in Step 9 (Implementation) becomes evident because variations in committee makeup and the policies they approve result in no standardized methodology for implementation. This inconsistency, coupled with earlier gaps in process definition and data management, underscores the overall timeliness challenges plaguing the policy development cycle.

14.3.3 Meetings Assessments

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to timeliness within the policy development cycle.

Table 44: Current State Assessment Theme 3: Timeliness

Timeliness Sub-Theme	Evidence	Source
Delays in Communication and Implementation	Region 1 attendees raised concerns regarding the timeliness of the policy development process. Specifically, during the discussion on Continuous Distribution of Kidneys, a member expressed concern that broader sharing of organs has resulted in an increase in non-use, with allocation taking too much time, especially for medically complex kidneys. They emphasized that any additional complexity should be accompanied by efforts to increase efficiency, highlighting the need for timely and efficient policy development to address these issues. This ensures that policies are effective and responsive to the challenges faced in the allocation process.	Regional Meeting Notes
Delays in Communication and Implementation	Region 2 attendees raised concerns about the complexity of the Multi-Organ Allocation Policies proposal and how allocation staff will interpret and apply it, especially in urgent situations.	Regional Meeting Notes
Delays in Communication and Implementation	Region 4 attendees discussed delays in communication and implementation, highlighting updates on various proposals and initiatives, including the timeline for the special election and the HHS/DoT modernization contract strategy.	Regional Meeting Notes
Delays in Communication and Implementation	Region 11 attendees expressed concerns about the untimely and uncoordinated policy development process for estimated Glomerular Filtration Rate	Regional Meeting Notes

Timeliness Sub-Theme	Evidence	Source
	(eGFR) monitoring requirements. These requirements were introduced separately from the policy change, causing confusion and an administrative burden on transplant programs as they had to adapt retroactively. Multiple members suggested that a more synchronized approach would have been beneficial. The lack of timely implementation led to difficulties, highlighting the need for better planning and execution in policy development.	
Delays in Communication and Implementation	During an MPSC meeting on 02/21/2025, members expressed concerns related to timeliness, emphasizing the importance of adding a 30-day time frame for reporting the third notification requirement to patients.	Membership & Professional Standards Committee Meeting Notes
Delays in Communication and Implementation	During an MPSC meeting on 12/13/2024, members expressed concerns related to timeliness, noting the high level of effort required to follow the current process for performance enhancement zone notifications.	Membership & Professional Standards Committee Meeting Notes
Delays in Communication and Implementation	During LDC meetings in the month of March 2025, members expressed concerns related to timeliness, noting the need to streamline the workflow for aborted procedures to ensure timely and accurate data collection.	Living Donor Committee Meeting Notes
Delays in Communication and Implementation	During the PAC meetings in early 2025, members noted that the current policy development process often leads to delays in implementing necessary changes, emphasizing the need for a more efficient approach.	PAC Meeting Notes
Delays in Communication and Implementation	A PAC member said the issue is not the committee structure but rather that the policy development process is cumbersome and takes too long.	PAC Meeting Notes
Delays in Communication and Implementation	During an Operations and Safety Committee meeting on 02/20/2025, members expressed concerns related to timeliness, noting that the policy development process often faces delays due to the need for extensive reviews and approvals by multiple committees.	Operations and Safety Committee Meeting Notes
Long Wait Times and Complication Rates	Region 9 attendees discussed the timeline for the potential enactment of a proposal for the escalation of status for time on Left Ventricle Assist Devices (LVAD), with implementation anticipated in 2026 if approved, highlighting the lengthy process involved.	Regional Meeting Notes

Timeliness Sub-Theme	Evidence	Source
Long Wait Times and Complication Rates	Region 5 attendees emphasized ongoing issues with long wait times and complication rates. They stressed the need for establishing consistent timeframes for unexpected events to clarify reporting requirements for transplant programs. Recommendations included policies to direct the match run for highly prioritized candidates, aiming to transform efficiency and equitable distribution. These points underscore the need for timely adjustments to policy for better patient outcomes and reduce the risks associated with long wait times and complications.	Regional Meeting Notes
Community Input and Delays	Region 11 attendees addressed a request for feedback on a complex multi-organ allocation proposal. Multiple opportunities for community input were noted to prevent delays, although the controversial nature of the proposal could still lead to significant delays. Additionally, attendees supported clarifying requirements for reporting unexpected disease transmissions to OPO operations.	Regional Meeting Notes
Community Input and Delays	Region 5 and 11 attendees raised concerns about the proposed 5–7-year period for escalation of status for time on LVAD, suggesting earlier escalation. Attendees also discussed modifying lung donor data collection and establishing a comprehensive multi-organ allocation policy, focusing on operational issues and tracking mechanisms.	Regional Meeting Notes
Community Input and Delays	Region 7 attendees pointed out the need for timely feedback from the community, with public comment periods of 30 and 60 days. Region 3 attendees felt that the time allocated for public comments was insufficient for thorough review and feedback on complex proposals.	Regional Meeting Notes

14.4 Theme 4: Data Availability

14.4.1 Interviews Assessments

More than half of participants thought data was inaccessible on some level. This included not being user-friendly, difficult to retrieve, understand or share. Although UNOS data is publicly accessible and HRSA has its own data request portal, obtaining these documents can be challenging and may involve a fee.

Interview Insight

> *"You know I see it, but they're not allowed to release it, or they're not allowed they get told they can't post it or HRSA blocks that process. And I don't understand it when it's there."* – Committee member

Some felt there was a lack of robust data, including data requested being limited or not available.

Interview Insight

> *"Every time we asked like, hey, we need more specific information about demographics or about specific conditions, it was always no, that's a data burden."* – Former Committee member

Strengths

Some felt OPTN data was available and accessible.

Interview Insight

> *"And by the time the POC sees these policies, we typically, if not always, nearly always have whatever data we might need to consider that policy."* – POC member

14.4.2 Desk Review Assessment

Failures identified within data availability include lack of long-term data in Step 1 (Idea), where long-term data such as complications, survival, quality of life, and post-transplant healthcare utilization are often lacking. Another concern is no formal guidance on problem analysis tools and timeframes in Step 2 (Problem Analysis). It remains unclear which tools or resources committees use to analyze a problem, or how members are informed of their availability. There is no documented process specifying a timeframe for completing an analysis or guidelines for documenting and reviewing the results, leaving committee members uncertain about best practices and next steps.

A further gap is no defined measures for stakeholder involvement in Step 2. There is no documented process for measuring how stakeholders, including with recipient patients, registered and prospective organ donors, donor patients, families, and other underrepresented groups, are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. No clear guidance exists on how committees formalize or execute collaboration strategies with stakeholders. Meanwhile, inconsistent data standards in Step 2 add additional obstacles. An inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements.

Complexities in SRTR Data Requests and Resource Allocation in Step 2 represent another difficulty. Committee members cannot make data requests to SRTR directly; requests must go through UNOS staff or potentially involve HRSA as an intermediary. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues.

There is no clear process for determining required resources in Step 2 and Step 4 (Evidence Gathering) either. It remains unclear how committees decide what resources, financial, technical, or expertise—are needed for developing and implementing a proposal. UNOS often guide methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise. This creates a risk that committees receive solutions shaped more by UNOS' understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed.

No clearly defined responsibility for data collation in Steps 2, 4 and Step 6 (Public Comment) also emerges as a shortfall. Although meeting minutes capture the discussion points and issues raised, it remains unclear who specifically compiles and organizes the data once it is collected. There appears to be no formal process to determine who consolidates these findings into a cohesive format, leaving ambiguity around how data is integrated and documented. Similarly, no standardized threshold for completing analysis in Steps 2 and 4 exists. It appears committees decide that analysis is "adequate" once all their questions are addressed, and any feedback—whether from formal surveys or informal discussions—is sufficiently documented. However, there is no clear, standardized criterion for determining when this point is reached. Committees typically create a slide deck or report to present their findings, but the ultimate decision to move forward hinges on whether the committee deems its write-up thorough rather than following a formal procedural benchmark.

Inconsistent data standards in the entire 10-Step process reappear as an overarching problem. An inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements. Quality standards in Step 5 (Public Comment Approval) also remain unclear. No official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement.

Moving on to no clear monitoring or responsibility for public notifications in Step 6 (Public Comment), it remains unclear how or whether social media channels are used for announcements, and there appears to be no formal process to verify that notifications reach all stakeholders or to confirm that the step has been completed. Since there are public comment summaries but no strict threshold for action in Step 6, this reflects a situation in which UNOS and OPTN compiles a response document summarizing public feedback, yet it is unclear whether the BOD or POC routinely reviews this final report. Moreover, there is

no formal metric to mandate changes when public concerns are strong; proposals can still advance despite substantial opposition.

An additional complication involves unclear fiscal impact workgroup roles and responsibilities in Step 6. While a fiscal workgroup is reportedly formed to determine whether proposals meet budgetary requirements, it remains unclear who is assigned to this workgroup, whether the same individuals participate across multiple projects, and how the selection process is decided. There is no documented method indicating who makes these choices or how consistency is maintained from one project to the next. Fiscal assessments appear to depend largely on staff consultation with the finance department, Chief Financial Officer (CFO), and relevant teams (e.g., IT or communications) rather than a structured or standing "fiscal workgroup." Membership can rotate based on the proposal's needs, but there is no documented, measurable set of criteria for determining a project's fiscal impact, leaving it unclear how cost estimates are consistently calculated or approved. Although the Finance Committee is presumed to be involved in evaluating a proposal's cost impacts, it remains unknown how the workgroup is formed, which members are selected, or what specific financial metrics are used.

Unknown metrics to measure public concern and critical comments in Step 7 (Pending BOD Approval) also pose a problem. There is no formal or consistent methodology to quantify or evaluate how public feedback influences final policy decisions, leaving it unclear how—or if—the comments meaningfully impact the outcome. The UNOS team's analysis of data from public comments is not made publicly available. Unspecified "Approved" or "Rejected" proposed policy metrics in Step 8 (BOD Approval) indicate that the exact metrics used to either approve or reject a proposed policy are unclear.

Turning to limited resources in Step 9 (Implementation) and Step 10 (Post-Implementation Review), some OPTN transplant centers, smaller transplant centers, and community-based organizations may lack the funding, staff, or time needed to fully comply with a new policy proposal. Smaller transplant centers or community-based organizations with fewer resources may face challenges in effectively participating in the review process or struggle to implement suggested changes, leading to unequal implementation across the system. Ongoing monitoring of policy proposal rollout in Step 9 is another weak point, as it remains unclear how the implementation process is monitored, making it harder to detect issues that may hinder the successful rollout of a policy. Lastly, insufficient long-term data in Step 10 completes the picture. Some policies may require more time to fully assess their long-term impact, and post-implementation reviews may not always account for the full range of effects over time. The UNet system is closed, so it is difficult to understand the methods of analysis being conducted, and qualitative data is often overlooked in favor of quantitative data.

14.4.3 Meetings Assessments

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to data availability within the policy development cycle. These observations reflect the challenges in data availability and data accuracy within the policy development cycle.

Table 45: Current State Assessment Theme 4: Data Availability

Data Availability Sub-Theme	Evidence	Source
HRSA Directives	Attendees in Region 3 discussed the importance of HRSA's directives for OPTN to collect data on patients before they are added to the waitlist and on ventilated patients prior to referral to an OPO. They emphasized that this data is crucial for understanding the total disease burden and potential donor numbers.	Regional Meeting Notes
HRSA Directives	Attendees in Region 5 stressed the need for clear, uniform processes across OPOs and transplant centers to promote consistency, fairness, and transforming health outcomes.	Regional Meeting Notes
Challenges in Data Reporting	Attendees in Regions 1, 3, and 8 expressed concerns about the potential confusion in data reporting due to patients being listed at multiple centers. This issue was expressed as a significant barrier to accurate data collection.	Regional Meeting Notes
Challenges in Data Reporting	Attendees in Region 3 expressed concerns regarding unclear data definitions and ambiguity regarding whether the new diagnostic test status applies to all or only required tests, whether fields can be modified after disposition closure, and whether reasons for incomplete tests (e.g., hospital capability) will be included. They also noted that the absence of an automatic notification system means OPOs must manually alert transplant centers about test results, which does not help efficiency.	Regional Meeting Notes
Challenges in Data Reporting	In Region 6, attendees raised concerns about the increased data reporting burden for OPOs, particularly with the new lung donor data collection requirements.	Regional Meeting Notes
Challenges in Data Reporting	During a MPSC meeting on 02/06/2025, members expressed concerns related to data availability, noting the two-year lag in CDC Multiple Cause of Death data for potential donors and the limitations in variables available for risk adjustment.	Membership & Professional Standards Committee Meeting Notes
Challenges in Data Reporting	During a MPSC meeting on 12/13/2024, members discussed the limitations of the current data, suggesting alternatives such as using newer data or Customer Service Management reports to determine which programs may need resources.	Membership & Professional Standards Committee Meeting Notes
Challenges in Data Reporting	During a MAC meeting on 11/18/2024, members discussed the need to retrospectively notify candidates of their eGFR modification eligibility and/or outcome, noting that this requirement could be burdensome for programs and confusing from a compliance perspective.	Minority Affairs Committee Meeting Notes

Data Availability Sub-Theme	Evidence	Source
Challenges in Data Reporting	During a MAC meeting on 10/16/2024, members discussed the need for transplant programs to have a documented process for confirming candidate race and seeking supporting documentation, highlighting the importance of clear and accessible data collection protocols.	Minority Affairs Committee Meeting Notes
Challenges in Data Reporting	During an Operations and Safety Committee meeting on 02/27/2025, members discussed issues with the availability of donor data collection and multi-organ allocation data availability, emphasizing that incomplete or outdated data can hinder effective policy formulation.	Operations and Safety Committee Meeting Notes
Complexity of Data Collection	Attendees in multiple regions, including Regions 1, 3, and 6, raised concerns about the complexity of data collection. They emphasized the need for standardized data elements to reduce the burden on coordinators and accuracy. Additionally, attendees in Region 1 emphasized the need for standardized terminology, such as using "cannabis" instead of "marijuana," to streamline data collection and reporting. Attendees in Region 6 expressed the need for specificity in data requests to avoid confusion and ensure accuracy as well as the need for more granular and data-driven approaches to policy adjustments.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 10 also emphasized the need for clear definitions and reporting requirements for lung transplant recipients, implying that there may be gaps or inconsistencies in the available data.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 11 highlighted the need for standardized practices and clearer priorities, questioning the allocation sequence for liver-intestine-pancreas patients and suggested calling out these combinations separately, indicating a need for more detailed data.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 1 and Region 6 noted that implementing new data fields requires modifications to existing systems, adding cost, time, and programming effort. This is crucial to avoid the burden of documenting information in multiple places during the transition period. Attendees in Region 6 raised concerns about the need for standardized data elements to reduce back-and-forth communication.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 2 also stated that modifying donor data collection may add an operational burden to the OPO community, which must be balanced against the	Regional Meeting Notes

Data Availability Sub-Theme	Evidence	Source
	benefits of better communication. Region 6 attendees emphasized the need for clearer guidance and definitions for reporting requirements to ensure accurate and efficient data collection.	
Complexity of Data Collection	An attendee in Region 8 pointed out that the efficacy of the Multi-Organ Allocation Policy would depend on whether recipient centers are using the same metrics, as comparisons cannot be made if they are not. Region 6 attendees added that the complexity of multi-organ allocation policies was a significant concern, with attendees pointing out the increased donor case times and the potential for errors due to the need to switch between multiple match runs.	Regional Meeting Notes
Complexity of Data Collection	Region 7 and Region 8 attendees both noted the importance of recipient centers using the same metrics for comparison and the potential for human error in using mathematical equations.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 11 expressed concern about donor families being unaware of the donor's tobacco and marijuana use, emphasizing the need for better data collection and communication.	Regional Meeting Notes
Complexity of Data Collection	During LDC meetings in the month of March 2025, members discussed the limitations of the current data collection process, suggesting enhancements to better align with the definition of a living donor and ensure accurate reporting.	Living Donor Committee Meeting Notes
Complexity of Data Collection	During LDC meetings in early 2025, members discussed the limitations of the current data collection process, suggesting enhancements to better capture barriers at the first in-person appointment.	Living Donor Committee Meeting Notes
Complexity of Data Collection	During the LDC meeting on 02/20/2025, members discussed the need for more granular data on alcohol consumption, particularly for liver donors, to ensure accurate and relevant data collection.	Living Donor Committee Meeting Notes
Complexity of Data Collection	During a MAC meeting on 12/16/2024, members discussed the need for alternative graphs on the Equity in Access dashboard to better reflect variability in access to transplantation by race/ethnicity, ensuring the data is more accessible and useful.	Minority Affairs Committee Meeting Notes
Complexity of Data Collection	During a MAC meeting on 12/16/2024, members highlighted the limitations of using data over 10 years old, suggesting that a more recent data cohort would better align with current data collection practices.	Minority Affairs Committee Meeting Notes

Data Availability Sub-Theme	Evidence	Source
Collaboration and Support	Attendees in Regions 4 and 10 highlighted the need for support and collaboration among community hospitals, OPOs, and other entities. They emphasized that this collaboration is necessary to ensure accurate and comprehensive data collection.	Regional Meeting Notes
Collaboration and Support	Region 3 attendees expressed that a plan to monitor transplant centers' use of the additional data elements is necessary. This requires ongoing collaboration and support from oversight bodies, data analysts, and transplant centers to ensure the data is used effectively and contributes to better decision-making.	Regional Meeting Notes
Collaboration and Support	Region 6 attendees suggested having the ensuing IT solution part of the Multi-Organ Transplantation Committee (MOTC) proposal to be able to integrate with DonorNet and to be as interactive as possible for ease of usability for the OPOs.	Regional Meeting Notes
Collaboration and Support	Region 10 attendees pointed out that the uniform Donor Risk Assessment Interview (uDRAI) does not always capture granular information, reinforcing the need for better data integration and collaboration to ensure comprehensive data availability. System changes would also require collaboration with other organizations to ensure seamless integration and reduce redundancy. Region 10 attendees also commented on the need for OPTN to collaborate with entities like AOPO and the American Association of Tissue Banks (AATB) regarding data collection tools to align lung donor data collection requirements.	Regional Meeting Notes
Collaboration and Support	Attendees in multiple regions, including Regions 1, 3, 6, and 8 suggested using AI chatbots to support waitlisted candidates and personalized decision-making in the organ offer process.	Regional Meeting Notes
Collaboration and Support	Presenter of Region 2 shared that to get data collected within the OPTN, you have to go through the Office of Management and Budget (OMB).	Regional Meeting Notes
Proposals for Data Collection Enhancements	Attendees in Regions 5, 6, and 9 discussed various challenges in data collection, such as modifying donor testing collection data, establishing consistent and granular data points, and streamlining communication between OPOs and transplant programs.	Regional Meeting Notes
Proposals for Data Collection Enhancements	An attendee in Region 5 also suggested defining "hard-to-place kidneys" and creating an algorithm to predict which kidneys will be hard to place. They also	Regional Meeting Notes

Data Availability Sub-Theme	Evidence	Source
	recommended developing a protocol for the placement of these kidneys to manage increased costs and geographic distribution challenges.	
Proposals for Data Collection Enhancements	An attendee in Region 8 suggested including patients' lived experiences in data collection (e.g., struggles, mental health, quality of life).	Regional Meeting Notes
Proposals for Data Collection Enhancements	During the PAC meetings in early 2025, members highlighted the need for more comprehensive and accessible data to inform policy decisions, stressing the importance of having accurate and timely information.	PAC Meeting Notes
Proposals for Data Collection Enhancements	A PAC member recommended that Committee members focus on providing the patient perspective regarding collecting data on patients.	PAC Meeting Notes

14.5 Theme 5: Prioritization Methodology

14.5.1 Interviews Assessments

More than half of participants felt there was inefficient prioritization of policies developed in the process. A few thought that unclear goals and priorities were the key challenges in the overall process. A few felt that there were unclear goals or strategic direction, a few others that the strategic direction is too reactive to events such as public comment or news articles, and a few others that there is a COI in what gets prioritized. Additionally, some expressed a lack of strong oversight of strategic direction.

UNOS often guides methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise.

Interview Insights

> *"I found the strategic plan was all encompassing in that if anybody had a loud enough voice or sharp enough explanation, anything could fall under the strategic plan."* – Transplant professional

> *"We're running top down with a tiny coterie of people at HRSA who overreact to every critical comment we receive...then it's all hands-on deck and all projects stop."* – Committee member

> *"I think we need to have a little bit of a tighter guardrail on that process. Let's come together earlier on and say, it's not really, the question is not really whatever you*

> *want to do to support the plan. Here's the plan. Here's what we really need you to do."* – Committee member

> *"In my experience, and I've been on a couple different committees, it's sort of, it's an ad hoc process which is facilitated by the contractor to some degree, but when you take an idea of conception to generate it into a policy, it happens organically, but I'm not sure the rules are super well codified."* – Committee member

Strengths

Some felt policies were prioritized correctly based on their overall importance.

Interview Insight

> *"I think the committees do a great job with the tasks they are given, you know, in meeting monthly and, you know, we do try to prioritize as we go along, you know, like, okay, is this idea, should we work on this first before we go on to, you know, anything else? And that's the way that, you know, we do it. So, I think that part works pretty well."* – Committee member

A shift in project origination and POC control in Step 3 (Project Approval) describes how policy ideas previously bubbled up from permanent committees to the POC for initial approval, whereas around 2020–2021, the process reversed, with the POC now identifying roughly 80% of new projects and then assigning them to committees for development.

14.5.2 Desk Review Assessment

Failures identified with Prioritization begin with the significant decision-making power held by a small group in Step 1 (Idea). Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritizations. There is no formal process for revisiting unprioritized policy proposals in Step 1 either, as the POC should periodically re-evaluate previously submitted ideas, prioritize them, and communicate any updates to the original submitters, yet there is no evidence that this happens. The absence of a defined schedule or clear feedback loop leaves the fate of unselected proposals in a "black box," making it unclear if they are ever reviewed again. Adding to these concerns, the expedited variance process lacks transparency in Step 1. There is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked.

A lack of ideas from diverse sources in Step 1 further complicates matters. Ideally, there should be a variability of people involved in proposing ideas. However, this can be difficult for people who do not

have a formal medical education. Since providers dominate in representation on the BOD, committees, and participation in conferences, they will submit more ideas than patients or donors. Some OPTN members have asked for more perspectives from people who are not typically involved or who represent overlooked problems. POC meeting notes show that proposals—especially in the early "idea" phase—need more diverse viewpoints and "recommended more patient feedback and involvement." Meanwhile, committees such as the Membership and Professional Standards Committee focus on transplant success metrics and do not measure how well they engage the public or share information openly. The OPTN has no set process or metric to ensure that donors, families, or other underrepresented groups have a voice early on. Without official guidelines or measures of engagement, it is hard to know if the process is truly transparent or successfully inviting all relevant perspectives. Providers—such as doctors, investigators, and transplant professionals—have a strong presence in the OPTN's policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories. Since providers dominate in representation on the BOD, committees, and conference participation, they submit more ideas than patients or donors. However, this can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. In addition, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the OPTN. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Provider-heavy committees can influence which projects the POC approves, given their technical expertise and alignment with OPTN's clinical goals.

Lastly, there is an unclear evaluation of needs and gap identification in Step 1. There does not appear to be a mechanism in place for ongoing evaluation of needs and gap identification that leads OPTN to investigate ways to fix issues.

Complexities in SRTR data requests and resource allocation in Step 2 (Problem Analysis) and throughout the 10-Step process arise because committee members cannot make data requests to SRTR directly; HHS/DoT holds the SRTR contract and approves data requests as they come through. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues. This ties into no clear process for determining required resources in Step 2, as it remains unclear how committees decide what resources—financial, technical, or expertise—are needed for developing and implementing a proposal. **UNOS often guide methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise.** This creates a risk that committees receive solutions shaped more by UNOS' understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed. Balancing clinical focus with patient/family perspectives in Step 2 is also

challenging. Providers often approach problems from a medical or operational standpoint, which can lead to the unintentional neglect of patient and family perspectives. To develop effective solutions, it is essential to include diverse viewpoints and gather feedback from all relevant stakeholders when examining issues and formulating solutions. The data used to develop project proposals may vary in consistency across transplant centers or OPOs, and geographic disparities in reporting quality, as well as differences in how data is collected and reported, can lead to gaps in the comprehensive data necessary to support proposals.

A shift in project origination and POC control in Step 3 (Project Approval) describes how policy ideas previously bubbled up from permanent committees to the POC for initial approval, whereas around 2020–2021, the process reversed, with the POC now identifying roughly 80% of new projects and then assigning them to committees for development. The POC meets monthly to review project status and ultimately allows the final approval before proposals advance to the BOD for a final decision, indicating a significant increase in POC oversight and control. Because the POC spans multiple committees, its discussions are broader than the committee-specific focuses—for example, an OPO committee discussion is largely confined to operational issues, whereas the POC reviews cross-cutting topics monthly and allows final approval before proposals move on to the BOD. Unclear Cost Evaluation and Resource audits in Step 3 persist, as there is no clear criterion within the POC's review process for determining acceptable costs or the appropriate level of resource allocation. Additionally, no audits or reconciliations appear to be in place to confirm whether initial cost or resource estimates accurately reflect real expenditures, leaving significant uncertainty about fiscal oversight and accountability. A project's budget is jointly estimated by the working committee and the POC, with committee liaisons providing guidance on available IT hours and total allocated funds. Even if a committee has budget left, UNOS IT resources might already be at capacity, meaning projects requiring significant development or reprogramming may be deferred. This illustrates how both financial and bandwidth factors influence which projects can move forward.

No defined authority for assigning strategic goals in Step 3 creates further ambiguity, as it remains unclear who officially assigns a primary strategic goal to each project. Neither the POC, BOD, nor the EC appears to have a documented process or explicit authority for determining this key designation. Moreover, no documented criteria for evaluating proposed projects in Step 3 exists; there are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there guidelines for evaluating outcomes, risks, technical resource needs, costs, or overall benefits. Without such standards, it's unclear how proposals are judged before moving forward. No clear criteria or early visibility for key review factors in Step 3 adds to the problem. While projects are expected to consider alignment with the OPTN Strategic Plan, NOTA and the OPTN Final Rule, resource requirements, and potential risks, there is no transparent process for documenting or assessing these factors. Cost estimates, for instance, are reportedly stored in an internal management system and may not be visible to HRSA until later in the policy development process, after UNOS and the sponsoring committee have conducted analysis. This lack of early insight limits the ability to measure intended effects, identify key metrics, and evaluate trade-offs in a timely manner. Historically, there was possibly a scoring document

or framework applied to policies for consistent assessment, but it is unclear whether the same tool remains in use or if the POC currently employs a different method.

Moving to evidence gathering, defining "enough" evidence in Step 4 (Evidence Gathering) is problematic, as documents do not specify how much stakeholder input or investigation is required before moving on to the next step. No standardized threshold for completing analysis in Step 4 compounds this issue, given that committees decide analysis is "adequate" once all their questions are addressed and any feedback is sufficiently documented. There is no clear, standardized criterion for determining when this point is reached, so the ultimate decision to move forward hinges on whether the committee deems its write-up thorough. Meanwhile, the NOTA/Final Rule Checklist used "behind the scenes" in Step 4 indicates that proposals move forward if no concerns are raised about compliance with its requirements, yet this checklist does not define the steps for that analysis. UNOS process documents mention using a spreadsheet to document situations where authority or applicability of requirements may be unclear or subject to differing interpretations, but the process documents fail to indicate when and by whom this spreadsheet is implemented.

Quality standards in Step 5 (Public Comment Approval) remain insufficient, as no official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Later in the policy cycle, public comment summaries but no strict threshold for action in Step 6 (Public Comment) become relevant because UNOS/OPTN compiles a response document summarizing public feedback, yet it remains unclear whether the BOD or POC routinely reviews this final report or if a formal metric mandates changes when concerns are strong. Proposals can still advance despite substantial opposition. The fiscal impact workgroup in Step 6 is another area of uncertainty, as it remains unclear who is assigned to this workgroup, whether the same individuals participate across multiple projects, and how the selection process is decided. Fiscal assessments appear to rely heavily on staff consultation with the finance department, CFO, IT, or communications, rather than on a structured or standing "fiscal workgroup." Although the Finance Committee presumably evaluates a proposal's cost impacts, the workgroup's membership, selection criteria, and specific financial metrics used remain unknown.

Shifting to public comment outcomes, clinical perspectives versus patient voices in Step 7 (Pending BOD Approval) highlight an imbalance where medical professionals may exert greater influence than donors, families, or advocacy groups, potentially prioritizing clinical viewpoints over firsthand experiences. Potential bias in donor, family, advocacy, and small organization representation emerges, while unknown metrics to measure public concern and critical comments in Step 7 result from having no formal or consistent methodology to quantify the impact of public feedback on final policy decisions. The UNOS team's analysis of data from public comments is not made publicly available. Adding to this, there is no formal process for incorporating public comment concerns pre-BOD approval in Step 7, leaving it unclear how, or if, feedback is systematically addressed before proposals reach the BOD, and influence of larger organizations in Step 7 continues to pose a risk to balanced input. Committee-based review lacks formal evaluation criteria in Step 7 means decisions hinge largely on stakeholder support or opposition, without a measurable set of criteria, and there is a lack of transparency in logging and reviewing all comments in Step 7 because no clear mechanism guarantees every public comment is

entered into a centralized system or reviewed. The unclear comment review and tracking process in Step 7 allows potentially violative comments to go unaddressed, and HRSA's role remains undefined.

Unspecified "Approved" or "Rejected" proposed policy metrics in Step 8 (BOD Approval) then follow, as the exact metrics for final decisions are unclear, and the implementation gap in Step 8 shows that review and approval lags can affect the timely adoption of critical policy changes. Limited resources in Step 9 (Implementation) and Step 10 (Post-Implementation Review) come into play because some OPTN transplant centers, especially smaller ones or those in community settings, may lack the resources (funding, staff, time) to comply with new policies, creating unequal implementation across the system. Resource constraints for smaller transplant organizations in Step 10 expand on this disparity, with challenges in both the review process and policy implementation due to limited capacity. Finally, insufficient long-term data in Step 10 highlights that some policies require more time to assess their true impact, yet post-implementation reviews may not always capture the full range of effects. The UNet system is closed, making it hard to understand how analyses are conducted, and qualitative data is often overlooked in favor of quantitative data.

14.5.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to prioritization methodology within the policy development cycle.

Table 46: Current State Assessment Theme 5: Prioritization Methodology

Prioritization Methodology Sub-Theme	Evidence	Source
Standardization of Allocation Policies	There is currently no OPTN policy instructing OPOs on multi-organ donor allocation. OPOs have differing allocation practices and laborious efforts to create allocation plans. The Multi-Organ Transplantation (MOT) Committee proposed a new policy to standardize the allocation order and balance the needs of single and multi-organ candidates. The proposal includes multi-allocation tables to standardize the order in which OPOs allocate organs across match runs, ensuring a more equitable and efficient allocation process.	Regional Meeting Notes
Standardization of Allocation Policies	Attendees in almost all of the regions agreed on the multi-organ allocations for liver/kidney and heart/kidney be prioritized based on the highest risk of death on the waiting list to ensure that the most critical patients receive timely transplants.	Regional Meeting Notes
Standardization of Allocation Policies	Region 1 and 8 attendees noted that the multi-organ allocation policies for liver/kidney and heart/kidney are cumbersome, and the requirement for chest X-rays for lung donors from deceased donor patients is not	Regional Meeting Notes

Prioritization Methodology Sub-Theme	Evidence	Source
	feasible for smaller donor hospitals. They also pointed out the need for clear and transparent prioritization frameworks to ensure fair and efficient organ allocation processes.	
Standardization of Allocation Policies	Region 2 attendee suggested adopting a flexible policy for the development of policies by all committees. The flexible policy will replace the "Policy Development Wheel" which has been unnecessarily time-consuming.	Regional Meeting Notes
Fairness in Allocation	Region 2, 4, 5, and 10 attendees expressed concerns about fairness of organ allocation, particularly for pediatric and highly sensitized candidates who face challenges in receiving high-quality kidneys. They usually receive the lowest offers and should be prioritized higher in the allocation tables.	Regional Meeting Notes
Fairness in Allocation	Region 6 attendees raised concerns on prioritization between pediatric kidney candidates and kidney-pancreas recipients, and the need for additional guidance to address operational challenges.	Regional Meeting Notes
Fairness in Allocation	Region 6 and 9 attendees raised concerns on the complexity and impact of the multi-organ allocation policies on different regions. They emphasized the importance of considering post-transplant survival and patient survival on the waiting list.	Regional Meeting Notes
Fairness in Allocation	During a MAC meeting on 11/18/2024, members highlighted the importance of assessing every kidney transplant candidate for eligibility regardless of waiting time criteria or waiting list status, including those registered for multi-organ transplant, to ensure fair and consistent prioritization.	Minority Affairs Committee Meeting Notes
Fairness in Allocation	During a MAC meeting on 10/16/2024, members highlighted the need to assess multi-organ transplant candidates for eGFR waiting time modifications, emphasizing the importance of fair and consistent prioritization for all candidates.	Minority Affairs Committee Meeting Notes
Operational Challenges and Efficiency	Region 1, 3, and 8 attendees suggested allocating organs closer to donor hospitals to reduce cold ischemic time and to assist transplant outcomes and efficiency.	Regional Meeting Notes
Operational Challenges and Efficiency	Region 9 attendee mentioned the difficulty in implementing policies operationally, especially for smaller programs that may struggle with regulatory burdens compared to larger centers with more resources.	Regional Meeting Notes

Prioritization Methodology Sub-Theme	Evidence	Source
Operational Challenges and Efficiency	The Modify Lung Donor Data Collection Project of the Lung Committee was prioritized because the OPTN BOD recently approved a policy to promote efficiency in lung donor allocation, and the committee saw an opportunity to enhance this goal with data collection.	Regional Meeting Notes
Operational Challenges and Efficiency	During a LDC meeting on 03/12/2025, members expressed concerns about the variation in evaluation processes among programs, suggesting that a standardized approach could help prioritize and address barriers more effectively.	Living Donor Committee Meeting Notes
Operational Challenges and Efficiency	During the LDC meeting on 02/26/2025, members discussed the balance of considerations for the start point of data collection, emphasizing the need to prioritize the most effective and least burdensome approach for transplant programs.	Living Donor Committee Meeting Notes
Operational Challenges and Efficiency	During an Operations and Safety Committee meeting on 02/20/2025, members emphasized the need for clear prioritization of tasks and responsibilities within the NRP guidance document, particularly in terms of pre-operative and intra-operative communication standards.	Operations and Safety Committee Meeting Notes
Community Involvement and Feedback	Region 3 and 4 attendees highlighted the importance of assessing whether policies achieve their intended goals and involving the community in discussing policy outcomes and in identifying groups who might have been impacted as bystanders.	Regional Meeting Notes
Community Involvement and Feedback	Region 3 and 4 attendees raised concerns about the allocation of resources to different policy initiatives, highlighting the need for a balanced approach that addresses both urgent and long-term needs. Attendees also emphasized the importance of clear criteria and processes for how policies are prioritized, ensuring that stakeholders understand the decision-making process.	Regional Meeting Notes
Community Involvement and Feedback	Region 10 Presenter highlighted the MPSC's efforts to prioritize and address issues early and ensure the best interest of the transplant community and the committee's goal to help rather than be punitive.	Regional Meeting Notes
Community Involvement and Feedback	During the PAC meetings in early 2025, members discussed the complexity of multi-organ allocation and the need for clear prioritization methodologies to ensure fair and equitable access to transplants.	PAC Meeting Notes

Prioritization Methodology Sub-Theme	Evidence	Source
Predictive Models and Data Utilization	During a MPSC meeting on 02/06/2025, members discussed the need for a reliable predictive model to account for the lag in data, emphasizing that the current model has a broad confidence interval and may not be suitable for evaluating individual OPO performance.	Membership & Professional Standards Committee Meeting Notes

15 Appendix D: Stakeholder Segment Findings

Appendix D presents stakeholder-specific findings from the OPTN mapping effort. It outlines key challenges for each group; Patients, Families, and Caregivers; Community; Governance; including regulatory, OPTN, and review; Providers, and Industry; and demonstrates how differences in representation, engagement, data access, timeliness, and policy prioritization affect each segment:

- Patients, Families, and Caregivers call for more inclusive BOD/committee structures, plain-language explanations of policies, and quicker updates to alleviate long wait times and disparities.
- Community organizations (such as advocacy groups) want regular policy updates and more transparent data to effectively champion patient needs.
- Governance stakeholders require understanding and ongoing engagement with the updated OPTN oversight system to build trust and coordinate efforts.
- Providers seek robust data, diverse representation (including rural and underrepresented clinicians), and a streamlined policy process that considers real-world clinical and logistical constraints.
- Industry stakeholders (e.g., technology, insurance, supply chain) highlight insufficient representation in committee discussions, needing better data flows, and a more comprehensive approach to the operational, financial, and technical aspects of organ procurement and transplantation policy implementation.

By detailing each group's perspective, Appendix D underscores the complexity of balancing multiple priorities—such as equitable access, efficient processes, reliable data, and collaboration across the OPTN.

15.1 Patients, Families & Caregivers

Need additional support and training to engage OPTN.

- **Issues Related to BOD and Committee Composition:**
  - Lack of minority representation, including racial and ethnic minorities.
  - Failure to create an inclusive environment on the BOD and committees inhibiting patient and family voices.

- Insufficient training on ways to engage in the policy-making process.
- Proposals are often too technical for patients/families.
- Many of the policies and committee meetings are tailored toward medical professionals with highly technical language.
- The size of the BOD is too large to be effective.

- **Issues Related to Engagement and Transparency:**
  - Lack of transparency/awareness about the OPTN policy-development process
  - Insufficient communication informing patients, families, caregivers how to participate.
  - The policy development process can be communicated in a manner that is too technical for laypeople.
  - Limited opportunities for patient and family engagement in each phase of the process.
  - Failure to communicate outcomes of previously solicited feedback to patients, families, and caregivers.

- **Issues Related to Data Availability:**
  - Patients, families, and caregivers do not always have direct access to the full range of data necessary to make fully informed decisions.
  - Available data is too technical to be understandable.
  - Key information, like organ allocation patterns, waiting list statistics, or disparities in access to organ procurement and transplantation, may not always be presented in a way that is immediately actionable for patients, families, and caregivers.
  - Even if data is made available to patients, families, and caregivers, interpreting it in the context of organ procurement and transplantation policy and understanding its real-world implications can be challenging.
  - Data dashboards do not accurately reflect the OPTN eco-system.

- **Issues Related to Timeliness:**
  - The policy-making process is too long and rigid. It needs to be more agile so it can respond to immediate needs and evolving medical information.
  - Patients often face long waiting times on transplant lists or encounter unfairness in the allocation system but changes to transform these aspects can take years to be implemented.
  - The OPTN Final Rule hinders making enhancements quickly.
  - Patients' lives depend on making enhancements. They do not have time to wait years for enhancements.

- **Issues Related to Prioritization:**

- Significant gaps in patient-related policies include policies ensuring equitable access, reducing wait times, providing clearer communication, and offering financial and emotional support.
- Policies that disadvantage people of color should be assessed and updated ASAP. Any policy or practice that disadvantages any group should be fast-tracked for review as a matter of principle and fairness.

15.2 Community

Need consistent and timely updates about OPTN policy to effectively advocate and support patients, families, and caregivers.

- **Issues Related to BOD and Committee Composition:**
  - The BOD is too large to be effective
  - Community/advocacy groups work to ensure that policies reflect the experiences of patients from various socioeconomic backgrounds, ethnicities, genders, ages, and geographic locations, as well as those with different medical conditions.

- **Issues Related to Engagement and Transparency:**
  - Need to be informed about new policies so they can advocate for patients, families, and caregivers.
  - Lack of transparency/awareness about the OPTN policy-development process.

- **Issues Related to Data Availability:**
  - Transparent data is essential to allowing advocacy groups to push for evidence-based policies that reflect real-world patient needs.
  - Making data publicly available is necessary for advocacy groups to evaluate the impact of existing policies, understand organ procurement and transplantation trends, and advocate for changes where necessary.

- **Issues Related to Timeliness:**
  - Delays in policy development or decision-making can limit the ability of advocacy groups to mobilize their communities and advocate for changes before critical decisions are made.
  - Issues like delays in receiving information, slow decision-making in committees, and extended policy development cycles can hinder community organizations' ability to engage in the process and with their members and then respond accordingly.

- **Issues Related to Prioritization:**
  - Community organizations advocate for policies that prioritize better health outcomes, access, and fairness, often highlighting issues like disparities in organ allocation, financial barriers, or gaps in post-transplant care.

- Community organizations provide essential feedback on proposed policies, ensuring they reflect the experiences and concerns of those directly affected by organ procurement and transplantation.
- Organizations advocate for OPTN to address disparities and barriers to ensure that all patients are truly prioritized.

15.3 Governance (Including Regulatory, OPTN, and Review)

Need fully defined system and oversight mechanisms to effectively support the OPTN.

- **Issues related to Transparency:**
  - Lack of coordination and differing requirements between regulatory agencies.
  - Misinformation and lack of trust in the OPTN system.
  - Lack of clarity about roles and oversight.

- **Issues Related to Efficiency/Timeliness:**
  - Loosely written processes that fail to define systems and give HRSA the power to enforce requirements.

- **Issues Related to Data:**
  - Lack of standardized data
  - Methodology

- **Issue related to Impact:**
  - OPTN's purview begins when patients are added to the waitlist. We are missing an opportunity to engage people until too late.

15.4 Provider

Need diverse representation and data for clinical decision-making.

- **Issues Related to BOD and Committee Composition:**
  - The OPTN Final Rule stipulates that the majority of the BOD and committee members must be providers.
  - Providers on the BOD tend to be older and more established in their field.
  - Many providers on the BOD represent hospitals, organizations, or laboratories in urban, affluent areas potentially impacting which policies get approved.
  - Younger providers from more rural areas are underrepresented on the BOD and committees.
  - Need to ensure consistent provider representation on the BOD and committees from OPTN's diverse geographic regions, as well as diverse minority and gender representation.

- **Issues related to Transparency:**

- Providers need accurate information for clinical decision-making even though it can be too technical for patients, families, and caregivers to understand when presented in proposals and meetings.
- Providers emphasized the need for donor and patient-centered language and graphics to help communicate complex information to patients.
- Providers have expressed a desire for the OPTN to be more transparent in defining its goals and aligning its performance metrics. During public comments regarding the updated Strategic Plan, many providers noted that the plan lacked specificity in measuring its success:
    - *"There is some concern that the pillars of the strategic plan did not explicitly mention metrics around safe and effective patient care outcomes which are integral to the work of the OPTN. The Committee [OPTN Transplant Administrators Committee] suggests incorporating metrics related to system costs, such as OPO costs, decline rates, and transportation modes, when considering policies."*
- Insufficient communication to providers in rural areas or from centers with less funding leads to inadequate provider engagement.

- **Issues Related to Data:**
    - Need for better data quality, data definition, and data and metric standardization between stakeholders (OPOs, transplant centers, OPTN, CMS) to accurately define the scope of problems and prevent misalignments and inefficiency among providers like transplant hospitals and OPOs.
    - Need for more data sharing and visibility between OPOs and transplant centers to help providers adjust their performance based on real-time metrics and align transplant centers and OPOs when allocating organs.
    - Need for better data tools across the OPTN eco-system and better integration within the policy development process (e.g., Digital platforms can facilitate a timely and accurate exchange of information among transplant centers and OPOs, reducing the potential for human error).
    - Need for more automated data collection with Electronic Medical Record (EMR) integration across platforms so that policy changes requiring new data collection will not create undue burden or adversely impact center operations.
    - Inaccurate and untimely data undermines practice review and policy development
    - Accurate data are necessary so that policy development simulations will be more representative of expected changes and, therefore, allow for appropriate decision making.
    - Data coordination among agencies is imperative. Metrics should be the same or aligned if they are different.
    - Gaps in data make it difficult to make decisions, especially for more disadvantaged demographics.

- Need for data analysts to assist with understanding data nuances so perceptions during policy development are not skewed (e.g., pediatrics represent a smaller proportion of the donor patient population and can be overlooked).
- Need for continuous data monitoring and alignment with real-world patient populations.
- Need to ensure that organ procurement and transplantation demographics match local population demographics (e.g., African American representation in a region).

- **Issues Related to Efficiency/Timeliness:**
  - Providers recommend implementation of AI, integrated EMRs, and data-sharing to reduce manual burdens.
  - Providers suggest using AI to streamline organ allocation processes and enhance patient matching.
  - Concern about the amount of time it takes to implement a proposed idea given how many stakeholders and committees are involved in the policy approval process.
  - A report by the National Academies of Sciences, Engineering, and Medicine (NASEM) criticized the OPTN for this slow process, noting that the "consensus-drive nature of the OPTN policy development process can create slowness and policy implementation challenges can further delay the process".
  - On the other hand, some providers worry about the tradeoff of expediting policy development at the expense of other priorities like patient safety.

- **Issues Related to Prioritization:**
  - OPTN regions can vary significantly along economics and race and some policies may be difficult to implement for providers, especially in rural areas that do not have sufficient resources. One OPTN member was quoted in a report stating:
    - *"Every program is in a different place in the United States with a different ethnic makeup of its patients, different races, and gender distribution. It would seem reasonable to have one of our outcomes be "are you transplanting the patients you are representing?" In other words, do the demographics of your transplant population reflect the demographics of those in need in your location. If your kidney population is 50% African American, is your transplant population 50% African American?".*
  - Providers question whether their clinical or operational concerns are meaningfully addressed before final BOD consideration. Though providers are engaged throughout the policy development process, it does not always serve the needs of everyone in this segment.
  - Policies should recognize the regional differences between hospitals, transplant centers, OPOs, and labs when considering idea proposals.
  - The impact of policy changes on organ procurement and transplant centers, including costs of implementation, should be considered as part of proposed policies.
  - Logistics of policy proposals need to be considered.

15.5 Industry

Need representation and ability to provide input regarding logistical requirements for policy proposals.

- **Issues Related to Board and Committee Composition:**
  - A lack of industry representation on committees and during the policy development process means practical issues they could highlight often are overlooked. As a result, policies may lack "teeth" when it comes to handling real-world logistics.
  - Failure to conduct targeted communication to industry members or their involvement as committee members.
  - Industry members are missing as members of committees.

- **Issues Related to Transparency:**
  - Lack of process to notify or involve industry members (like private insurers or health data companies) in policy proposals. Businesses and organizations may not even realize a new policy that could affect them is being considered. Consequently, they risk being left out of important discussions and decisions that could significantly impact their operations

- **Issues Related to Data:**
  - Need to enable the OPTN to collect potential donor data directly from hospitals to drive more enhancement in OPOs and diversify the pool of registered and prospective organ donors. Industry could play a major role in transforming data flows if the OPTN adopted modern technology (open-sourced, cloud-based technology) from government-approved providers with advanced, user-friendly systems.
  - Need for a central data warehouse under an OPTN entity to standardize metrics.

- **Issues Related to Prioritization:**
  - Lack of Industry representation in idea generation.
  - Failure to obtain Industry input when considering resources and steps needed to make policies work in practice.
  - Failure to obtain industry input when considering the cost and operational impact of policy ideas on organ procurement and transplant centers to ensure they can be implemented.
  - Language within the OPTN Strategic Plan 2024-2027 is too vague (data metric goals are not specific or measurable) so it will be difficult to determine success.
  - Need to conduct impact evaluations to ensure rural or resource-poor centers are not left behind.

- **Issues Related to Efficiency/Timeliness:**

- Without a thorough evaluation of the resources and steps needed to make policies work in practice policies can lack "teeth" to make them work.
- Need to factor in cost and operational impact of policy ideas on transplant centers to ensure they can be sustainably implemented.
- There is insufficient attention to logistical challenges.
- Need to speed up or optimize certain processes through cross-collaboration among OPTN, CMS, and hospitals.
- Need to allow third-party innovators to create effective software that meets the needs
- of OPOs.
- Need to increase oversight from HRSA across the full organ procurement and transplantation process.

16 Appendix E: Stakeholder Interview Participants

External: Patients, Families, and Caregivers/Community

- ORGANIZE
- Transplant Families
- American Association of Kidney Patients
- National Multicultural Action Group

External: Providers

- Donor Network of Arizona
- Children's Mercy Hospital
- American Society of Transplantation
- Association of OPOs

Internal: Governance

- OPTN
  - Policy Oversight Committee
  - Patient Affairs Committee
  - Minority Affairs Committee
  - Data Advisory Committee
  - Operations and Safety Committee
  - Regulatory
  - HRSA Subject Matter Experts

17 Appendix F: Pain Points

The table below highlights Pain Points identified through the Current State Analysis and Assessment.

Table 47: Pain Points by Theme

Theme	Pain Point	Definition
Committee/BOD Composition & Size	**COI**	Committees face less conflict than the BOD but still struggle with COI.
Committee/BOD Composition & Size	**Patient Involvement**	Patient awareness and involvement are often drowned out by louder voices.
Committee/BOD Composition & Size	**Size and Variety**	Committees lack variety and often have the wrong people in the wrong roles, requiring training and facilitation.
Committee/BOD Composition & Size	**Transparency in Selection**	There is a lack of transparency in the selection process.
Committee/BOD Composition & Size	**Functional Misalignment**	Committees should be based on function rather than organ-specific roles.
Committee/BOD Composition & Size	**Performance Variability**	Different committees have varying performance levels, with some never producing policy.
Engagement and Transparency	**Accountability and Process Clarity**	There is a lack of clarity regarding who is responsible or accountable for various stages of the process.
Engagement and Transparency	**Diverse Idea Sources**	The process suffers from a lack of diverse idea sources, with smaller organizations struggling to advance their policies.
Engagement and Transparency	**Patient Involvement**	There is a notable lack of patient involvement, and even when included, patients often lack the training to participate effectively.
Engagement and Transparency	**Transparency in Idea Movement**	There is no system to provide transparency into how ideas move through the process or to engage the submitter.
Engagement and Transparency	**Public Engagement**	There is skepticism about whether public engagement is genuinely considered in policy proposals.
Engagement and Transparency	**Role Misalignment and Training**	There is misalignment and lack of clarity in role definitions between HHS/DoT, OPTN, UNOS, and committees.
Engagement and Transparency	**Long-Term Data Visibility**	The process lacks the ability to see long-term data, contributing to disheartenment among participants.
Engagement and Transparency	**Transparency and Engagement**	The current system fails to meet transparency and engagement criteria, leading to a lack of trust and participation.
Timeliness	**Prolonged Timelines**	The process is excessively long and stagnant, with no specific guidelines on how long each stage should take.
Timeliness	**Process and Role Definition**	The absence of clear process and role definitions at all stages results in extended timelines.

Theme	Pain Point	Definition
Timeliness	**Data Acquisition Delays**	Obtaining necessary data takes an inordinate amount of time, and the public comment period is also prolonged.
Timeliness	**External Factors**	Changes at HHS and negative news stories contribute to the slow pace of policy changes.
Timeliness	**Committee Turnover**	The average timeline for policy approval is so lengthy that committee members often leave before their ideas are approved.
Data Availability	**Standardization Issues**	Data is not reported in a standard way, and there are no defined measures throughout the process.
Data Availability	**Misaligned Metrics**	The focus is often on measuring downstream outcomes rather than addressing root problems.
Data Availability	**Data Access Barriers**	Data requests must navigate through UNOS/HHS/DoT, leading to committees being unaware of available data.
Data Availability	**Divergent Data Requirements**	CMS and OPTN have different data requirements.
Data Availability	**Delayed Data Delivery**	Obtaining data from SRTR is a prolonged process.
Data Availability	**Public Data Sets**	While some stakeholders acknowledge the availability of good data in publicly accessible sets, this view is not universally shared.
Data Availability	**Inadequate Dashboards**	Existing dashboards fail to provide the necessary data for adequate oversight.
Data Availability	**Oversight Challenges**	The poor quality of data and lack of comprehensive oversight mechanisms prevent a clear understanding of policy impacts on patient outcomes.
Prioritization Methodology	**Inefficient Prioritization**	Policies are prioritized inefficiently due to a lack of strategic direction, resulting in unclear system and committee goals.
Prioritization Methodology	**External Distractions**	Changes at HHS/DoT and news stories often divert attention, leading to a phenomenon described as "chasing squirrels."
Prioritization Methodology	**COI**	COI leads to poor prioritization, with "unpopular" proposals being squashed and those that benefit certain individuals being advanced.
Prioritization Methodology	**Role Definition**	There is a lack of clear role definition regarding accountability for ensuring policies measure patient outcomes and align with strategic priorities.
Prioritization Methodology	**Poorly Set Metrics**	Metrics are poorly set, driving functionality based on project progression rather than patient impact.

Theme	Pain Point	Definition
Prioritization Methodology	**Transparency Issues**	The process lacks transparency, making it feel like ideas go into a "black box," which hinders sustained support.
Prioritization Methodology	**Data Quality**	There is a lack of good data from regions, which hampers policy development and issue identification.

18 Appendix G: Recommendations

Appendix G presents process metric theme-specific recommendations from the OPTN mapping effort. Process metrics were validated with HRSA and used to measure the efficiency and performance of the policy development process. A service blueprint identified key metrics to evaluate OPTN's current policy development processes, highlighting strengths and challenges.

18.1.1 Theme 1: Committee & BOD Composition

OPTN BOD and Committee composition gaps and challenges are related to lack of clarity of existing regulations, guidance, roles, and responsibilities and inadequate public engagement and transparency. Recommendations are based on challenges across stakeholders and sources:

1. Develop clear regulations regarding the nomination and selection processes and required representation from stakeholder groups.
2. Ensure HHS/DoT's role in the nomination and selection process is clearly defined and communicated.
3. Improve public engagement to increase awareness of opportunities to participate in the nomination and committee processes.
4. Increase transparency including information about schedules/timing of nomination, selection, and performance review processes, past and present nominees, and committee members.
5. Define roles, responsibilities, and implementation methods across committees and the policy process.
6. Review the current committees and organizational structures to define committee function and accountability, size, and representation (e.g., geographic, stakeholder group, etc.), and required facilitation support within the modernized OPTN.

The table below highlights subthemes within Theme 1 and where each subtheme was identified. The text in this table has been condensed. Please refer to Mapping Report for full text.

Table 48: Current State Assessment Committee/BOD Comp & Size Subtheme/Stakeholder Group

Committee/BOD Composition & Size Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meetings

BOD Composition: BOD lacks variety in stakeholder representation, hindering balanced policy decisions.	**X**	**X**		**X**
BOD Size: BOD size affects efficiency and variety.	**X**	**X**	**X**	**X**
Committee Composition: Committees lack diverse and adequate representation, hindering comprehensive policy making.	**X**	**X**	**X**	**X**
COI: Conflicts undermine policy development.	**X**	**X**		
Training and Role Definition Training gaps and unclear roles hinder effective policy making.	**X**	**X**		
Transparent Nomination Process: Opaque nomination process undermines trust.	**X**	**X**		

18.1.2 Theme 2: Engagement & Transparency

Engagement and transparency gaps and challenges relate to the lack of documented criteria for evaluating projects, insufficient stakeholder engagement (especially from patients and underrepresented groups), and transparency concerns throughout the policy development process.

Recommendations are based on challenges across stakeholders and sources:

1. Document criteria and metrics for evaluating and expediting proposed policy projects including adequacy of evidence, assessment of risks, resources needed, costs, benefits, and outcomes.
2. Define requirements for stakeholder engagement in policy process, (e.g., what stages stakeholder engagement is critical and the process for ensuring input from varied stakeholders including patients, donors, etc.).
3. Identify responsible individual(s) or develop an accountability matrix to ensure policy proposals are managed through the process from idea generation through outcome monitoring.
4. Centralize, track, and repurpose an existing dashboard with status of policy proposals through the entire process.

The table below highlights subthemes within Theme 2, providing a cross-sectional view of where each concern was raised and discussed. The text in this table has been condensed. Please refer to Mapping Report for full text.

Table 49: Current State Assessment Engagement & Transparency Subtheme/Stakeholder Group

Engagement & Transparency Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meetings

Regular Engagement and Updates: Lack of regular engagement hinders involvement and trust.	X	X		X
Communication Channels and Feedback: Poor communication channels hinder feedback.	X	X		X
Transparency in Decision-Making: Unclear public comment integration undermines trust.	X		X	X
Community Involvement and Representation: Insufficient patient voices hinder trust.	X	X		X
Best Practices and Information Sharing: Lack of info sharing hampers transparency.	X	X	X	X
Role Alignment and Training: Misaligned roles and poor training hinder policy making.	X	X		
Accountability Systems: Poor accountability systems undermine trust.	X	X		
Defined Evaluation Criteria: Undefined criteria cause inconsistencies.	X			
Expedited Action Criteria: Unclear action criteria delay responses.	X			
Expedited Variance Process: Opaque variance process undermines trust.	X			
Resource and Implementation Concerns: Resource limits hinder policy implementation.	X			

18.1.3 Theme 3: Timeliness

Timeliness gaps and challenges relate to the need for a more streamlined, transparent, and efficient policy development process.

Recommendations are based on challenges across stakeholders and sources:

1. Ensure timely decision-making and reduce delays by identifying (an) individual(s) or develop an accountability matrix to ensure policy proposals are managed through the entire process.
2. Document criteria and metrics for evaluating and expediting proposed policy projects such as adequacy of evidence, assessment of risks, resources needed, costs, benefits, and outcomes.
3. Standardize proposal submission process, timeline, and requirements for advancing to the next review stage.
4. Develop/document expedited processes for high-priority or time-sensitive policy changes.
5. Provide clear guidance and timeframes for problem analysis and evidence gathering stages including what is required and who is responsible.

The table below highlights subthemes within Theme 3. The text in this table has been condensed. Please refer to Mapping Report for full text.

Table 50: Current State Assessment Timeliness Subtheme/Stakeholder Group

Timeliness Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meetings
Delays in Communication and Implementation: Slow policy implementation causes inefficiencies.	X	X	X	X
Long Wait Times and Complication Rates: Delayed updates increase wait times and may cause complications.	X	X		X
Community Input and Delays: Lack of timely feedback delays policy changes.	X	X		X
Efficiency in Policy Development: Efforts to balance thoroughness and efficiency contribute to implementation delays.	X	X		

18.1.4 Theme 4: Data Availability

Data availability gaps and challenges relate to the lack of data standardization, accountability for data collection, guidance on acceptable data at each stage of the process, and data transparency around public comments.

Recommendations are based on challenges across stakeholders and sources:

1. Clearly define roles for data collection and analysis at each policy development process stage to prevent delays.
2. To support evidence-based decision-making;
    a. Support implementation of consistent data standards across the OPTN ecosystem (e.g., transplant centers and OPOs).
    b. Develop guidance and metrics for long-term data collection on complications, survival, quality of life, and post-transplant healthcare utilization.
3. Develop guidance on acceptable public comment engagement and analyses, including addressing and communicating about concerns raised during public comment periods.

The table below highlights subthemes within Theme 4. The text in this table has been condensed. Please refer to Mapping Report for full text.

Table 51: Current State Assessment Data Availability Subtheme/Stakeholder Group

Data Availability Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Challenges in Data Reporting: Data reporting issues hinder data collection.	X	X	X	X
Complexity of Data Collection: Complex data collection requirements reduce accuracy.	X	X	X	X

Collaboration and Support: Lack of collaboration amongst agencies hampers data collection.	X			X
Proposals for Data Collection enhancements: Inadequate data collection processes hinder policy decisions.	X		X	X
Fiscal Assessment: Unclear measures for fiscal assessment causes inefficiencies.	X			
Public Feedback Metrics: Lack of feedback metrics affects policy decisions.	X			
Resource Limitations: Resource limits faced by smaller transplant centers and community-based organizations challenge policy compliance.	X			
Monitoring and Review: Lack of a clearly defined monitoring process hampers policy review.	X			

18.1.5 Theme 5: Prioritization Methodology

Prioritization methodology gaps and challenges relate to lack of patient and community input into policy prioritization, clear policy assessment criteria that leads to alignment with strategic priorities, resource allocation, and evidence gathering, and long-term data to evaluate the effect of policy changes on patient outcomes.

Recommendations are based on challenges across stakeholders and sources:

1. Ensure policy priority decision-making includes patients and community.
2. Ensure policy proposals generation includes patients and the community.
3. Develop and implement standardized policy proposal assessment, resource allocation, and evidence gathering criteria.
4. Use future long-term data on patient outcomes to inform prioritization methods.

The table below highlights subthemes within Theme 5. The text in this table has been condensed. Please refer to Mapping Report for full text.

Table 52: Current State Assessment Prioritization Methodology Subtheme/Stakeholder Group

Prioritization Methodology Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meetings
Standardization of Allocation Policies: Lack of standardized policies leads to inequitable organ distribution.	X			X
Fairness in Allocation: System fails to prioritize pediatric and sensitized candidates.	X		X	X
Operational Challenges and Efficiency: Operational issues burden smaller programs.	X		X	X

Community Involvement and Feedback: Non-representative community involvement affects policy decisions.	X	X	X	X
Predictive Models and Data Utilization: Unreliable models hamper organ allocation evaluation.	X		X	
Strategic Oversight and Direction: Lack of clear goals and oversight leads to ineffective decisions.	X	X		

19 Appendix H: Goals

Developing a transformational strategy to re-engineer the OPTN's policy development process and governance structure required identifying specific goals and actions. A design process using the SMART criteria (Specific, Measurable, Achievable, Relevant, Time-Bound) was employed to create goals that accurately reflect the OPTN's current policy development system while incorporating stakeholder experiences.

The following SMART goals were established to measure progress and align with the revised vision for the policy framework, governance model and stakeholder expectations.

Refer to Appendix F: Pain Points for details. Note: Some percentage values are intentionally left blank.

19.1.1 Theme 1: BOD/Committee Composition & Size Goals and Recommendations

Table 53: BOD/Committee Composition & Size Expanded Goals, Recs, & Pain Points

BOD/Committee SMART Goal	Recommendations & Pain Points
SMART Goal #1: 100% of committees meet minimum representation criteria	**Recommendation:** Foster greater representation on committees and the OPTN committee structure **Details**: Improve the variety and range of the committees by including more with recipient patients, registered and prospective organ donors, donor patients, families, and stakeholders specializing in data analytics, logistics, IT, and database management. The OPTN will establish committee composition recommendations to include more patient voices, increase gender and racial variety. The OPTN will establish committees or involve subject matter expertise in the committee structure, such as IT and logistics management experts. **Pain Points Addressed:** • **Patient Involvement** • **Size and Variety**

BOD/Committee SMART Goal	Recommendations & Pain Points
SMART Goal #2: 100% of BOD members meet minimum representation criteria	**Recommendation:** Reduce the number of members and diversify the composition of the BOD and various committees **Details:** Improve the timeliness of policy development and include stakeholders in the process who represent the variety of the network. Adopt committees focused on certain demographics or initiatives (e.g., include nurses and other medical professionals who can manage transplant care for patients). Training and learning opportunities are cornerstone; also reduce redundancies. **Pain Points Addressed:** • **Patient Involvement** • **Size and Variety** • **Performance Variability**
SMART Goal #3: 100% of stakeholders understand how BOD and committee members are nominated and selected	**Recommendation:** Publish nomination and selection criteria online and disseminate widely. **Details:** Publish nomination and selection criteria online and disseminate widely. Maintain nominee and selection documentation. Periodically review to identify engagement gaps and consider targeted engagement. **Pain Points Addressed:** • **Patient Involvement** **Recommendation:** Standardize definitions and reporting requirements **Details:** Establish clear definitions and reporting protocols for consistent communication among procurement and transplant programs. For instance, defining what constitutes an unexpected disease transmission can ensure timely reporting, enhancing patient safety and system accountability. **Pain Points Addressed:** • **Accountability & Process Clarity** • **Diverse Idea Sources**
SMART Goal #4:100% of members complete member training within 60 days of onboarding	**Recommendation:** Implement an orientation program for new OPTN members

BOD/Committee SMART Goal	Recommendations & Pain Points
	Details: Develop a comprehensive orientation program for new members to familiarize them with the OPTN, its policy development process, and associated roles. This facilitates greater participation for each member working on the BOD and/or committees and increases the representation of the network. **Pain Points Addressed:** • **Role Misalignment & Training** **Recommendation:** Ongoing training development for committee members **Details:** Training and other professional development opportunities are ways to improve committee members' understanding of the clinical, regulatory, and ethical implications of the policies they push forward. Adequate training is essential for informing BOD and committee members how to access resources and how to contribute their diverse viewpoints. **Pain Points Addressed:** • **Patient Involvement** • **Accountability & Process Clarity** **Recommendation:** Include training or learning program for non-medical professionals who are participating on the BOD or a committee **Details:** Include training or learning programs tailored to non-medical professionals participating on the BOD or committees. This could involve an Education and Engagement Committee that tailors medical terminology for patients and implements educational/engagement programs for procurement and transplant professionals, especially young people newly entering the field. **Pain Points Addressed:** • **Accountability & Process Clarity** • **Size and Variety** • **Performance Variability**
SMART Goal #5: Reduce number of committees by 57% from 26 to 10	**Recommendation:** Reduce the number of current committees by identifying areas of overlapping expertise to gain efficiencies

BOD/Committee SMART Goal	Recommendations & Pain Points
committees under the new PPP Governance Structure	**Details:** By reducing the number of BOD members and consolidating redundant or non-policy producing committees a more expeditious process can be achieved. The lack of variety among the BOD and committees means that many demographics are excluded from policy discussions. **Pain Points Addressed:** • **Size and Variety** • **Performance Variability** **Recommendation:** Employ a facilitator to expedite the policy process, mitigate COIs, and improve engagement and transparency **Details:** A facilitator would expedite the policy process, mitigate COIs, improve engagement and transparency. The facilitator represents a neutral position on the BOD and committees to identify when to move along in discussions and ensure all stakeholders have a voice. **Pain Points Addressed:** • **Performance Variability**

19.1.2 Theme 2: Engagement and Transparency Goals and Recommendations

Table 54: Engagement and Transparency Expanded Goals, Recs, & Pain Points

Engagement & Transparency SMART Goal	Recommendations & Pain Points
SMART Goal #1: 100% of valid policy data requests acknowledged according to SLAs pertaining to specific data request categories	**Recommendation:** Review and repurpose existing OPTN dashboards to make them more patient centric **Details:** Patient-centered dashboards are easy to understand, include few technical terms, and offer actionable information that can help patients make informed choices. They may also include links to educational resources to bridge knowledge gaps for patients and families. **Pain Points Addressed:** • **Transparency & Engagement** • **Patient Involvement**

Engagement & Transparency SMART Goal	Recommendations & Pain Points
	• **Long-Term Data Visibility** **Recommendation:** Data lineage, quality, and workflow management (e.g., Collibra, Informatica, Alation, etc.) **Details:** Track and monitor policy origins, movements, and transformations within the dashboard while addressing data discrepancies, incompleteness, and submission practices. This would provide transparency into the history of the policy and its movement. **Pain Points Addressed:** • **Transparency in Idea Movement**
SMART Goal #2: Increase the number of stakeholders who are engaged with the organ procurement and transplantation policy process, procedures and policy idea submission process	**Recommendation:** Implement a policy platform (e.g., Salesforce) **Details:** A policy platform can be used to modernize the OPTN by automating inbound correspondence routing, tracking and monitoring engagement, and providing a patient and family portal with AI guidance for the procurement and transplant process and OPTN resources. **Pain Points Addressed:** • **Accountability & Process Clarity** • **Transparency in Idea Movement** **Recommendation:** Implement a Clear Process and Role Definition Framework **Details:** Implement a clear process and role definition framework for each stage of the policy development lifecycle. This framework would include detailed process maps that define each step, assigned roles and responsibilities, and accountability measures to ensure that every stakeholder knows their specific duties and deadlines. **Pain Points Addressed:** • **Accountability & Process Clarity** **Recommendation:** Expand public awareness and education programs

Engagement & Transparency SMART Goal	Recommendations & Pain Points
	Details: Increase funding for national and regional public education campaigns. Misconceptions and lack of awareness contribute to low registration rates. Programs should include K-12 and college curricula, workplace campaigns, culturally tailored messaging, and collaboration with Department of Motor Vehicles (DMV), faith groups, and influencers. **Pain Points Addressed:** • **Role Misalignment & Training** • **Accountability & Process Clarity** **Recommendation:** Scoring criteria for policies or other areas in the process **Details:** Develop a scoring process to prioritize policy proposals and address other areas in the OPTN and development process. This could include determining the optimal degree of engagement and transparency for various stakeholders, including patients and their families. **Pain Points Addressed:** • **Transparency & Engagement** • **Misaligned Metrics** **Recommendation:** Improving the Transparency of Organ Allocation and Distribution - Build public trust through openness **Details:** The Final Rule should be updated to improve the transparency of the organ allocation process, including making allocation data publicly available and ensuring accountability for decisions made within the system. Public dashboards with waitlist and match data, transparent appeals and variance processes, and patient education on allocation factors. **Pain Points Addressed:** • **Accountability & Process Clarity** • **Transparency in Idea Movement**

Engagement & Transparency SMART Goal	Recommendations & Pain Points
	Recommendation: Review and repurpose existing OPTN dashboards to make them more patient centric **Details:** Patient-centered dashboards, which are easy to understand, include a few technical terms, and offer actionable information that can help patients make informed choices. Dashboards could also include educational resources that bridge knowledge gaps for patients and families. **Pain Points Addressed:** • **Transparency & Engagement** • **Patient Involvement** • **Long-Term Data Visibility** **Recommendation:** Strengthen Governance Structures of the Organ Procurement and Transplantation System (Overall) **Details:** Incorporating ethical considerations into allocation policies, such as continuous distribution frameworks, ensures that decisions are made based on principles of fairness and utility. This recommendation is key to modernizing the BOD and Committee governance structures moving forward. **Pain Points Addressed:** • **COI** • **Functional Misalignment**
SMART Goal #3: Increase the number of patients added to or engaged with OPTN communication channels	**Recommendation:** Describe and promote updated HHS/DoT oversight and authority content **Details:** Describe and promote updated HHS/DoT oversight and authority content to increase transparency of OPTN processes and build public trust through openness **Pain Points Addressed:** • **Accountability & Process Clarity** • **Transparency in Idea Movement** **Recommendation:** Webpage to promote and explain engagement activities for patients and the public

Engagement & Transparency SMART Goal	Recommendations & Pain Points
	Details: Create a webpage for available engagement opportunities across the network. Examples of engagement opportunities but not limited to the following: suggesting ideas, public input, proposed rules open for comment, engagement training for the public. **Pain Points Addressed:** • **Patient Involvement** • **Public Engagement** • **Transparency & Engagement** **Recommendation:** Scoring criteria for policies or other areas in the process **Details:** Develop a scoring process to prioritize policy proposals and address other areas in the OPTN and development process. This could include determining the optimal degree of engagement and transparency for various stakeholders, including patients and their families. **Pain Points Addressed:** • **Transparency & Engagement** • **Misaligned Metrics** **Recommendation:** Review and repurpose existing OPTN dashboards to make them more patient centric **Details:** Patient-centered dashboards, which are easy to understand, include a few technical terms, and offer actionable information that can help patients make informed choices. Dashboards could also include educational resources that bridge knowledge gaps for patients and families. **Pain Points Addressed:** • **Transparency & Engagement** • **Patient Involvement** • **Long-Term Data Visibility**
SMART Goal #4: BOD and Committee members complete COI disclosures annually	**Recommendation:** Strengthen COI Policies in Organ Procurement and Transplantation Governance

Engagement & Transparency SMART Goal	Recommendations & Pain Points
	Details: Strengthened COI policies will ensure that decisions are made in the best interest of patients and the public, not unduly influenced by financial, institutional, or professional self-interest. • Implement Robust COI Disclosure Requirements • Establish an Independent Ethics and Compliance Oversight • Authorize this body the authority to recuse or disqualify members from decision-making where conflicts exist. • Limit Industry and Institutional Dominance Standardize Recusal and Abstention Protocols **Pain Points Addressed:** • **COI**

19.1.3 Theme 3: Timeliness Goals and Recommendations

Table 55:Timeliness Expanded Goals, Recns, & Pain Points

Goal	Recommendation & Pain Points
SMART Goal #1: Reduce average policy development cycle time by 25%	**Recommendation:** Use modeling software like Simul8 to assess the success of policies **Details:** Modeling software can provide data-driven insights into potential outcomes of proposed policies. This can allow stakeholders to evaluate policies for factors like effectiveness, positive/negative outcomes, and efficiency. It can also be used to simulate the policy development process overall to create new timelines for reviewing policy proposals. **Pain Points Addressed:** • **Process & Role Definition** **Recommendation:** Establish defined timelines and specific guidelines for each stage of the policy development process **Details**: Establish defined timelines and specific guidelines for each stage of the policy development process. This should include setting target timeframes for every critical step, from initial drafting to final approval, and accountability mechanisms to ensure

Goal	Recommendation & Pain Points
	that deadlines are met. Each stage should have clear milestones and criteria for progress, with regular check-ins to ensure adherence to the timeline. **Pain Points Addressed:** • **Prolonged Timeliness** **Recommendation:** Develop a "data lake" or central platform for stakeholders to use **Details:** Eliminate technology silos between providers and organize everything through a central platform/website. OPTN stakeholders would need to access platforms to search, download, and upload donor/organ information for others to retrieve. Employing a data lake means healthcare organizations can collect and standardize data, such as claims, clinical information, patient registries, and data from electronic health records and EMRs no matter how it's collected or enters the health system. **Pain Points Addressed:** • **Data Acquisition Delays** **Recommendation**: Reduce and Diversify the Composition of the BOD and various committees **Details:** The large size of the BOD and various committees makes it difficult to facilitate the policy development process. Too many BOD members and committees has created a bottleneck and further impedes policy development. By reducing the number of BOD members and consolidating committees that are redundant and/or don't contribute policy ideas, a more expeditious process can be achieved. **Pain Points Addressed:** • **Prolonged Timeliness** **Recommendation**: Latency/timeliness tracking **Details:** Define and document reasonable timeframes for each stage of the policy development process based on successful implementation, e.g., continuous

Goal	Recommendation & Pain Points
	distribution and policies that have taken longer than expected. This will help standardize the time it takes for a policy to move through the process. **Pain Points Addressed:** • **Prolonged Timeliness** • **Process & Role Definition**
SMART Goal #2:100% of policy proposals tracked through standardized stage gate framework; (requires establishing standards, timelines per stage and defining milestones)	**Recommendation:** Website to track all policy proposals, updated to reflect where it is in the process **Details:** A policy-tracking website would improve the transparency and accountability of the process. OPTN members would have more awareness of which policies are currently being discussed and get a better understanding of their importance for the organ network. With more people aware of each policy and how they have been assigned in the process, the chance that favored policies will be prioritized over others will be lessened. **Pain Points Addressed:** • **Transparency in Idea Movement** • **Transparency Issues** **Recommendation**: Implement a Clear Process and Role Definition Framework **Details:** Implement a clear process and role definition framework for each stage of the policy development lifecycle. This framework would include detailed process maps that define each step, assigned roles and responsibilities, and accountability measures to ensure that every stakeholder knows their specific duties and deadlines. **Pain Points Addressed:** • **Accountability & Process Clarity** **Recommendation:** Establish defined timelines and specific guidelines for each stage of the policy development process **Details:** Establish defined timelines and specific guidelines for each stage of the policy development process. This should include setting target timeframes

Goal	Recommendation & Pain Points
	for every critical step, from initial drafting to final approval, and accountability mechanisms to ensure that deadlines are met. Each stage should have clear milestones and criteria for progress, with regular check-ins to ensure adherence to the timeline. **Pain Points Addressed:** • **Prolonged Timeliness**

19.1.4 Theme 4: Data Availability Goals and Recommendations

Table 56: Data Availability Expanded Goals, Recs, & Pain Points

Data Availability SMART Goal	Recommendations & Pain Points
SMART Goal #1: 100% of policies are reviewed for effectiveness within 12 months	**Recommendation:** Standardized Data Reporting Framework **Details:** Implement a standardized data framework that aligns metrics across the entire process and incorporates root-cause analysis rather than just downstream outcomes. This framework would include a set of defined measures for consistent data reporting and standardized public engagement metrics to ensure transparency and effective stakeholder involvement. **Pain Points Addressed:** • **Oversight Challenges** • **Divergent Data Requirements** • **Standardization Issues** • **Misaligned Metrics** **Recommendation:** Leveraging Technology for Real-Time Feedback **Details:** Using technology such as collaboration platforms, document-sharing tools, and project management software can drastically reduce delays in policy review and approval. Real-time feedback can facilitate smoother communication, faster decision-making, and ensure that committee members are always on the same page, even if they are working remotely or have limited time for meetings. **Pain Points Addressed:** • **Inadequate Dashboards**

Data Availability SMART Goal	Recommendations & Pain Points
	Recommendation: Scoring Criteria for Policies or other areas in the process **Details:** A scoring criterion will help determine which policy proposals should be given priority. As technology and science rapidly changes, the policy process needs to keep pace in order to remain relevant. Also, as more attention will be invested in the highest scoring policies, this can avoid any concerns about patient safety being compromised in a more accelerated process. **Pain Points Addressed:** • **Misaligned Metrics**
SMART Goal #2: 100% of data request tools and dashboards are available and demonstrating ongoing member engagement	**Recommendation:** Implement a policy platform (e.g., Salesforce) **Details:** A policy platform can be used to modernize the OPTN by automating inbound correspondence routing, tracking and monitoring engagement, and providing a patient and family portal with AI guidance for the organ procurement and transplant process and OPTN resources. **Pain Points Addressed:** • **Standardization Issues** • **Misaligned Metrics** • **System Integration** **Recommendation:** Review and repurpose existing OPTN dynamic dashboard for real time data decision-making **Details:** A structured approach to dashboard design is essential for real-time decision-making. HHS/DoT should consider a Balanced Scorecard model, which integrates financial, customer, internal process, and learning/growth perspectives, adapting it to the OPTN context. A Standardized Data Collection Framework is critical to ensure consistency and accuracy. **Pain Points Addressed:** • **Standardization Issues** • **Misaligned Metrics**

Data Availability SMART Goal	Recommendations & Pain Points
	Recommendation: Automate public comment feedback with a repurposed pre-existing dashboard platform **Details:** Develop/use a data analysis visualization tool to aggregate common themes/critical comments across public comment data. Automating the public comment process can lead to better tracking and analysis of comments. It will be easier to identify critical themes and comments. **Pain Points Addressed:** • **Inadequate Dashboards** • **Transparency & Engagement** **Recommendation:** Data Lineage, Quality, Workflow Management (e.g., Collibra, Informatica, Alation, etc.) **Details:** Track and monitor policy origins, movements, and transformations should be available within the dashboard while also addressing data discrepancies, incompleteness, and submission practices. **Pain Points Addressed:** • **Inadequate Dashboards** • **Oversight Challenges** • **Misaligned Metrics**

19.1.5 Theme 5: Prioritization & Post-Implementation Review Goals and Recommendations

Table 57: Prioritization & Post-Implementation Review Expanded Goals, Recs, & Pain Points

Prioritization & Post-Implementation Review SMART Goal	Recommendations & Pain Points
SMART Goal #1: 100% of proposals scored using rubric (urgency, fairness, feasibility, impact)	**Recommendation:** Implement a policy prioritization framework for policy development using the CDC Polaris Policy Process **Details:** Develop a modified version of the "CDC Polaris Policy Process" to assess policy options based on four metrics: effectiveness, feasibility, economic impact, and fairness. This structured prioritization framework ensures that implementation efforts will be focused on the most urgent and impactful issues.

Prioritization & Post-Implementation Review SMART Goal	Recommendations & Pain Points
	Pain Points Addressed: • **Inefficient Prioritization** • **Poorly Set Metrics** **Recommendation:** Use modeling software like Simul8 to assess the success of policies **Details:** Modeling software can provide data-driven insights into potential outcomes of proposed policies. This can allow stakeholders to evaluate policies for factors like effectiveness, positive/negative outcomes, and efficiency (all important to determine pre-implementation). **Pain Points Addressed:** • **Inefficient Prioritization** **Recommendation:** Establish a "fast-track" process for high-priority policies **Details:** Define clear criteria for which policies qualify for the fast-track process (e.g., policies that directly address urgent public health concerns, policies affected by leadership changes at HHS, or those addressing a media crisis). This process involves streamlining the review and approval stages by creating a dedicated, cross-functional team to expedite decisions. **Pain Points Addressed:** • **External Distractions** **Recommendation:** Scoring Criteria for Policies or other areas in the process **Details:** A scoring criterion will help determine which policy proposals should be given priority. As technology and science rapidly changes, the policy process needs to keep pace in order to remain relevant. Also, as more attention will be invested in the highest scoring policies, this can avoid any concerns about patient safety being compromised in a more accelerated process. **Pain Points Addressed:**

Prioritization & Post-Implementation Review SMART Goal	Recommendations & Pain Points
	• **Poorly Set Metrics** • **Inefficient Prioritization** **Recommendation:** Addressing Health Fairness in organ procurement and transplantation: Eliminate disparities in listing, allocation, and post-transplant care **Details:** Amend NOTA to address these disparities by ensuring that vulnerable populations (e.g., minority groups, low-income individuals) have equal access to organ procurement and transplantation. This could include specific initiatives to improve engagement, education, and access to procurement and transplant programs for underserved communities. **Pain Points Addressed:** • **Inefficient Prioritization** • **Transparency Issues** **Recommendation:** Cost effectiveness analysis **Details:** This methodology prioritizes cost based on specific outcomes and goals. It improves project and policy alignment with the four strategic goals highlighted by HHS/DoT. During the current state review, it was found that policies and projects that are suggested did not always take the four strategic goals HHS/DoT prioritized into consideration until later. This method will help align those policies in the beginning. **Pain Points Addressed:** • **Inefficient Prioritization** **Recommendation:** Use key components of RE-AIM framework which provides more structure in the policy development process **Details:** Provide more structure in the policy development process. The overall goal of the RE-AIM framework is to encourage more attention to essential program elements including external validity that can improve the sustainable adoption and implementation of effective, generalizable, evidence-based intervention.

Prioritization & Post-Implementation Review SMART Goal	Recommendations & Pain Points
	Pain Points Addressed: • **Inefficient Prioritization** • **COI**
SMART Goal #2: All policy decisions shared publicly with rationale within xx business days	**Recommendation:** Review and repurpose existing OPTN dashboards to make them more patient centric **Details:** Patient-centered dashboards, which are easy to understand, include a few technical terms, and offer actionable information that can help patients make informed choices. This would make patients aware of their current status, including when and why they were accepted or rejected for an organ donation. dashboards could also include educational resources that bridge knowledge gaps for patients and families. In addition, a dashboard could also include information regarding the policy development process and any policy discussions that may be relevant to them, thereby increasing engagement and transparency in the process. **Pain Points Addressed:** ○ **Transparency Issues**
SMART Goal #3: All policy decisions requiring formal vote include recorded participation from relevant committee members (appropriate stakeholders)	**Recommendation:** Implement a policy platform (e.g., Salesforce) **Details:** A policy platform can be used to modernize the OPTN by automating inbound correspondence routing, tracking and monitoring engagement, and providing a patient and family portal with AI guidance for the organ procurement and transplantation process and OPTN resources. **Pain Points Addressed:** • **Transparency Issues** • **Role Definition** **Recommendation:** Review and repurpose existing OPTN dashboards to make them more patient centric **Details:** Patient-centered dashboards, which are easy to understand, include a few technical terms, and offer actionable information that can help patients make informed choices. This would make patients aware of their current status, including when and why they were

Prioritization & Post-Implementation Review SMART Goal	Recommendations & Pain Points
	accepted or rejected for an organ donation. dashboards could also include educational resources that bridge knowledge gaps for patients and families. In addition, a dashboard could also include information regarding the policy development process and any policy discussions that may be relevant to them, thereby increasing engagement and transparency in the process. **Pain Points Addressed:** • **Transparency Issues**

20 Appendix I: Missing Policies and Bylaws within OPTN

Effective and comprehensive governance documents are crucial for clarifying responsibilities, defining processes, mitigating risks, and ensuring compliance with legal requirements. To support HHS/DoT's OPTN modernization efforts, it is necessary to update the existing OPTN governance documents. Current OPTN policies are disproportionately focused on transplant centers, with less clarity on OPO operations and responsibilities. A missing policy and bylaw gap analysis identified policies and bylaws that do not exist across the OPTN ecosystem and that will help define OPTN functions.

Table 58: Missing Policies & Bylaws within OPTN

Gap Analysis by Policy Process Step	Gap Identified
Pre-Step 1: Committee Formation and Identification of Need Please describe the nomination process for committee formation. • How are nominations solicited?	• Lack of Transparency in Solicitation: While the OPTN's Nominating Committee conducts a needs assessment and releases a public Call for Nominations, the methods for soliciting nominations across all stakeholder segments are not comprehensively detailed.
• How are stakeholders informed about the process?	• Stakeholder Awareness: Information on how stakeholders are informed about the nomination process and encouraged to participate is limited, potentially leading to underrepresentation of certain groups.
• How do UNOS and the Nominating Committee ensure that nominations are received from all stakeholder segments? • How does UNOS determine that the slate of new committee members meets composition requirements in Section 121.3 of the Final Rule?	• Committee Composition Requirements: The process by which the Nominating Committee ensures compliance with composition requirements outlined in Section 121.3 of the Final Rule lacks specificity, particularly regarding the evaluation of variety in professional expertise and demographics.

Gap Analysis by Policy Process Step	Gap Identified
• Who determines which members of the BOD are on the EC? • How does OPTN ensure that there is equal representation from all stakeholders on the EC?	• Selection Criteria: Details on how members of the BOD are selected for the EC, including criteria for ensuring equal representation from all stakeholders, are not explicitly defined in current policies.
• Please describe the final process for voting in new committee members.	• Final Appointment Procedures: The procedures for finalizing committee appointments, including the roles of the President-Elect and the BOD in approving the slate of nominees, are outlined but may benefit from further clarification to enhance transparency.
• What is HHS/DoT's role in oversight of OPTN committee formation?	• Governance Oversight: While HHS/DoT has initiated steps to strengthen OPTN governance, including the formation of a Transitional Nominating Committee, the extent and mechanisms of HHS/DoT's ongoing oversight in committee formation processes require further elaboration.
Step 1: Idea Submission and Initial Review • Does OPTN have an established, end to end process or tracking system for intake, review, and follow-up on new ideas?	• Process Formalization: The OPTN's current policy development process involves gathering information from various sources; however, the existence of a formal, end-to-end tracking system for new policy ideas, including submission, review, and follow-up, is not clearly documented.

• Please describe the different ways ideas for a new proposal/policy can be submitted to the OPTN (e.g., email, fax, mail, Dropbox, phone, etc.).
  ○ Does OPTN have an established, end-to-end process or tracking system for intake, review, and follow-up on new ideas?
  ○ Who is responsible for receiving and putting the ideas for a policy/proposal in the queue to be entered into the electronic system?
  ○ Who ensures that every idea has been logged?
  ○ Who ensures that every idea is followed up on?
  ○ Who tracks the source of the idea, the problem facing the organ procurement and
	• Submission Channels: Specific details on the methods available for stakeholders to submit new policy ideas (e.g., email, online forms) are not clearly outlined.
	• Responsibility for Idea Management: The roles and responsibilities of individuals or departments in receiving, logging, and tracking policy ideas are not explicitly defined, potentially leading to inconsistencies in idea management.

Gap Analysis by Policy Process Step	Gap Identified
transplant community, and any proposed solutions?	
• Please describe the typical timeframe from the time an idea is submitted to the UNOS PCR to the time the idea is given to a committee to develop into a proposal.	• Review Timelines: The average time from committee project approval to BOD approval has been documented; however, the timeframe from initial idea submission to committee assignment lacks clear benchmarks, which may affect the efficiency of policy development.
• How are OPTN stakeholders and the public informed of the ability to submit ideas and the ways to do it?	• Awareness of Submission Opportunities: Information on how stakeholders and the public are informed about the ability to submit policy ideas and the available channels for submission is limited, indicating a need for improved communication strategies.
• Please describe the EC's role in prioritizing proposals. Can the EC vote to approve an idea? Or does the vote need to wait until the BOD meets?	• Decision-Making Authority: The EC has the authority to approve committee proposals for public comment distribution; however, the extent of its role in prioritizing new policy ideas before full BOD meetings requires further clarification.
• Please describe the process for revisiting proposals that have been put on hold or not prioritized to move forward after the idea was initially reviewed. ○ How often does this occur (e.g., quarterly, annually)? ○ Is there a regular schedule for reviewing every idea? ○ Can the EC vote to table an idea? Or does this decision have to be made by the BOD? ○ How is the result of the re-review communicated to the person/entity who submitted the idea? ○ Is there a database of ideas that have not made it past the prioritization process?	• Review Process: The procedures and frequency for revisiting policy proposals that have been put on hold or not prioritized are not well-defined, which leads to failure to reconsider of potentially valuable ideas.
• Does the BOD define what ideas go through alternate pathways? ○ How is "emergent public health issue" or "patient safety factor" defined?	• Criteria Definition: The definitions and criteria for categorizing proposals as "emergent public health issues," "patient safety factors," or "non-controversial" are not explicitly stated, leading to potential ambiguity in the policy development process.

Gap Analysis by Policy Process Step	Gap Identified
○ How is "non-controversial" defined?	
• How is it decided which committee is assigned the proposal? ○ Are other committees with an interest in a new proposal able to contribute?	• Assignment Procedures: The process for assigning new policy proposals to appropriate committees, including the involvement of other interested committees, lacks detailed documentation, which may affect interdisciplinary collaboration.
• How are committees notified that a new proposal/policy proposal has been assigned to them?	• Communication Protocols: The methods and timelines for notifying committees about new policy assignments are not clearly outlined, potentially impacting the timely initiation of policy development work.
• Is there a separate pathway for sourcing and tracking a policy variance proposal outside of this process?	• Separate Processes: Information on whether there is a distinct pathway for sourcing and tracking policy variance proposals outside the standard process is not readily available, suggesting a need for policy clarification.
• How are technical estimates generated? Are they typically accurate / is this tracked?	• Estimation Accuracy: While UNOS staff prepare resource estimates for policy implementation, details on the methodologies used and the tracking of estimation accuracy over time are not extensively documented.
• Who defines who is a "critical constituency" for a particular proposal? How are they brought into the process?	• Definition and Engagement: The criteria for defining "critical constituencies" for specific proposals and the strategies for their engagement in the policy development process are not explicitly stated, indicating an area for policy enhancement.
Step 2: (Problem Analysis): • Please describe the typical timeframe from the time a committee is assigned a new proposal and idea until the time a written proposal statement is added to the proposal form and the proposal moves to Step #3 (Proposal Approval).	• No policy clarifies the timeframe from the beginning of Step 2 to Step 3. There are missing policies specifying the length of time a committee must work at this step.
• Please describe the problem analysis process. ○ How does the committee determine which tools to use for proposal analysis? ○ What is the typical timeframe for analysis?	• Missing policy regarding any specific tools to use or how long the analysis portion should take. There is language regarding how ideas may be evaluated using literature reviews, Failure Mode and Effects Analysis, or other tools but no clarification as to who committees determine which analysis tools to utilize.

Gap Analysis by Policy Process Step	Gap Identified

• How are requests to SRTR and/or the UNOS Research Department managed?
  ○ Are there any budgetary constraints for these requests?
  ○ Are there any other types of constraints?
  ○ Where are requests/results documented?
  ○ Can committee members reach out to SRTR directly?
  ○ How does the sponsoring committee develop the plan for collaborating with stakeholders?
	• No policy delineating who is responsible for each area of the analysis step.

Step 3 (Project Approval): • What is the typical timeframe for this phase?	• No policy exists that specifies the timeframe for this portion of the step.

• How does the POC evaluate the proposal based on the following?
  ○ Overall cost of proposal?
  ○ Overall benefit of proposal?
	• No specificity regarding how the POC measures the overall costs and benefit of a project proposal. May use the Project Benefit Score or something similar.

• Once the POC approves the proposal/policy, who notifies the BOD the proposal is ready for review?	• Missing policy delineating party responsible for notifying the BOD that proposal is ready. Would this be the leadership of the committee working on the proposal?
• How long does it typically take from the time the POC approves the proposal until the BOD votes?	• No policy exists that specifies the timeframe for this portion of the step.
• Who notifies the sponsoring committee once the proposal has been approved? ○ How soon after the BOD vote is the committee required to be notified?	• Missing policy stating when committee should be notified after vote and who should inform them.

Gap Analysis by Policy Process Step	Gap Identified
Step 4 (Evidence Gathering) • Who notifies the various resources required (SRTR, UNOS IT, UNOS Research Dept., etc.)?	• Missing policy around notification of various resources required.
• How is it determined when adequate stakeholder input has been obtained?	• Missing policy on determining when adequate stakeholder input has been obtained.
• Who puts the data together once it has been obtained?	• Missing policy on who puts the data together once it has been obtained.
• How long from the time the sponsoring committee votes to distribute the proposal for public comment until the proposal is submitted to the POC for review?	• Missing policy on how long from the time the sponsoring committee votes to distribute the proposal for public comment until the proposal is submitted to the POC for review.
• What is the typical timeframe for the Evidence Gathering phase?	• Missing policy on typical timeframe for the evidence gathering phase.

Step 5 (Public Comment Approval):
 	
• Please describe the process for writing the Public Comment proposal.
  ○ Who writes it?
  ○ Who reviews it?
  ○ Who from the sponsoring committee approves it?
  ○ What is the typical timeframe for this process?
  ○ Is the Public Comment Proposal written before or after the sponsoring committee votes to distribute the proposal for public comment?
	• Missing policy around the process of conducting the public comment process from end-to-end (this may be a SOP but have not located it).

• What are the methods and metrics used to analyze public comments? • How do the POC and the BOD evaluate the proposal based on the following:	• Missing policies around process and suitable tools/metrics for analyzing public comment feedback.

Gap Analysis by Policy Process Step	Gap Identified
○ The same factors evaluated during the Project Approval phase. ○ Are the factors evaluated differently at this phase in the process? ○ Whether ample stakeholder engagement occurred. ○ Whether the solution is tailored to the problem. ○ Whether the proposal meets fiscal implications.	
• Please describe the typical timeframe for this phase. • How long does it typically take from the time the POC is notified that a policy is ready for approval until it is voted on by the POC? • How long does it typically take from the time the POC has approved a proposal until the BOD votes?	• Missing policies around the public comment review process. Mentions the process overall should be 45 days but not specific to the stages of work within said days.
• Please describe the process for informing stakeholders and the general public about the proposal's public comment. ○ Who is responsible for the notification? ○ What are the different methods of notification (social media, OPTN website, etc.) ○ What is the process for monitoring to ensure this step has occurred?	• Missing policy around how to communicate public comment feedback with public. No standard on when and how to let the public know why decisions were made or the process of making decisions.
Step 6 (Public Comment): • Who logs each comment in the general electronic system? ○ Who tracks to ensure that all comments are entered into the system and reviewed?	• Missing policies around who logs and tracks policies to ensure that they can be reviewed.

Gap Analysis by Policy Process Step	Gap Identified
• Who reviews each comment to ensure it does not violate OPTN public comment principles? ○ What is the process for sending comments that might violate the principles to UNOS leadership for review? ○ What is the timeframe for UNOS leadership to review the comments? ○ Who tracks to ensure the comments are reviewed by leadership? ○ Who follows up to ensure the comments are put back in the general comment queue? ○ Who monitors to ensure every comment is entered into the system, reviewed by appropriate groups, and followed up on?	• Missing policies around who is responsible for sending comment violations to UNOS, including the process.
• Please describe the process for initiating and implementing a fiscal workgroup during this Step. ○ Who initiates the fiscal workgroup for each proposal? ○ Who determines the composition of the workgroup? ○ What measurable criteria does the fiscal workgroup use to determine the fiscal impacts of the proposal?	• Missing policies around the fiscal workgroup and their responsibility in the public comment process, including initiation and overall process.
• Please describe the OPTN committee comment review process, when committees review comments as SMEs (ethics, minority, etc.).	• Missing polices around the OPTN comment review process in general, did speak to the comment review process for expedited actions.

Gap Analysis by Policy Process Step	Gap Identified
○ What measurable criteria are used for the evaluation of the proposal?	
Step 7 (Pending BOD Approval) • What are the exact metrics used to analyze data from public comments?	• Missing policy around defining metrics used to analyze data from public comments.
• How long does this process take?	• Missing policy around process timeline.
Step 8 (BOD Approval) • How does the BOD prioritize proposed policies?	• Missing policy around how BOD prioritizes, rejects, or approves proposed policies.
• Does the BOD have enough time to understand the proposed policies if they only meet twice a year?	• Missing policy on how the BOD understands the proposed policy if they only meet twice a year.
• If the EC also has voting power, why don't they have more responsibility? ○ Who determines which members of the BOD are also on the EC? ○ Why does the BOD not also just fill the role of the EC?	• Missing policy on the responsibility of the EC.
• What are the metrics that the BOD uses to approve or reject proposed policies?	• Missing policy around the metrics used for BOD policy approval.
• Who develops these metrics?	• Missing policy about who develops policy prioritization and approval metrics.
• How does the BOD determine the feasibility of a proposed policy?	• Missing policy about how the BOD determines policy feasibility.
• How does the BOD determine a timeline for implementation for an approved policy?	• Missing policy about the timeline for policy implementation post-approval.
• What are the metrics used by the BOD to determine whether a proposal meets fiscal requirements?	• Missing policy on metrics used by the BOD to determine whether a proposal meets fiscal requirements.
• How does the BOD decide to stop implementation of a policy or to not implement a policy even if it has been approved?	• Missing policy about parameters and process for stopping implementation of a policy.

Gap Analysis by Policy Process Step	Gap Identified
Step 9 (Implementation): • What steps are taken to address any concerns that arise during the implementation process?	• Missing policy around addressing any concerns that arise during the implementation process.
• How do UNOS staff ensure that the new policy is implemented consistently across multiple regions and transplant centers?	• Missing policy on ensuring that the new policy is implemented consistently across multiple regions and transplant centers.
• How does the BOD decide to halt the implementation of a policy even after it has been approved?	• Missing policy on how BOD decides to halt the implementation of a policy even after it has been approved.
Step 10 (Post-Implementation Review): • Are there continuous feedback mechanisms in place for stakeholders to speak to their concerns?	• Missing policy on continuous feedback mechanisms in place for stakeholders to speak to their concerns.
• How does UNOS ensure that the data from the post-implementation review are used to make improvements to existing policy?	• Missing policy around how UNOS ensures that the data from the post-implementation review are used to make improvements to existing policy.

Post-Steps:
 	
• Implement Changes
  ○ How does UNOS staff prioritize changes to the policy based on data and feedback?
  ○ If there are significant changes to the policy, how do UNOS staff ensure that stakeholders are adequately trained or supported to adapt?
	• Missing policy around how UNOS staff prioritize changes to the policy based on data and feedback.
	• Missing policy on If there are significant changes to the policy, how do UNOS staff ensure that stakeholders are adequately trained or supported to adapt.

• Ongoing Monitoring
  ○ How is the ongoing monitoring process made to be adaptable to new changes?
  ○ How do UNOS staff ensure that data that is being
	• Missing policy on ongoing monitoring process made to be adaptable to new changes.
	• Missing policy on UNOS staff ensuring that data that is being received is reported in a consistent format.

Gap Analysis by Policy Process Step	Gap Identified
received is reported in a consistent format?	

Note: Data adapted from BOD EC - OPTN (n.d.), BOD Nominating Committee - OPTN (n.d.), How to volunteer: Appointment - OPTN (n.d.), HRSA Announces Key Technology and Governance Milestones in its OPTN Modernization Initiative (2025, January), Advisory Committee on Organ Transplantation | HRSA (n.d.), and The U.S. Organ Transplantation System and Opportunities for Improvement (2022).

21 Appendix J: Incomplete Policies & Bylaws within OPTN

Writing an effective policy or bylaw means creating a document that is clear, practical, enforceable, and aligned with organizational goals and legal requirements.

Elements of an effective policy or bylaw include:

- A well-defined purpose and scope that clearly outlines the intent and applicability of the policy or bylaw
- Incorporation of legal frameworks, guidelines, or criteria that provide a foundation for the policy or bylaw
- A glossary of key terms and definitions relevant to the policy or bylaw
- A detailed, step-by-step procedure outlining how to comply with the policy or bylaw
- Supporting forms or documentation required to implement the procedure effectively
- Clearly assigned roles, responsibilities, and resources needed for implementation
- A structured process for monitoring, evaluation, and periodic review of the policy or bylaw
- Documented key dates, including implementation, review, and revision timelines
- Defined success metrics or evaluation criteria to measure the effectiveness of the policy or bylaw

An evaluation of OPTN's current policies and bylaws identified missing elements that should be included to enhance their effectiveness.

Table 59: Incomplete Bylaws & Policies within OPTN

INVEST Bylaws Name	Defined/Clearly Articulated (Y/N)	Purpose (Y/N)	Scope (Y/N)	Legal Components (Y/N)	Guidelines (Y/N)	Criteria	Definitions Included	Terms Defined	Step by Step Procedures	Compliance	Accountability/ Governance	Metrics
Article I: Purpose and Definitions	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Article II: Members of INVEST	Y	Y	Y	Y	Y	Y	**N**	Y	**N**	Y	Y	No clear metrics

Article III: BOD	Y	Y	Y	Y	Y	Y	**N**	**N**	**N**	Y	Y	No clear metrics
Article IV: Nominating Committee	Y	Y	Y	Y	Y	Y	**N**	**N**	**N**	Y	Y	No clear metrics
Article V: Executive and other Committees	Y	Y	Y	Y	Y	Y	**N**	**N**	**N**	Y	Y	No clear metrics
Article VI: Executive Director	Y	Y	Y	Y	Y	**N**	**N**	**N**	**N**	Y	Y	No clear metrics
Article VII: Officers	Y	Y	Y	Y	Y	**N**	**N**	Y	**N**	Y	Y	No clear metrics
Article VIII: Indemnification	Y	Y	Y	Y	Y	**N**	**N**	**N**	**N**	Y	Y	No clear metrics
Article IX: Amendment of Bylaws	Y	Y	Y	Y	Y	**N**	**N**	Y	Y	Y	Y	No clear metrics

Table 60: Incomplete Management & Membership Policies within OPTN

Management and Membership Policy Name	Defined/Clearly Articulated (Y/N)	Purpose (Y/N)	Scope (Y/N)	Legal Components (Y/N)	Guidelines (Y/N)	Criteria	Definitions Included	Terms Defined	Step by Step Procedures	Compliance	Accountability/ Governance	Metrics
Policy A: Permanent Standing Committees	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy B: Financial Considerations	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	Revenue and funds
Policy C: Regions	Y	Y	Y	**N**	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy D: Code of Conduct	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy E: Adoption of Policies	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy F: Membership	Y	Y	Y	**N**	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 1: Administrative Rules and Definitions	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 2: Deceased Organ Procurement	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 3: Candidate Registrations, Modifications, and Removals	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 4: Histocompatibility	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics

Management and Membership Policy Name	Defined/Clearly Articulated (Y/N)	Purpose (Y/N)	Scope (Y/N)	Legal Components (Y/N)	Guidelines (Y/N)	Criteria	Definitions Included	Terms Defined	Step by Step Procedures	Compliance	Accountability/ Governance	Metrics
Policy 5: Organ Offers, Acceptance, and Verification	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 6: Allocation of Hearts and Heart-Lungs	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 7: Allocation of Intestines	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	No clear metrics
Policy 8: Allocation of Kidneys	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 9: Allocation of Livers and Liver-Intestines	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 10: Allocation of Lungs	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 11: Allocation of Pancreas, Kidney-Pancreas, Islets	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 12: Allocation of Covered Vascularized Composite Allografts	Y	Y	Y	Y	Y	Y	Y	**N**	Y	N	Y	Wait times
Policy 13: Kidney Paired Donation	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 14: Living Donation	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 15: Identification of Transmissible Diseases	Y	Y	Y	Y	Y	Y	Y	**N**	Y	Y	Y	No clear metrics
Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics
Policy 17: International Organ Transplantation	Y	**N**	**N**	Y	**N**	**N**	**N**	**N**	**N**	**N**	**N**	No clear metrics
Policy 18: Data Submission Requirements	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Patient Health Care data
Policy 19: Data Release	**N**	**N**	Y	Y	**N**	**N**	**N**	**N**	**N**	**N**	**N**	No clear metrics
Policy 20: Travel Expense and Reimbursement	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	No clear metrics

Management and Membership Policy Name	Defined/Clearly Articulated (Y/N)	Purpose (Y/N)	Scope (Y/N)	Legal Components (Y/N)	Guidelines (Y/N)	Criteria	Definitions Included	Terms Defined	Step by Step Procedures	Compliance	Accountability/ Governance	Metrics
Policy 21: Composite Allocation Score Reference	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Waiting list survival formula Post Transplant outcome formulas Biological disadvantages formula

22 Appendix K: Acronyms & Abbreviations

Table 61: Acronyms & Abbreviations

Acronym	Full Name & Definition
AATB	American Association of Tissue Banks An industry association organization that accredits tissue banks in the United States (and internationally). Established in 1976, the AATB sets standards and best practices to ensure the safety, quality, and ethical sourcing of human tissue used for organ procurement and transplantation, investigation, and education. Its accreditation program involves rigorous inspections and compliance checks, helping to maintain high standards for donor screening, tissue recovery, processing, storage, and distribution. The AATB provides educational resources, training, and advocacy efforts to advance the field of tissue banking. By working closely with regulatory agencies such as the FDA, as well as with clinicians, analysts, and tissue banks, the AATB promotes responsible tissue donation and facilitates continuous improvements in tissue-related services and transplant outcomes.
AI	Artificial Intelligence Technology enabling computer systems to perform tasks that typically require human intelligence, such as pattern recognition, decision-making, or predictive modeling.
AoA	Analysis of Alternatives A process for assessing options and determining the best solution for a problem.
AOPO	Association of Organ Procurement Organizations A national trade association representing the non-profit organizations known as Organ Procurement Organizations (OPOs) responsible for organ recovery, procurement, preservation, and transportation.
APDF	Agile Policy Development Framework A framework for policy or process development that emphasizes flexibility and responsiveness using iterative and adaptive methods.
API	Application Programming Interface A set of rules allowing different software applications to communicate and share data, often enabling seamless integration and automation.
APP	Advanced Practice Providers APPs typically refer to healthcare professionals—such as nurse practitioners (NPs), physician assistants (PAs), and sometimes clinical nurse specialists (CNSs)who have advanced clinical training and can perform many of the same diagnostic and treatment functions as physicians. They often play key roles in patient evaluation, post-transplant follow-up, coordinating care, and managing chronic conditions in transplant recipients.

Acronym	Full Name & Definition
AST	American Society of Transplantation A professional organization supporting transplant professionals and promoting review, education, and public policy to better patient outcomes.
ASTS	American Society of Transplant Surgeons A professional society representing transplant surgeons and related surgical professionals, focused on advocacy, education, and review in transplantation.
BOD	Board of Directors The governing body of an organization, responsible for major decisions, strategic direction, and overall oversight.
BPR	Business Process Re-engineering Business Process Re-engineering (BPR) is a strategic approach that involves the radical redesign of core business processes to achieve significant improvements in performance, efficiency, and effectiveness.
CDC	Centers for Disease Control and Prevention A national public health agency in the United States focused on protecting public health and safety through the control and prevention of disease, injury, and disability.
CFO	Chief Financial Officer The senior executive responsible for managing the financial actions of a company, including financial planning, risk management, record-keeping, and financial reporting.
CFR	Code of Federal Regulations The official record of all rules and regulations issued by federal agencies in the United States.
CMS	Centers for Medicare & Medicaid Services A federal agency under the Department of Health and Human Services (HHS) that administers Medicare, Medicaid, and other health programs.
COI	Conflict of Interest A situation where an individual's personal, financial, or professional interests may potentially influence or bias their judgment, compromising their ability to act impartially and in the best interests of all stakeholders.
CRM	Customer Relationship Management

Acronym	Full Name & Definition
	A strategic process that organizations use to manage, analyze, and improve their interactions with customers, leveraging data-driven insights to optimize communication, enhance customer satisfaction, and drive sustainable growth.
DoT	Division of Transplantation A division within the U.S. Department of Health and Human Services (HHS) that oversees the nation's organ and blood stem cell transplant systems. The DoT implements programs and initiatives to increase organ and blood stem cell donations in the United States.
DMV	Department of Motor Vehicles A government agency responsible for driver's licenses, vehicle registration, and road safety.
EC	Executive Committee A subset of organizational leaders drawn from the full BOD and authorized to make interim or time-sensitive decisions on behalf of the BOD or membership. Although both the EC and BOD meet within the OPTN, the EC is distinct in its formal scope and authority: it operates with a smaller membership and is specifically tasked to act on matters requiring prompt attention between full BOD meetings.
ED	Executive Director The individual in charge of day-to-day operations and ensuring organizational goals and regulatory requirements are met. Annual performance reviews of the ED are part of UNOS's tasks alongside composition reviews and public calls for nominations.
EDOC	Effective Date of Contract The date the contract goes into effect.
eGFR	estimated Glomerular Filtration Rate A calculation used to gauge how well the kidneys are filtering waste from the blood. eGFR is a critical measure for assessing kidney function, diagnosing the stage of chronic kidney disease (CKD), and determining the urgency of a transplant.
EMR	Electronic Medical Record A digital version of a patient's paper chart, used by healthcare providers to store clinical data and track patient information.
EPIS	Exploration, Preparation, Implementation, and Sustainment A framework used to guide the implementation of evidence-based practices in various settings.
FAQ	Frequently Asked Questions

Acronym	Full Name & Definition
	A compilation of common questions and their answers, designed to provide users or customers with information on frequently occurring concerns or problems quickly and efficiently.
FDA	Food and Drug Administration A U.S. government agency responsible for protecting public health by regulating food, drugs, medical devices, cosmetics, and other health-related products.
GPS	Global Positioning System A satellite-based navigation system that provides location, velocity, and time information anywhere on Earth. It is widely used for navigation, mapping, and timing across various industries.
HCD	Human-Centered Design A methodology that places the user at the heart of the design process. It seeks to deeply understand users' needs, behaviors, and experiences to create effective solutions catering to their unique challenges and desires.
HHS	U.S. Department of Health and Human Services The federal department responsible for protecting the health of all Americans and providing essential human services.
HRSA	Health Resources and Services Administration An agency within the U.S. Department of Health & Human Services (HHS) responsible for bettering healthcare access for people who are geographically isolated or economically or medically vulnerable. HRSA (now HHS/DoT) oversees the Organ Procurement and Transplantation Network (OPTN) and enforces federal requirements governing organ donation, procurement, and transplantation.
IBM	International Business Machines A globally renowned technology company.
INVEST	Independent Network of Volunteers for Equitable and Safe Transplants The former BOD for the OPTN has been renamed INVEST. Under the designation and oversight of HHS/DoT, INVEST now serves as the OPTN BOD consistent with federal law and regulations, including NOTA. As such, INVEST's newly updated bylaws (most recently amended on December 24, 2024) also function as the bylaws of the OPTN whenever INVEST is acting as the OPTN BOD. Meanwhile, related policies were most recently updated on March 5, 2025.
IRC	Independent Regulatory Commission A federal agency created by Congress that is responsible for regulating specific activities or interests. These commissions operate autonomously from direct political influence, allowing them to create regulations with the force of law.

Acronym	Full Name & Definition
IT	Information Technology The use of systems (computers, hardware, software, networks) for processing, storing, and exchanging electronic data.
KPI	Key Performance Indicator A measurable target used to gauge how effectively individuals or businesses are achieving their strategic goals.
LDC	Living Donor Committee Responsible for developing, reviewing, and monitoring policies related to the procurement of organs from living donors (e.g., kidney, liver lobes). The LDC helps maintain high standards of safety, ethics, and efficacy in living organ donation, advancing policies that support donors and recipients throughout the procurement and transplantation process.
LMS	Learning Management System An online platform designed to host, share, and track digital training programs for businesses.
LVAD	Left Ventricle Assist Device A mechanical pump that supports the left ventricle—the heart's main pumping chamber—when it can no longer function effectively on its own. LVAD plays a crucial role within the U.S. transplant system by keeping heart failure patients stable and extending survival during the sometimes-lengthy wait for a suitable donor heart.
MAC	Minority Affairs Committee The MAC focuses on ensuring that racial, ethnic, and other minority populations receive equitable access to organ procurement and transplantation services. Ensures that the OPTN upholds fairness in organ procurement and transplantation, reducing barriers and improving outcomes for minority patients across the United States.
ML	Machine Learning A subset of artificial intelligence (AI) focused on developing algorithms and statistical models that enable computers to learn from and make predictions or decisions based on data.
MOTC	Multi-Organ Transplantation Committee A committee is charged with developing and proposing allocation policies that address multiple organ groups and the practice of multi-organ allocation.
MPSC	Membership and Professional Standards Committee

Acronym	Full Name & Definition
	The OPTN committee with delegated authority from the OPTN BOD responsible for reviewing and monitoring member performance, compliance, and professional standards.
NASEM	National Academies of Sciences, Engineering, and Medicine A private, nonprofit institution that provides independent, expert advice on scientific, technological, and medical matters to federal agencies and other organizations. In the context of HHS/DoT and the OPTN, NASEM's reports and recommendations often influence policy decisions and enhancements in organ procurement and transplantation practices.
NIH	National Institutes of Health The primary agency of the United States government responsible for biomedical and public health study and analysis.
NLP	Natural Language Processing A subfield of computer science and artificial intelligence (AI) that focuses on enabling computers to understand, interpret, and generate human language.
NOTA	National Organ Transplant Act A U.S. federal law that established the Organ Procurement and Transplantation Network and prohibited the sale of human organs.
NPS	Net Promoter Score A standard measuring gauge for measuring customer loyalty and satisfaction.
NRP	Normothermic Regional Perfusion A technique used to preserve organs by perfusing them at normal body temperature after circulatory death.
OECD	Organisation for Economic Co-operation and Development It is an international organization that works to build better policies for better lives by promoting economic progress and world trade.
OIG	Office of Inspector General A government office responsible for conducting audits, investigations, and inspections to prevent and detect fraud, waste, abuse, and mismanagement within federal agencies.
OMB	Office of Management and Budget The OMB is an executive branch agency responsible for overseeing the federal budget, management, and regulatory policies, providing guidance and oversight to federal agencies.
OPO	Organ Procurement Organization

Acronym	Full Name & Definition
	A non-profit organization designated to coordinate organ procurement in a specific area, responsible for surgical recovery, preservation, and transportation of donated organs.
OPTN	Organ Procurement and Transplantation Network A nationwide system established by federal law and overseen by HHS/DoT that matches donated organs with patients on the national waiting list, develops organ allocation policies, and collects and analyzes transplant data to better outcomes and ensure fairness.
OS	Operating System Software that manages computer hardware and software resources, providing common services for computer programs.
PAC	Patient Affairs Committee A body within the OPTN that ensures patient, donor, and family perspectives are incorporated into the development, review, and revision of organ procurement and transplantation policies. Members often include transplant recipients, living donors, donor families, and patient advocates who contribute firsthand experiences, helping to promote transparency, impartiality, and patient-centered decision-making throughout the OPTN.
PC	Policy Committee A committee charged with developing and implementing policies.
PCR	Policy and Community Relations (Department) A department (within UNOS or related structure) focusing on policy development, communication, and community contact.
PDF	Portable Document Format PDF is a file format developed by Adobe that allows documents to be presented in a manner independent of application software, hardware, and operating systems.
PDT	Policy Design Team A team of SMEs assigned to develop and implement specific policy ideas.
PIM	Policy Implementation Matrix A communication tool used to outline how each item in a policy will be implemented in practice and to assist in evaluating implementation outcomes and success.
POC	Policy Oversight Committee A committee responsible for guiding the policy agenda, ensuring proposals align with strategic goals, and monitoring policy development progress.

Acronym	Full Name & Definition
PPP	Public-Private Partnership A collaborative arrangement between a government agency and a private-sector company to finance, build, and operate public infrastructure projects. These partnerships leverage private sector technology and innovation with public sector incentives to complete projects efficiently.
QR	Quick Response A type of barcode that can be scanned using a smartphone or other digital device to quickly access information or perform actions, such as filling out a form or visiting a website.
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance A framework used to evaluate the impact of health interventions, focusing on how well they work in real-world settings and their viability over time.
RFID	Radio Frequency Identification A technology that uses radio waves to automatically identify and track tags attached to objects. RFID systems consist of tags, readers, and software, enabling efficient inventory management, asset tracking, and enhanced security.
RFP	Request for Proposal A business document that announces a project, describes it, and solicits bids from qualified contractors to complete it.
ROI	Return on Investment A performance measure used to evaluate the effectiveness or efficiency of a proposed or implemented solution.
SEC	Securities and Exchange Commission A U.S. government agency responsible for enforcing federal securities laws and regulating the securities industry to protect investors and maintain fair markets.
SLA	Service Level Agreement A contract that outlines and defines the types and standards of services to be offered.
SMART	Specific, Measurable, Achievable, Relevant, and Time-bound A framework for setting effective goals, ensuring they are Specific, Measurable, Achievable, Relevant, and Time-bound.
SME	Subject Matter Expert An individual with in-depth knowledge or expertise in a particular area, often consulted to inform decisions or guide project work.

Acronym	Full Name & Definition
SOP	Standard Operating Procedure A set of detailed, step-by-step instructions designed to help workers carry out routine operations efficiently and consistently, ensuring quality and compliance within an organization.
SPPDF	Six-Phase Policy Development Framework A policy development framework designed to modernize and standardize OPTN policy development, address the demand for advanced technologies, and address key pain points identified in the current process.
SRTR	Scientific Registry of Transplant Recipients The SRTR is a federally funded program administered by the HHS/DoT. The program is managed under a contract awarded to a single entity. Currently, Hennepin Healthcare Research Institute (HHRI) serves as the contractor responsible for data collection, analysis, and reporting on transplant outcomes, organ allocation, and policy impact.
uDRAI	Uniform Donor Risk Assessment Interview A standardized version of the Donor Risk Assessment Interview (DRAI), designed to ensure that all OPOs ask essentially the same questions in the same way. uDRAI was developed to meet OPTN policy requirements and align with HHS/DoT and CDC guidelines. uDRAI aims to minimize variability or gaps in donor history collection and improve overall safety and consistency nationwide.
UNet	The UNOS secure transplant network system A suite of online systems maintained by UNOS to manage transplant data, match organ donors to recipients, and ensure secure information exchange.
UNOS	United Network for Organ Sharing A private, nonprofit organization contracted by the federal government to manage the OPTN.

23 Appendix L: References

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